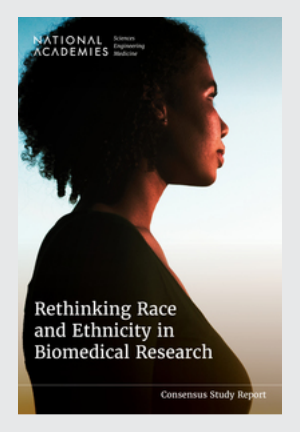

Rethinking Race and Ethnicity in Biomedical Research (2024)

DETAILS

270 pages | 7 x 10 | PAPERBACK
ISBN 978-0-309-72463-0 | DOI 10.17226/27913

CONTRIBUTORS

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SUGGESTED CITATION

National Academies of Sciences, Engineering, and Medicine. 2024. *Rethinking Race and Ethnicity in Biomedical Research.* Washington, DC: The National Academies Press. https://doi.org/10.17226/27913.

NATIONAL ACADEMIES Sciences Engineering Medicine

NATIONAL
ACADEMIES
PRESS
Washington, DC

Rethinking Race and Ethnicity in Biomedical Research

M. Roy Wilson, Sarah H. Beachy,
and Samantha N. Schumm, *Editors*

Committee on the Use of Race and
Ethnicity in Biomedical Research

Board on Health Sciences Policy

Board on Population Health and Public
Health Practice

Board on Health Care Services

Health and Medicine Division

Prepublication Copy—Uncorrected Proof

Consensus Study Report

NATIONAL ACADEMIES PRESS 500 Fifth Street, NW, Washington, DC 20001

This activity was supported by contracts between the National Academy of Sciences and the Doris Duke Foundation (Grant No. 2023-0143) and the Burroughs Wellcome Fund (Grant No. 1196654). Any opinions, findings, conclusions, or recommendations expressed in this publication do not necessarily reflect the views of any organization or agency that provided support for the project.

International Standard Book Number-13: 978-0-309-XXXXX-X
International Standard Book Number-10: 0-309-XXXXX-X
Digital Object Identifier: https://doi.org/10.17226/27913

This publication is available from the National Academies Press, 500 Fifth Street, NW, Keck 360, Washington, DC 20001; (800) 624-6242 or (202) 334-3313; http://www.nap.edu.

Printed in the United States of America.

Suggested citation: National Academies of Sciences, Engineering, and Medicine. 2024. *Rethinking race and ethnicity in biomedical research*. Washington, DC: National Academies Press. https://doi.org/10.17226/27913.

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This Consensus Study Report was reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise. The purpose of this independent review is to provide candid and critical comments that will assist the National Academies of Sciences, Engineering, and Medicine in making each published report as sound as possible and to ensure that it meets the institutional standards for quality, objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process.

We thank the following individuals for their review of this report:

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Although the reviewers listed above provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations of this report nor did they see the final draft before its release. The review of this report was overseen by **CARLOS DEL RIO** of Emory University and **ROBERT B. WALLACE** of the University of Iowa. They were responsible for making certain that an independent examination of this report was carried out in accordance with the standards of the National Academies and that all review comments were carefully considered. Responsibility for the final content rests entirely with the authoring committee and the National Academies.

Acknowledgments

The study committee and project staff acknowledge that the National Academies of Sciences, Engineering, and Medicine occupies space on what was the traditional and ancestral land of the Nacotchtank (Anacostan) people. We recognize that the Anacostians are gone but today have relatives in the Piscataway People. The committee and staff honor the Anacostian stewardship of what is now the D.C. area from time immemorial through to the beginnings of this country. We acknowledge the Piscataway People who continue to steward the land in the greater area today. Beyond acknowledgement, the committee and staff aspire to uphold a responsibility to the land and to honor the First People and their descendants while completing our work.

The study co-directors thank the sponsors, the Doris Duke Foundation and the Burroughs Wellcome Fund, for recognizing the importance of this topic and for supporting this work. The co-directors recognize and thank the staff team across the Boards on Health Sciences Policy, Population Health and Public Health Practice, and Health Care Services for their commitment and persistence to thoughtfully navigating a challenging and complex topic. The committee and project staff are grateful to Michael Zieler for his drafting and editorial assistance to prepare this report. The committee and project staff are thankful for the many other National Academies staff who contributed to this report, including Christie Bell from the Office of the Chief Financial Officer, the National Academies Research Center, and the Health and Medicine Division Office of Communications staff. The committee and staff appreciate the contributions of Sarah Forthal for her approach to categorizing multiracial research participants (Appendix C). The committee and staff express their gratitude to the individuals who donated their time and expertise as speakers to share their work and personal experiences during the study process.

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Preface

The difficulty of precisely defining race was captured by the Harvard historian Evelyn Brooks Higginbotham in 1992: "When we talk about the concept of race, most people believe that they know it when they see it but arrive at nothing short of confusion when pressed to define it."[1] More than 30 years later, despite mapping of the human genome and an understanding that race is not a scientifically valid measure of genetic variation, defining *race* still poses a challenge.

How individuals identify with race and its meaning varies across time and generations. My Japanese mother raised me by herself for the first 5 years of my life, and I would have identified racially as Asian; later during my teenage years and into late adulthood, I identified unequivocally as Black; more recently, I identify just as often as multi-racial. My father identified as Negro and was offended at the designation of Black. My two children, both now grown, are not familiar with the term Negro, except perhaps in a vague historical sense. How do they identify racially? I really don't know, and I don't think they ponder it much.

Herein lies the conundrum in defining race: racial identity is complex, dynamic, and personal, and it is influenced by our perceptions of ourselves and the perceptions others have of us. Science, on the other hand, tends toward reductionism and categorical thinking. Reconciling this gap takes effort. But it is an effort well worth expending because race, however defined, commands an outsize role in our society, influences the distribution of resources and opportunities, and these in turn, influence health and health outcomes. In order to better serve society, our biomedical research methods must better represent what race means in people's lives.

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[1] Evelyn Brooks Higginbotham. 1992. African-American Women's History and the Metalanguage of Race. *Journal of Women in Culture and Society*. University of Chicago Press.

Our committee had a challenging task: to balance the complexity of race (and ethnicity) as social constructs while also offering pragmatic recommendations in the use of these constructs; to confront the sordid history of racial categorization while also acknowledging that even though history may influence what happens today, it may not fully represent current-day circumstances; and finally, while it may be discomforting, square up to the fact that racism occurs even today and has profound impacts on the health of those bearing the brunt of it.

Our committee, composed of an amazing group of experts, proved up to the task. More than their expertise, each brought different perspectives that were shaped by their individual experiences and fields of study. Through the sharing of their knowledge and perspectives, a consensus on a difficult, often contentious topic was shaped with skilled prodding and guidance from a terrific staff. The committee's conclusions and recommendations lay out challenges and opportunities for advancing biomedical research that use race and ethnicity. The topic of race and ethnicity is often fraught with controversy. I thank the sponsors for tackling the use of these constructs in biomedical research and for tasking our committee to grapple with its many dimensions. The work of our committee was enriched by outside experts and community members who participated in the public sessions as well as the reviewers of our draft report. The committee acknowledges their enormous contributions and thanks them for being an important part of our report.

M. Roy Wilson, *Chair*
Committee on the Use of Race and
Ethnicity in Biomedical Research

Summary[1]

The concepts of race and ethnicity have been used in a variety of contexts throughout history, and their use has evolved over time. Often connected to observable traits such as skin color, “race” developed from a belief in innate differences between socially created groups of people and has been used to justify unequal treatment. The use of race can be traced to the origins of the United States and hundreds of years into history.[2] Ethnicity, sometimes used as a synonym for race, can be defined as a more recent socially and politically constructed term used to describe people from a similar national or regional background who share common cultural, historical, and social experiences. As sociopolitical constructs, race and ethnicity have been used in society to determine citizenship, rights, status, and in other discriminatory ways.

The everyday use of race and ethnicity is so engrained in U.S. society that these constructs are commonly used as demographic identifiers in many settings—on a loan application or at the doctor’s office. Race and ethnicity are widely used in medicine, including in cardiology, nephrology, obstetrics, urology, and pulmonology. A recent systematic review found that 30 percent of 414 pediatric clinical practice guidelines incorporated race or ethnicity phrases, often in harmful ways. Yet race and ethnicity are an important part of how people describe themselves and experience the world.

With the ubiquitous use of race and ethnicity, it is unsurprising to find the terms used in biomedical research, which spans research on human health and disease from preclinical methods to population health. Federal biomedical research grants require the use of the U.S. Office of Management and Budget (OMB) minimum set of racial and ethnic categories for tracking enrollment of study participants. The OMB directive states, “the race and ethnicity categories set forth are sociopolitical constructs and are not an

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[1] References are not included in this report summary. Citations appear in subsequent report chapters.

[2] See Chapter 2 for discussion of the meaning and history of race and ethnicity.

attempt to define race and ethnicity biologically or genetically." However, using these categories for the purpose of inclusion has been conflated with other uses, such as scientific analyses.

These categories are not useful proxies for biology because there is no genetic, or biological, basis for race. The Human Genome Project found in 2003 that humans were 99.9 percent identical to each other at the DNA level. Moreover, genetic variation overlaps across racial and ethnic groups instead of creating distinct clusters. A single racial category used in social and political contexts encompasses people with diverse genetic features. Combining these individuals into one group for scientific analyses can lead to oversimplification, misinterpretation, and inaccurate science. Moreover, the use of race and ethnicity in this scientific context can distract from deeper investigations into the true drivers of disease (e.g., genetics, environmental exposures).

It is well established that race and ethnicity are not valid biological markers, but there is a lack of consensus as to whether and how they should be used in research studies or in medical decision making. For example, race and ethnicity categories have been useful in identifying and tracking health disparities such as the profound disparities during the COVID-19 pandemic. Conversely, practices of race correction or race adjustment—that is, developing clinical calculators or guidelines that modify their output based on the patient's race or ethnicity—have faced criticism in recent years for contributing to health disparities and reinforcing the misconception that there are innate biological differences between racial and ethnic groups. However, removing race and ethnicity from clinical tools, algorithms, and guidelines is complicated and requires comprehensive evaluation to assess potential tradeoffs that can vary across populations and depend on the health outcome of interest.

Given the complexity of these considerations, researchers need guidance for deciding if, when, and how to use race and ethnicity, so that when they choose to do so, their approach is rigorous and valid. This report provides resources to guide decision making about the use of race and ethnicity in biomedical research, including consideration of when other measures could better address scientific aims. The committee engaged in this work with the goal that the biomedical research community will move beyond harmful uses of race and ethnicity that create or perpetuate health inequities to a future where race and ethnicity are used thoughtfully in research and its clinical applications.

THE COMMITTEE'S TASK AND APPROACH

The National Academies assembled an ad hoc committee, composed of biomedical scientists, physician and nurse scientists, epidemiologists, social scientists, and experts in law, anthropology, ethics, and clinical informatics, to assess the current use of racial and ethnic categories in biomedical research, review existing guidance, and provide recommendations to guide the future use of race and ethnicity. The Doris Duke Foundation and Burroughs Wellcome Fund asked the committee to provide guidance to the research community on whether, when, and how to use race and ethnicity in biomedical studies.

In developing its approach, the committee defined biomedical research as scientific research across biological, social, and behavioral disciplines that pertains to human health.[3] This report focuses on biomedical research beyond preclinical models on the translational spectrum because race and ethnicity become increasingly relevant in research with groups of people.

The committee assessed current practices related to race and ethnicity across a range of research contexts including race correction, medical devices, secondary data analysis, and clinical decision-making tools, including the expanding use of artificial intelligence (AI)[4] in clinical algorithms. The committee also examined existing guidance for the use of race and ethnicity in related sectors such as publishing guidelines and clinical guidelines development. Based on this analysis, the committee developed recommendations for biomedical scientists, journal publishers and editors, professional societies, and funders of biomedical research. The committee created resources, which can be found throughout the report, to help researchers implement its high-level recommendations.

COMPLEXITY AND NUANCE IN DEFINING AND UNDERSTANDING RACE AND ETHNICITY

Using race and ethnicity in biomedical research is challenging because there are multiple truths and realities that coexist in tension with one another. For instance, describing race and ethnicity as social constructs gives rise to an intrinsic tension—race and ethnicity affect people's experiences and social realities, yet these concepts are not themselves suitable proxies for biological mechanisms. In addition, the concepts of race and ethnicity are defined, understood, and used differently across various domains of research and medicine, which has exacerbated confusion and misunderstanding. Sociology, for example, has long described race and ethnicity as socially constructed, but other disciplines and public perception have been slower to adopt this understanding. This section will unpack why race and ethnicity are not suitable proxies for biology, discuss why it is inappropriate to ignore race and ethnicity altogether, and address apparent contradictions in certain use cases.

The pervasive use of race and ethnicity in society has driven a persistent misconception that humans can be divided into biologically separate groups with distinct characteristics. This idea, known as "race science," has been disproven by decades of research. Research has made clear that race has no genetic basis—that is, race does not explain human genetic variation and vice versa. Human genetic variation is continuous and overlapping, thus refuting the notion of discrete human races. Some genetic variants can be geographically clustered, reflecting long periods of geographic isolation of human populations, which is why some genetic diseases appear

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[3] The committee did not focus specifically on genetics and genomics research, because these fields were addressed by a 2023 National Academies report, *Using Population Descriptors in Genetics and Genomics Research*.

[4] See Chapters 3, 4, and 6 for more information on AI.

more prevalent in some racial and ethnic groups than in others. For example, sickle cell disease has been stereotyped as a "Black" disease in the United States, but the geographic distribution of sickle cell trait is explained by the global distribution of malaria, not race. An evolutionary adaptation that protects against malaria, sickle cell trait occurs in many countries, in people who may identify with various racial and ethnic categories.

Perhaps seeming at odds with these findings, differences in individual characteristics such as eye, skin, and hair color are partially explained through genetic inheritance, but the idea that race has a biological basis is erroneous. Skin color is often viewed as synonymous with race but is a complex trait with contributions from multiple genes and the environment. Skin color does not follow a clear distribution based on racial and ethnic categories, and it is not a substitute for measuring underlying biological mechanisms. In other words, visible differences in traits like eye color do not mean that cells in the eye function differently, nor is eye color a proxy for eye function. The purported connection between race and biology falls apart completely when examining other complex traits and genetic variation.

> *Conclusion 5-5:*[5] *Genetic differences among groups of people are not racial differences. Genetic differences may have meaning in biology and a role in medicine and research. Race, though, is not a substitute for unseen or unmeasured biological predictors of interest.*

Though not biological, race and ethnicity shape social realities and lived experiences. Identity is highly personal, and race and ethnicity are important elements of how people see themselves, relate to others, and experience the world. An added complexity is that the terms individuals use to identify themselves have changed across generations as has the extent and form of racism they have experienced. Referring to race and ethnicity as *social constructs* may be useful among scientists to reinforce that these concepts are not rooted in biology, but this phrase can appear dismissive, labeling the social reality and impacts of race and ethnicity as imagined or unimportant.

Health disparities are one manifestation of the social realities of race and ethnicity. While research may uncover differences in the prevalence or severity of disease across groups of people, evidence indicates that race and ethnicity do not themselves *cause* health differences. Rather, because they are socially constructed, race and ethnicity can be correlated with factors such as social determinants of health (e.g., socioeconomic status, discrimination), which influence biological systems and health. Differences in disease prevalence and contributing social and environmental factors do not indicate that underlying biological mechanisms differ across racial and ethnic groups. For example, rates of cardiovascular disease may vary across populations, but the cellular mechanisms and biological pathways are generally the same despite some genetic variation among individuals. In fact, many molecular and cellular

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[5] The conclusions in this summary are numbered according to the chapter of the main text in which they appear.

mechanisms are so fundamental that they often do not differ across species, much less racial or ethnic groups.

In clinical settings race and ethnicity are commonly described as risk factors and used to assess patients' disease risk. This can sometimes be misconstrued as suggesting that these factors have some biological basis. While risk factors are attributes associated with increased likelihood of developing a disease or a health outcome, the presence of a risk factor does not make a particular health outcome inevitable. Many variables affect human health, including genetics and environmental exposures, and there remains much to learn about their interactions and impact on health outcomes.

Based on these examples and evidence, race and ethnicity should never be construed as biological, observed group associations should not be mistaken for causal explanations, and an individual's race or ethnicity should not be relied upon to predict health outcomes. Despite these potential pitfalls, race and ethnicity can serve several purposes in research—for instance, to ensure adequate rigor with sample populations representing a range of life experience and social contexts, to track health disparities, and to account for how individuals self-identify.

CURRENT USE OF RACE AND ETHNICITY IN BIOMEDICAL RESEARCH

U.S. funders such as the National Institutes of Health often require the use of categories from OMB Statistical Policy Directive 15 to report demographic information about research participants to monitor inclusion in study enrollment. The OMB categories are widely used both by government agencies and by many nongovernmental institutions, such as health care systems. Directive 15 specifies that the categories should not be considered scientific, biological, or anthropological in nature, but sometimes they are used unnecessarily for scientific analysis.

> *Conclusion 5-1: The OMB categories are a minimum set of categories unique to the United States. The OMB categories are often required for inclusion reporting purposes in research. However,*
>
> 1. *the OMB categories are a sociopolitical construct with no biological basis.*
> 2. *the OMB categories are a minimum set of categories, but federal agencies and the scientific community can collect more detailed information.*
> 3. *the OMB categories do not need to be used for scientific analysis, even if they are required for reporting recruitment statistics.*

Due in part to the emphasis on the OMB categories, the current use of race and ethnicity in research is sometimes seen as an exercise in checking boxes or a matter of using the "right" labels rather than understanding why they are used. However, improving the use of race and ethnicity in biomedical research will require thinking about race and ethnicity with intentionality at every step of the research process and understanding the nuances involved in doing so.

SOUND USE OF RACE AND ETHNICITY DEPENDS ON PERSISTENT ASSESSMENT AND DECISION-MAKING

Decisions about the use of race and ethnicity in biomedical research require careful deliberation. Although some situations may be clear-cut, most are nuanced,[6] involving balanced consideration of ethical, contextual, and scientific factors. Even for well-intentioned purposes, such as recruiting a diverse population of participants, the correct approach to using race and ethnicity depends on the research question and the specific context. Context can encompass a variety of biological, social, cultural, behavioral, and environmental factors, including social and historical background that may have contributed to the existing evidence base. In addition, the context varies throughout the research process—from study design, to recruitment, to analysis, and dissemination of results. Therefore, race and ethnicity require ongoing consideration throughout the entire study process to determine whether their use is appropriate or inappropriate.

> *Conclusion 6-1: Both deciding to use race and ethnicity and deciding to omit race and ethnicity can have advantages and disadvantages in biomedical research. It is important to evaluate potential implications, benefits, and risks not only of using race and ethnicity but also of forgoing collection of these data entirely.*
>
> *Conclusion 6-2: Addressing the use of race and ethnicity at only one stage of a study fails to capture the unique factors and consequences that can emerge at subsequent steps of the process.*
>
> **Recommendation 1: At every stage throughout the biomedical research process, researchers should scrutinize, evaluate, and decide whether the use of race and ethnicity is appropriate or inappropriate. Researchers should:**
> - **Identify how the historical or social context, including prior uses of race and ethnicity in research, affects the underlying evidence base for the question of interest;**
> - **Use race and ethnicity in ethical ways based on the context and research question, with a principled scientific rationale documented throughout the study;**
> - **Understand the contexts and requirements for partnering with specific populations and communities, which could include American Indian or Alaska Native Tribes and their distinct political status as sovereign nations;**
> - **Consider the benefits of collecting race and ethnicity information for research purposes, including promoting diverse representation and equity when these constructs are not central to the research question;**

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[6] See discussion in Chapters 3 and 4 about pulse oximetry, race correction, and clinical decision-making tools.

- **Refrain from making unsupported inferences from the analysis, such as relying on race and ethnicity as causal attributes that drive biomedical research outcomes in individuals; and**
- **Weigh the potential implications, limitations, benefits, or harms of using or not using race and ethnicity.**

In publications, researchers should articulate their decisions about whether and how to use race and ethnicity in their research studies and reflect on the outcomes.

RIGOROUS METHODS TO STRENGTHEN SCIENTIFIC INQUIRY ABOUT RACE, ETHNICITY, AND RELATED CONCEPTS

Race or ethnicity has often been used as a proxy for concepts or variables that may be more precise or better suited to the scientific line of inquiry (Box S-1). This reliance on race and ethnicity, especially the OMB categorization, collapses multidimensional information about people into simple labels, making it challenging to tease apart nuanced mechanisms of interest. Furthermore, using race and ethnicity as interchangeable terms exacerbates confusion among researchers and the public. However, avoiding conflation and identifying more targeted approaches can reveal more dynamic and meaningful information. For example, such concepts as structural racism and social determinants of health reveal how broader social contexts have consequences for everyone's health. As another example, race and ethnicity have sometimes been relied on to capture unspecified variation, and further investigation into biomarkers, physiological mechanisms of action, and environmental factors may better explain observed differences and phenomena in biomedical research.

BOX S-1
Concepts Related to Race and Ethnicity

Race and ethnicity categories are often used as proxies for the true concepts or variables of interest. In addition to self-identified race and ethnicity, researchers may choose to investigate:

- Relational aspects of race
- Structural racism
- Social determinants of health (e.g., environment)
- Ethnic and cultural practices (e.g., language, religion)
- Immigration status and degree of acculturation
- Indigeneity
- Skin color and pigmentation
- Known ancestry
- Genetic markers, genetic variation
- Social and stress-related biomarkers
- Other biomarkers and biological indicators

> *Conclusion 6-5: Race and ethnicity conflate many concepts and collapse multidimensional information about people's experience and identity. There is a need for disaggregation of related concepts and for increased granularity in the data collected to better capture the information for which race has been a proxy. Greater methodological specificity will be required to disentangle the various concepts that are often collapsed into a single "race or ethnicity" descriptor or variable.*

Decisions to use race and ethnicity should uphold scientific validity, given the research question of interest. It is important to consider whether race and ethnicity are best suited to the scientific purpose or whether another measure might better address the question. Since race and ethnicity can be measured in various ways, as can other related concepts,[7] reporting definitions and methodology clearly will be essential as more of this work is undertaken.

> **Recommendation 2: Whether conducting primary research or secondary data analysis, biomedical researchers should provide an operational definition of race and ethnicity, if used, in all grant applications, manuscripts, and related products. Within these products, researchers should explain their rationale and the limitations of their approach as well as describe attributes of data provenance, such as:**
>
> - **Which race and ethnicity categories were used for enrollment and/or scientific analyses and why (e.g., which version of the Office of Management and Budget categories was used);**
> - **How race and ethnicity data were reported (e.g., self-identified or socially assigned);**
> - **When data were collected;**
> - **Whether any subcategories were aggregated, including whether samples were relabeled, combined, or harmonized across various sources;**
> - **Whether any race and ethnicity data were derived (e.g., imputation, estimation), and how; and**
> - **Whether bias may exist due to the way categories were defined and handled (e.g., sampling, classification, method of data collection, completeness of data).**

> **Recommendation 3: Researchers should operate with transparency at every stage in the development, application, and evaluation of biomedical technology that may influence health (e.g., clinical algorithms, artificial intelligence [AI] models and tools, medical devices). Researchers should assess and report the performance of biomedical technology across a range of racial and ethnic groups.**

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[7] See Chapters 5 and 6 and Table 6-1 for more information about race- and ethnicity-related concepts and ways to measure them in research contexts.

> **Recommendation 4: Researchers should strive to identify which concepts often conflated with race or ethnicity (e.g., environmental, economic, behavioral, and social factors, including those related to racism) are relevant to their study. Based on those concepts, researchers should select applicable measures and do the following:**
>
> - **Researchers should not rely solely on self-identification with OMB race and ethnicity categories.**
> - **To the greatest extent possible, researchers should incorporate multiple measures in study design, data collection, and analysis to allow for comparison or combination.**
> - **If using a single measure, researchers should articulate a clear scientific justification for why it was chosen and discuss its limitations.**

As specified in Recommendation 1, in addition to thoughtfully selecting variables for study design and analysis, care should be taken when interpreting and reporting results to avoid making misleading or unsubstantiated conclusions. In general, race and ethnicity cannot be isolated as independent variables in an experimental setting in biomedical research. Therefore, race and ethnicity can be correlated with an outcome, but the constructs did not *cause* the outcome. Even so, sometimes results are misattributed to race and ethnicity, and it is important to be aware of limitations surrounding these constructs in biomedical studies.

PRACTICAL APPROACHES TO ACHIEVE INCLUSION THROUGHOUT THE RESEARCH PROCESS

Some research participants are left out of research analyses due to missing race or ethnicity data or because none of the available categories reflects their identity. Others are excluded due to small group sizes or because they selected multiple race and ethnicity categories, making their data more challenging to analyze. There is no single best practice for analyzing data from people who are members of small populations or are multiracial, but the research question and context can guide methodological decisions. Moreover, it is worth considering methods that retain as much information about individuals as possible. Since much of the existing evidence base excludes data that are difficult to work with, there is a need for more research in this area.

> *Conclusion 6-6: Many people are left out of research analysis either due to missing data or because none of the available categories reflects their background. More granular categories may be aggregated, potentially obfuscating missing data or a misalignment of participants' identities with the available categories. "Other" is a category label sometimes used to aggregate data—combining race and ethnicity categories that are too small for separate analysis, individuals with missing data, and individuals who do not identify with the available race and ethnicity categories.*

Conclusion 6-7: There is an increase in multiracial identification in the U.S., but there is no standard way to account for multiracial or multiethnic people in biomedical research. Even if they are recruited, many people who are multiracial or multiethnic are left out of analysis, often because of small sample sizes or uncertainty about how to conduct the analysis. There is a need to include people with mixed ancestry or multiple identities in biomedical research and to appropriately incorporate them in analysis to the greatest extent possible to ensure a diverse sample population.

Recommendation 5: At each stage of the research process, all racial or ethnic category inclusions and exclusions should be based on a clear scientific rationale motivated by the research question.

Researchers should:

- **Consider oversampling for smaller populations to ensure adequate power for analysis.**
- **Describe and characterize all recruited populations, even if some cases cannot be included in analysis due to limits of small sample size.**
- **Articulate the purpose of aggregating categories, deriving missing data, or omitting cases.**
- **Use aggregate category labels that are motivated by the research question (e.g., "Members of minoritized racial and ethnic groups") or reflect the analytical approach (e.g., "Remaining participants").**
- **Justify the choice of reference population.**

Researchers should not:

- **Combine categories solely to improve statistical power.**
- **Make inferences about residual categories.**
- **Aggregate participants into the nonspecific categories "Other" or "non-White" because these labels can be isolating and reinforce one category as the norm.**

Recommendation 6: Researchers should consider the inclusion and analysis of multiracial and multiethnic participants at each stage of the research process, especially when developing research questions and designing the study. Throughout the course of a study, researchers should:

- **Identify relevant concepts (e.g., ancestry, self-identification);**
- **Ensure that respondents can select multiple races, ethnicities, or ancestries during data collection;**
- **Report granular data for multiracial or multiethnic respondents to the greatest extent possible, while respecting confidentiality concerns; and**
- **Identify a plausible classification scheme for including multiracial and multiethnic people in analysis, based on the research question or context; or provide a comparison of results using alternate approaches.**

In line with broader community-engagement efforts, the committee emphasizes partnering with communities to understand how race, ethnicity, and related concepts affect people's experiences. Collaborative engagement at every stage of the research process is essential to doing this work in alignment with ethical and scientific principles.[8] However, the most suitable type of engagement depends on the type of study, line of scientific inquiry, and community context. For example, biomedical studies that emphasize social aspects have a higher need for community partnership than basic science studies about biological questions (e.g., analyzing a biological mechanism, identifying drug targets).

> *Conclusion 6-8: Basic, preclinical, and proof-of-concept studies that seek only to interrogate a biological mechanism can, but need not, invoke questions of race and ethnicity. Regardless of this choice, representing human biological diversity, including in early-stage research, is essential to assure generalizability. Biomedical studies that involve human populations and that hold social and clinical implications necessitate a high degree of cooperative community engagement or partnership.*

Forming partnerships with community leaders and members requires patience, time, funding, and expertise. Early on, study teams should incorporate the necessary expertise, including experts in community engagement or community leaders and liaisons. Community members can provide valuable input throughout a study, from development of research questions to collection and analysis of race and ethnicity data and dissemination of results. It is important for the study timeframe to account for the steps and time required for successful community outreach. Considerations for building community partnerships should be embedded at each stage of the research process to customize the use of race and ethnicity based on the study and community context. For instance, American Indian or Alaska Native Tribes have a unique legal status as sovereign nations in the United States, so conducting research with a Tribe may require demonstrated understanding of its history and entails unique requirements for institutional review board approval, data sovereignty, and dissemination of results.

> **Recommendation 7: Researchers collecting and using race and ethnicity data in biomedical research with human populations should identify and partner with specific communities relevant to the research context. Researchers should collaborate with community engagement experts and organizations and, to the greatest extent possible, partner directly with community members to optimize authentic, continuous, and sustained researcher-community member engagement undergirded by mutual trust.**
>
> - **From the earliest stages of the project, these partnerships should be established to inform hypothesis development and study design, including how race and ethnicity information should be collected and used, through results interpretation and dissemination.**

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[8] See Chapter 2, section "Guiding Principles."

- **Research teams should communicate potential benefits to community partners from project initiation through results dissemination.**
- **In the case of secondary data use, researchers should consult documentation or original investigators from participating studies to understand how communities were involved in the process.**

VISUAL SUMMARY

As this report emphasizes, race and ethnicity must be addressed in an ongoing manner. To help researchers operationalize these recommendations, the committee identified four key considerations to bear in mind at each stage of the research process (Figure S-1):

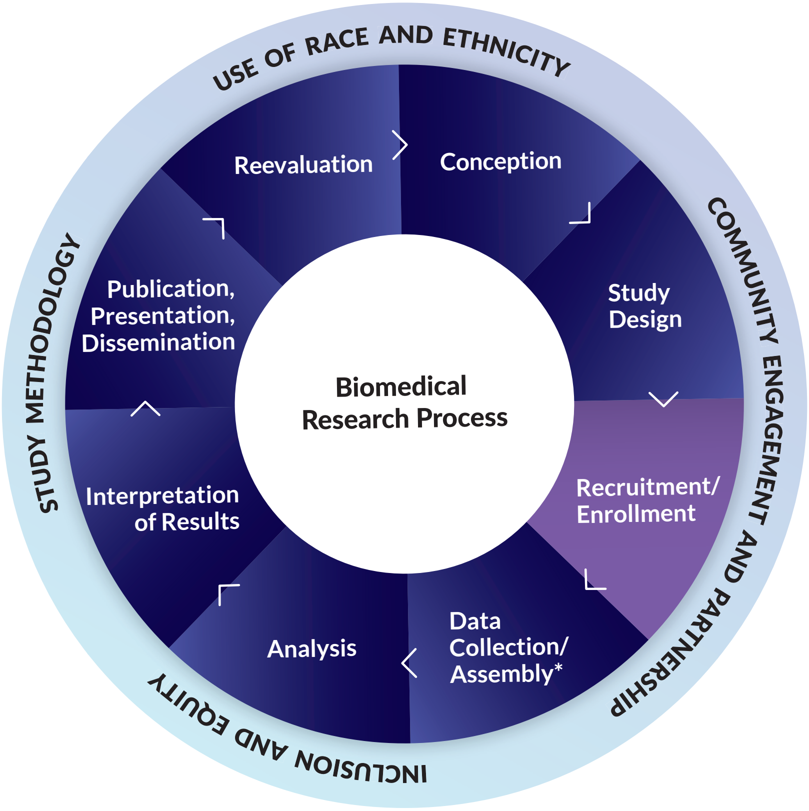
1. Assessing whether to include race and ethnicity and, if so, how to use them.
2. Forming enduring partnerships with communities.
3. Ensuring inclusion and equity for everyone involved in the study and those most affected by the study results.
4. Recognizing and characterizing data biases and limitations.

LOOKING FORWARD

This report offers ways to change how race and ethnicity are used, analyzed, and reported in biomedical research. When implemented, these changes have the potential to improve the scientific rigor of biomedical research, mitigate bias that continues to affect research and health care, and build lasting trust among the scientific community and racial and ethnic communities. As this report underscores, appropriate or inappropriate use of these concepts is context dependent. Adopting these recommendations will require coordinated efforts and investment across the biomedical research ecosystem. Addressing the complex issues inherent in how to use race and ethnicity thoughtfully in biomedical research will require sustained, in-depth conversations across disciplines and sectors. It will take time and effort to unlearn old thought patterns and to retrain the workforce with new ways of thinking. Key sectors, such as biomedical journal editors and funders of biomedical research, could help cultivate intentionality, ensure accountability, and catalyze change for the better.

Recommendation 8: Funders, sponsors, publishers, and editors of biomedical research should provide consistent guidelines to assist researchers in developing and examining their work and to promote the thoughtful use of race, ethnicity, and related concepts to enhance adoption of these recommendations.

- **Journal publishers and editors, research funders, and sponsors should require researchers to provide a scientific rationale for their use of race and ethnicity, describe data provenance, and acknowledge limitations of their use.**
- **Journal editors and funding agencies should provide reviewers with specific guidelines for reporting race and ethnicity that should be used to assess publication and funding decisions.**



Use of Race and Ethnicity
- Disaggregate race and ethnicity
- Define concepts and measurements
- Disclose limitations

Community Engagement and Partnership
- Build trust
- Sustain community partnerships
- Ensure transparency
- Respect data sovereignty
- Form interdisciplinary study teams, including community members

Inclusion and Equity
- Account for time for outreach
- Ensure equitable benefit sharing with the community
- Incorporate multi-racial and multi-ethnic individuals

Study Methodology
- Collect more granular data
- Use appropriate categories and measurements for analysis
- Disclose limitations of legacy datasets

● Applies to all studies ● May not apply to studies not recruiting participants

*Researchers conducting observational studies with existing data may enter the cycle here but should consider data provenance and prior stages.

FIGURE S-1 Key considerations for the use of race and ethnicity throughout the biomedical research process.

- **Funders of research to develop health technologies should require researchers to report results across racial and ethnic groups and encourage researchers to provide datasets, algorithms, and code in an open-source format to the greatest extent possible.**

Funders, sponsors, publishers, and editors of biomedical research should periodically evaluate their policies on the use of race and ethnicity to assess the extent to which the policies are followed and upheld, monitor progress, consider the need for updates, and ensure the guidelines reflect current best practices.

Recommendation 9: To support partnerships between communities and research teams, funders and sponsors should require as appropriate a community engagement plan as part of the application. Funders should provide resources and timelines that encourage researchers to build and sustain collaborations. Research institutions, medical centers, and other biomedical research organizations should develop and support lasting, equitable relationships with community partners.

The report represents a vision of the future where the biomedical community moves beyond the limits of focusing on race to adopt practices that will facilitate an understanding of the true factors of disease.

Conclusion 6-12: The biomedical research enterprise has long emphasized race at the expense of exploring other concepts such as racism and discrimination that may have more direct effects on health. Much of the existing evidence base has deep-rooted bias and requires reexamination. Rebuilding the evidence to examine the role of racism and other associated concepts beyond race and ethnicity categories will require investment from funders and sponsors of biomedical research.

Moving forward starts with recognizing and acknowledging assumptions, biases, and flaws in the existing evidence base. Yet making progress does not have to be daunting. It is an exciting time for the biomedical research community to chart a path forward to improve the use of race and ethnicity for better science and better health.

1

Introduction

The completion of the Human Genome Project in 2003 indicated that humans are 99.9 percent identical at the DNA level and that race has no genetic basis (Duello et al., 2021; NHGRI, n.d.). Most biomedical scientists now realize that race is a socio-political construct that has been used to establish or to rationalize a social hierarchy. However, there is a lack of consensus as to whether race is "biologically meaningless" and whether it should be used in the design of research studies or in medical decision making. Because human populations were relatively isolated throughout much of their history, genetic variants can be geographically clustered, and some of this variability may portend differential disease risk. Since race and geographic ancestry share considerable overlap, some biomedical scientists and physicians believe that, in some cases, race may serve as a proxy, albeit imperfect, for geographic ancestry and thus could provide useful information in biomedical contexts (Futterman et al., 2024). Yet, the potential benefits of using race must be balanced against the potential for harm, and scientific validity must always be scrutinized.

History is replete with the inappropriate and harmful use of race in biomedical research. "Race science," which posits that humans can be divided into biologically separate groups that manifest distinct physical and mental characteristics, has influenced biomedical research for centuries.[1] Different expressions of human characteristics have contributed to the perception of biological racial differences, but research in the genomic era has found that genetic variation among populations follows overlapping, continuous distributions (Jorde and Wooding, 2004). As problematic uses of race garnered attention, many turned to ethnicity as a more palatable alternative, but ethnicity suffers from similar shortcomings in research, and the two constructs are often used interchangeably. Despite race science having been disproven by decades of research, persistent misuse

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[1] https://race.undark.org/ (accessed September 4, 2024).

of race and ethnicity in biomedical research and health care continues to harm racial and ethnic minority groups. Race and ethnicity continue to be used in some biomedical research that has been used to construct medical standards for the diagnosis, prognosis, and treatment of many diseases, including in cardiology, cardiac surgery, nephrology, obstetrics, urology, oncology, endocrinology, and pulmonology (Vyas et al., 2020). Race and ethnicity are also used in diagnostic testing and research regarding cholesterol, bone density, ultraviolet damage in human skin, pain tolerance, neonatal jaundice, body mass index thresholds, diabetes, and breast cancer, to name a few.

LEARNING FROM PAST INJUSTICES AND CHARTING A PATH FORWARD

It is important to acknowledge the dark history in biomedical research using human participants. Both historical and contemporary injustices have resulted in persistent health and health care disparities for racial and ethnic minority groups. Members of racial and ethnic minority groups were disproportionately exploited in previous biomedical research studies, which served as the basis for modern-day standards for genetics, clinical guidelines, and medical practices for all races. For instance, unethical medical research conducted in Nazi Germany on Jewish and other minority groups continues to affect medical knowledge and practice today (Hildebrandt, 2021; Yee et al., 2019). In addition, current gynecological standards and practices are based on exploitive experiments done on Black enslaved women in the United States (Gamble, 1997; Ojanuga, 1993; Washington, 2006) (see Chapter 3 for information on obstetrics). The hormone pills used to protect women against anemia and ovarian cysts—as well as to significantly reduce women's risk of ovarian cancer, colon cancer, and endometrial cancers—were tested unethically in experiments on Puerto Rican women (Blakemore, 2018; Liao and Dollin, 2012). Research on sexually transmitted diseases without the consent of participants has disproportionately used members of racial and ethnic minority populations, including the U.S. Public Health Service Syphilis Study at Tuskegee and U.S. Public Health Service studies of syphilis in Guatemala (Gray, 2002; Reverby, 2010; Rodriguez and García, 2013). In a more contemporary example, blood samples from members of the Havasupai Tribe that were originally collected for a diabetes study were unethically used for other genomic studies without proper informed consent from the Tribe, prompting legal action against researchers at Arizona State University in the early 2000s (Chadwick et al., 2019; Garrison, 2013; Garrison and Carroll, 2023). These harms have contributed to ongoing mistrust of the research and medical establishment among racial and ethnic minority populations.

Even though members of racial and ethnic minority groups were often used as subjects in biomedical research that serves as the basis for medical standards for all racial groups, some biomedical research perpetuated the misguided notion that these individuals are biologically different from White individuals—a practice that harms people of all races by misidentifying the causes of disease (Williams et al., 2019; Yearby, 2021). For example, sickle cell disease is often misrepresented in medical guidelines, standards of care, and biomedical research based on erroneous assumptions that sickle cell was a Black disease (Adler and Rehkopf, 2008; Herrick, 1910; NIH, 2002; Okwerekwu, 2017; Solovieff et al., 2011; Tanabe et al., 2019). It is true that birth prevalence rates of sickle-cell-related hemoglobinopathies are higher among Black individuals (Feuchtbaum et al., 2012; Ojodu et al., 2014). However, people from different places (Afghanistan, Bangladesh, Burma, Greece, Honduras, India, Indonesia, Italy, Spain, and Turkey), who may identify with different racial and ethnic categories (Asian, White, Latino), also suffer from sickle cell disease but may be overlooked for testing and treatment (Bloom, 1995; Wilkinson, 1974). By the 1950s, researchers began to argue that the disease was linked to environmental factors (Allison, 1954; Wailoo, 1996), and studies have since shown that the geographic distribution of sickle cell trait reflects the global disease burden of malaria, such that sickle cell disease is not equally prevalent throughout Africa (Piel et al., 2010). Despite evidence demonstrating the role of environment, the disease is often still racialized (Nelson and Hackman, 2013; Shriner and Rotimi, 2018; Swetlitz, 2016; Wakefield et al., 2018). Sickle cell disease also offers an illustrative example of the intersection between health, race and ethnicity, and biomedical research. As a condition that has been labeled as a primarily “Black” disease in the United States, sickle cell disease receives less research funding than does cystic fibrosis, which has been labeled as a disease that primarily affects White populations (Farooq et al., 2020).

Importance of Health Equity

To combat these injustices, a commitment to health equity can help eliminate disparities and prevent future harm. Health equity is defined as “the attainment of the highest level of health for all people. Achieving health equity requires valuing everyone equally with focused and ongoing societal efforts to address avoidable inequalities, historical and contemporary injustices, and the elimination of health and health care disparities” (HHS, n.d.). This definition of health equity has been adopted by the Centers for Disease Control and Prevention and published in Healthy People 2030, a report used to set national health goals (see Chapter 5 for more discussion). Health equity efforts strive to eliminate injustices in biomedical research and make the legal requirements of nondiscrimination, found in the 14th Amendment of the Constitution, Title VI of the Civil Rights Act of 1964, and Section 1557 of the Patient Protection and Affordable Care Act of 2010, a reality for members of racial and ethnic minority groups. Government policies, such as the National Institutes of Health inclusion enrollment form and U.S. Food and Drug Administration (FDA)’s draft guidance for collecting race and ethnicity data,[2] seek to ensure that all individuals can participate in and have access to research that may benefit individual health.

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[2] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/collection-race-and-ethnicity-data-clinical-trials-and-clinical-studies-fda-regulated-medical (accessed October 16, 2024).

Making Progress Toward Health Equity through Biomedical Research

Biomedical research can help make progress toward achieving health equity by intervening earlier in the research and health care pipeline. Harmful mistakes and longstanding assumptions get "baked in" to research results and are hard to later excavate, as discussed above in the example of sickle cell disease. There are many challenges the biomedical research community will need to navigate, ranging from making erroneous assumptions to the pressure to publish, that can further entrench existing practices. In addition, research participation among diverse racial and ethnic communities is a complex issue and requires ongoing attention, and nondiverse study teams often set research agendas that neglect diseases or concerns that affect racial and ethnic minority populations.

Recently, the rise of artificial intelligence (AI), including machine learning, is highlighting existing bias in the biomedical research evidence base and unresolved concerns about past research practices. Inconsistent evaluation of results, models, and tools as well as varied findings have generated uncertainty and debate over whether to use race and ethnicity in clinical decision tools and how to rectify issues of inequitable health care for members of racial and ethnic minority populations (see Chapter 3, section "History and Current Practices of Race Correction" for further discussion) (Gershengorn et al., 2021; Rosen et al., 2023; Tipton et al., 2023; Tsai et al., 2021; Vyas et al., 2020; Yearby, 2021). Some tools, such as clinical algorithms, clinical practice guidelines, and clinical care pathways, are susceptible to human-introduced racial biases that can affect decisions about who receives disease diagnoses and treatment (Rosen et al., 2023; Tipton et al., 2023; Vyas et al., 2020). Once these clinical tools have been designed and implemented in clinical practice, there is often insufficient evaluation of whether these tools perpetuate health inequities (Tipton et al., 2023). In addition, despite wide variability in the ascertainment and completeness of race and ethnicity information in datasets, some researchers continue to use suboptimal datasets to make inferences and inform their work. Therefore, clear standards and best practices are needed to address how race and ethnicity are used in research design and clinical decision-making tools.

Biomedical researchers are faced with deciding when and how to use race and ethnicity for their studies (Knerr et al., 2011); however, why race and ethnicity should or should not be used is often unclear (Roberts, 2012; Roberts, 2021). For example, federal research grants require the use of a minimum set of racial and ethnic categories for the purposes of monitoring inclusion in studies. Although the categories are "not an attempt to define race and ethnicity biologically or genetically" (OMB, 2024, p. 22183) (see Chapter 2 for more information about U.S. race and ethnicity categories), using race and ethnicity for inclusion purposes can easily be conflated with their use for scientific analyses. For all these reasons, clear guidance is needed to clarify and improve the use of race and ethnicity in biomedical research.

Given these complexities and the lack of clarity for navigating them, this committee was assembled to assess the current use of racial and ethnic categories in biomedical research, review existing guidance for the use of these constructs, and provide recommendations to the research community to guide the future use of race and ethnicity.

STUDY BACKGROUND AND THE COMMITTEE'S TASK

Much has been written in peer-reviewed journals and debated by professional societies to try to stem the misuse of race and ethnicity in biomedical research and clinical care. Among these publications are five National Academies of Sciences, Engineering, and Medicine (National Academies) reports and a workshop proceedings that were published in 2022 and 2023, each focusing on the use of race and ethnicity in research, clinical care, and STEMM (science, technology, engineering, mathematics, and medicine) education. The publications are:

- *Advancing Antiracism, Diversity, Equity, and Inclusion in STEMM Organizations: Beyond Broadening Participation;*
- *Federal Policy to Advance Racial, Ethnic, and Tribal Health Equity;*
- *Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups;*
- *Structural Racism and Rigorous Models of Social Inequity: Proceedings of a Workshop;*
- *Toward Equitable Innovation in Health and Medicine: A Framework;* and
- *Using Population Descriptors in Genetics and Genomics Research: A New Framework for an Evolving Field.*

This current report, sponsored by the Doris Duke Foundation (DDF) and the Burroughs Wellcome Fund, seeks to build upon these research studies and reports. To address some of the root causes of health inequities, the study's sponsors are investing in projects such as Racial Equity in Clinical Equations, a DDF initiative that is dedicated to providing "the evidence necessary to move beyond the use of [clinical] tools that are known to be inconsistent in their use of race as a factor" and "to accelerate the creation of uniform evidence-based guidelines for the use of race information in research related to the design and use of clinical decision-making tools" (Doris Duke Foundation, 2023). This National Academies study was developed under DDF's broader portfolio of work to provide a landscape exploration of how race and ethnicity are used across biomedical research as a whole. The National Academies assembled an ad hoc committee comprised of biomedical scientists, physician and nurse scientists, epidemiologists, social scientists, and experts in law, anthropology, ethics, and biomedical informatics. All of the 16 committee members conduct research in health disparities, health equity, or the impacts of social forces like structural racism and discrimination.

The committee's charge was to evaluate how the social constructs of race and ethnicity are currently used in biomedical research and to provide guidance to the scientific community on the future use of race and ethnicity in biomedical research (see Box 1-1 for the Statement of Task). During the committee's first public session, the sponsors presented the charge to the committee and clarified the statement of task, which includes developing a report with findings, conclusions, and recommendations regarding the use of race and ethnicity in biomedical research and implementation strategies to help enhance the adoption of best practices across the biomedical research community.

BOX 1-1
Statement of Task

An ad hoc committee of the National Academies of Sciences, Engineering, and Medicine will assess the current use of the social constructs of race and ethnicity in biomedical research and provide recommendations to guide the scientific community in the future use of race and ethnicity in biomedical research.

More specifically, the committee will:

- Document and evaluate how racialized group and ethnic categories are currently being used in biomedical research (e.g., as a descriptor, to stratify data, to apply race norming, to infer differences between groups due to environmental and social impacts), including describing consequences and contributions to health inequities in current clinical practices;
- Identify the circumstances in which it is appropriate to use the social constructs of race and ethnicity in biomedical research, for example in studying the health effects of racism, and the circumstances in which race and ethnicity should not be used to inform inferences;
- Review existing guidance for researchers on the use of race as a variable in biomedical research.

Based on its review of the literature and other expert input, the committee will develop a report with its findings, conclusions, and recommendations for entities such as researchers, funders, publishers, scientific and medical societies, health systems, and industry regarding:

- The use of race and ethnicity in biomedical research, including identifying current practices that should be continued, stopped, or modified;
- Policy changes to reform the use of race and ethnicity in biomedical research, with specific attention to the practice of race norming or race correction;
- Implementation strategies to help enhance the adoption of best practices across the biomedical research community.

The committee's work will focus on the use of racialized group and ethnic categories across the spectrum of biomedical research, including the development of clinical prediction models and other clinical decision tools. Related topics in the provision of clinical care, such as inequitable access to health care and racism in care delivery, are beyond the scope of this study.

In the inaugural meeting of the committee, the sponsors identified two central goals for this study. The first is that any researchers who introduce or come across race or ethnicity information in their study designs will thoughtfully and methodically decide whether to use this information to draw inferences and, if they choose to do so, will understand the implications of their decisions, including how they may perpetuate the notion that race or ethnicity is biological or could lead to harm. The second goal is for the report to provide to researchers in academia, government, industry, funding agencies, journals, and professional societies a set of clear best practices on how to determine when the consideration of race and ethnicity in research design is rigorous, especially when the outcome of the research will be used for clinical purposes. The sponsors emphasized the value of characterizing standards of rigor for the research community to uphold regarding the use of race and ethnicity in biomedical research. Specifically, the sponsors asked the committee to provide guidance to the research community on whether, when, and how to use race and ethnicity in the design, development, and evaluation of clinical tools, methods, and devices, with the objective of improving health equity. Therefore, this report provides guidance to researchers to enable them to reconcile their mandate to include diverse populations in their studies or to study the effects of racism without falling into the trap of misusing race, ethnicity, and related terms in ways that impede scientific advances and aggravate health inequities.

Scope of the Report

Although race and ethnicity were the focus of this study, these concepts are associated with the concept of ancestry. Ancestry can be defined as a person's origin or descent, lineage, "roots," or heritage, including kinship (NASEM, 2023). People are familiar with their family tree, which is made up of their biological ancestors and thus reflects in one way their personal ancestry. Acknowledging the ways that ancestry, race, and ethnicity are intertwined, the committee has included ancestry considerations within the scope of this report. Certainly, race, ethnicity, and ancestry are not an exhaustive set of ways to describe individuals and populations of people in research contexts. Although biological sex, gender identity, and sexual orientation are important, nuanced dimensions of identity and health, this study does not include recommendations on sex, gender, or other dimensions of identity as they are out of scope of the statement of task. For a recent National Academies report on sex and gender, see *Measuring Sex, Gender Identity, and Sexual Orientation* (NASEM, 2022). Though sex and gender were defined as beyond the scope of this report, this is an important area of ongoing inquiry with rich scholarship (e.g., Almeling, 2020; Fausto-Sterling, 2000 Richardson, 2013). Future work will be needed to integrate these findings and recommendations across domains and to incorporate intersectional approaches across dimensions of identity (Bauer, 2024; Evans, et al. 2018; Homan et al., 2021; Merz et al., 2023).

Of note, the report focuses on the research context, and topics directly related to inequitable access to health care or clinical care delivery (e.g., physician–patient interactions) are beyond the scope. Similarly, the sponsors clarified that a comprehensive assessment of clinical practice guidelines and care pathways would be beyond the scope.

However, such guidelines sometimes reference clinical algorithms and other decision-making tools developed based on biomedical research that made inferences about race and ethnicity. Guidelines built with tools and algorithms that may have racial and ethnic biases built into their modeling could also be biased. A survey of clinical guidelines could offer lessons and themes that could apply to the research context, for example, as biases occur across phases of research and in development of tools and products. However, a full assessment of clinical care or medical education is beyond the scope of this report. In addition, the reference to policy in the statement of task was understood to mean research best practices, rather than legal or government policy.

Biomedical research is a global enterprise in which data, reagents, and related resources are often shared across national borders. Clinical trials, in particular, recruit globally with only about 24% of clinical trial participants enrolled in the United States (FDA, 2024; see also Petryna, 2009 and Pollock, 2019). However, as discussed further in Chapter 6, racial and ethnic descriptors vary greatly in different parts of the world, calling for additional nuance beyond the scope of this report. Further, countries vary in their laws and privacy regulations for collecting data, which makes it difficult to use consistent racial and ethnic group categories on a global scale. Groups such as the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) can help with developing harmonization for data collection on a global scale, and it is important that groups like the ICH critically examine the use of classificatory categories. Given this added complexity and in discussion with the sponsor during their first meeting, the committee decided to focus this report primarily on the biomedical research enterprise in the United States, with the understanding that the harmful misuse of social constructs such as race and ethnicity in research and medicine is not a phenomenon unique to the United States and with the potential for this report to serve as a resource for other more global efforts.

Audiences of the Report

There are multiple audiences for this report. First and foremost are biomedical, behavioral, and clinical researchers working across a spectrum of different types of research and research settings (e.g., academia, industry). The committee defined biomedical research expansively (see Chapter 2). This approach made it impractical to provide specific guidance for every subfield of biomedical research but serves to welcome many researchers to consider how to use race and ethnicity in their work (including those who may not have considered the role or implications for race and ethnicity in their work). Biomedical researchers, such as those conducting applied research related to clinical tools and equations, and biomedical engineers developing wearable devices and medical instruments, as well as social and behavioral scientists, epidemiologists, and public health professionals constitute the primary audience to whom this report is directed.

Biomedical researchers will need support from other entities in the research ecosystem to successfully operationalize the report's recommendations. The people who work for funding entities, regulatory agencies, biomedical and medical journals, professional societies, health and health care systems, and industry all have critical roles to play. In particular, the report outlines how funders, sponsors, publishers, and editors of biomedical research can incentivize investigators to adhere to these recommended best practices and can support scientists and engineers to increase adoption of the recommended best practices in this report.

THE COMMITTEE'S APPROACH AND ORGANIZATION OF THE REPORT

The committee's goal is that biomedical researchers and others in the research ecosystem will move beyond harmful uses of race and ethnicity that create or perpetuate health inequities to a future where race and ethnicity are used thoughtfully in research and its clinical applications. To address its charge, the committee met to discuss the evidence, deliberate, and develop recommendations. The committee reviewed current literature, including existing guidance on the use of race and ethnicity in research to inform its work. The committee also hosted four public meetings to gather additional information and viewpoints. One of these meetings focused on community perspectives on the use of race and ethnicity in research. Appendix A includes more information on the study methods, including terms used in literature review and public meetings agendas.

The topic of race and ethnicity is one where it can be challenging to arrive at consensus. With members from different backgrounds and areas of expertise, the committee began by discussing fundamental questions about the meaning of race and ethnicity, concepts that are used differently across fields of research (see Chapter 2). The committee acknowledges that some feel that race should be done away with entirely. A thorough explanation about why race and ethnicity are social concepts and not based in biology is included in Chapter 2. However, given the need to track persistent health disparities and comments from community members about the importance of race and ethnicity to their identities, the committee sees value in continuing to collect race and ethnicity data, as discussed further in Chapters 3 and 6.

The committee also acknowledges the importance of language and terms. In the context of this report, the committee uses "racial and ethnic minority groups" when referring to multiple populations who have been racialized or minoritized based on their racial or ethnic identity in the United States. However, there are multiple terms, including minoritized and marginalized, that are in use in contemporary literature and could be suitable depending on the context. The committee recognizes that terms change over time and will continue to evolve to best reflect contemporary understanding and as demographic shifts occur in the United States. Throughout the report, the committee uses the term "race and ethnicity" where relevant because the concepts are closely intertwined in common understanding and in practice. However, the committee details how dimensions of race and ethnicity can be differentiated in research through careful measurement in Chapter 5.

Defining biomedical research, which is a varied and multidisciplinary field, was also a core discussion that shaped the committee's approach to the task. A more thorough accounting of their discussion can be found in Chapter 2 "Foundations and Background." The committee considered different approaches for organizing their analysis and review of the evidence. Given an expansive definition of biomedical research, the committee determined that providing specific guidance for individual subfields would be impractical and could risk missing some disciplines. Instead, the committee took a more generalized approach based on the research process. This framework, which progresses from study design to data collection, analysis, interpretation, and publication, offers a common touchpoint across fields of biomedical research. Throughout the report, the committee balanced this approach by including examples that illustrated the connections between biomedical research, clinical practice, and health outcomes. Based on the gaps identified in their review of the evidence, the committee developed guidance for the future use of race and ethnicity. Future use is rooted in articulating a context-specific scientific rationale for when to use, or when not to use, the concepts of race and ethnicity, so the committee also examined other concepts and measures associated with race and ethnicity that could prove useful as tools of study throughout biomedical research. Finally, the committee formulated a set of conclusions, recommendations, and tools for researchers and other actors in the biomedical research ecosystem.

Reflecting the committee's approach, the report is organized as follows. Chapter 2 lays the foundations for this work, providing a set of guiding principles, foundational definitions of race and ethnicity, and background about the use of these concepts in the United States. Chapter 3 examines different ways that race and ethnicity are currently used in biomedical research broadly and some of the problems that result from misuse, such as race correction in clinical practice guidelines and bias in the output from optical-sensing medical devices. Some of the existing guidance on using race and ethnicity is presented in Chapter 4, including guidance from FDA and academic journals, guidance for working with communities, and suggestions for developing clinical practice guidelines and algorithms that avoid racial and ethnic biases. Chapters 5 and 6 provide the committee's advice for reconsidering ways of using race and ethnicity information in biomedical research and for studying variables, like social determinants of health, for which race and ethnicity are too often used as proxies. Chapter 6 includes a set of recommendations that, when implemented, will facilitate the adoption of best practices in the use of race and ethnicity in biomedical research.

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2

Foundations and Background

This chapter provides the foundations for the report, beginning with a set of scientific and ethical principles that grounded the committee's work. Race and ethnicity are often used and defined differently across fields and by different individuals. To develop a common understanding from which to build analysis and recommendations, this chapter presents the committee's definitions of race and ethnicity and includes background on how these concepts have been commonly used in the United States. The chapter defines biomedical research and concludes with a brief discussion of the complexities that arise at the intersection of social context and biology.

GUIDING PRINCIPLES

Chapter 1 described injustices that have contributed to health disparities and mistrust of the research establishment among some racial and ethnic groups. Researchers and other parties in the biomedical research ecosystem have a responsibility to uphold values and principles that merit trust in scientific findings. The trustworthiness of biomedical research depends on both its integrity and ethical foundations. In the context of race and ethnicity, trust influences how these data about identity are ascertained, disclosed, and documented, which in turns influences the quality of data that will be used in research. In keeping with the National Academies of Sciences, Engineering, and Medicine's (the National Academies') commitment to responsible and ethical science, this report and its recommendations are built on a set of guiding principles, comprehensive propositions that reflect the highest ideals of science (NASEM, 2017). For biomedical research to be ethical, it must both be scientifically valid and have social value (Freedman, 1987). The guiding principles that frame this report are the scientific standards of validity, objectivity, rigor, reproducibility, replicability, openness, and transparency, together with the ethical principles of justice, respect for persons, beneficence, equity, and inclusion.

Principles are comprehensive, fundamental truths, laws, or assumptions that serve as the rationale for a system of reasoning, belief, or behavior. Principles reflect values and experience but are also based in evidence, logic, and reason. The principles of responsible and ethical science often overlap, and related terms may be used in multiple ways. Moreover, in some situations, the demands of two or more principles may conflict (e.g., beneficence and autonomy in ethics). Thus, the committee recognizes that its principles should be understood in context—not as absolutes, but as guides to further analysis and reasoned action.

Scientific Principles

- *Validity* refers to the extent to which a measure, test, or study correctly or truthfully represents the concept, characteristic, or phenomenon intended to be assessed. Validity is a benchmark for the integrity of research (George et al., 2003).
- *Objectivity,* or freedom from bias, is a fidelity to facts and evidence arising from research that is largely free of biases, emotions, and untestable beliefs. It is key to the validity and reproducibility of research, particularly awareness and minimization of bias in the framing of a research question, the design and conduct of the study, and the interpretation and reporting of results.
- *Rigor*, the strict and controlled application of careful research design and scientific method across all stages of a study, is a foundation of responsible biomedical science (NIH, 2023).
- *Reproducibility* is the consistency of the results obtained using the same data, methods, and conditions of analysis, which may confirm the validity of prior work. Reproducibility is particularly important for computational data, as detailed in reports from the National Academies of Sciences, Engineering, and Medicine (NASEM) (e.g., NASEM, 2019).
- *Replicability* is the consistency of research results from work that asks the same question with different methods. The term replicability is often conflated with reproducibility in common use, but reproducible research may not be replicable (NASEM, 2019).
- *Openness* is the willingness to share methods, processes, and data, which is fundamental to the reproducibility and replicability of research within and across disciplines and contexts
- *Transparency*, which is related to but distinct from openness, is the disclosure of information necessary for the reproduction, verification, and evaluation of research and the evaluation of its potential biases (Resnik, 2023).

Ethical Principles

The well-known Belmont principles for ethical research with human beings are at the core of this report's framework (HEW, 1979), complemented by specific considerations for larger ethical questions related to race and ethnicity in research.

- *Respect for persons* in the context of general research refers both to the conviction that individuals should be treated as autonomous agents whose considered opinions and choices should be honored and to the commitment that persons with diminished autonomy should be protected, even to the point of excluding them from activities that may do them harm (Emanuel, et al., 2000). In the context of this report, as in NASEM's 2023 report on population descriptors, respect calls for understanding the preferences, norms, and values of individuals and communities to inform the ways in which people are described in research (NASEM, 2023a).
- *Beneficence* in research encompasses both the commitment to prevent and minimize possible harms and the need to maximize possible benefits. Beneficence is linked to the social value of research, in that ethical studies should produce meaningful benefit for the public at large and, to the greatest extent possible, benefit for individuals and communities that participate in it. In the context of this report, beneficence requires consideration of how the use of race and ethnicity as research variables may harm or benefit a study's participants, their communities, and wider society.
- *Justice* is a multifaceted principle that, in the context of research with human participants, addresses the fair distribution of the benefits and burdens of research across communities and populations (NASEM, 2023b). Unlike respect for persons and beneficence, the principle of justice requires inclusion of disadvantaged groups for potentially beneficial research, but this inclusion must be balanced to protect groups from being overburdened (Yearby, 2017, 2021). Here, justice particularly involves determinations of whom to study and how to characterize them related to a particular biomedical question. Justice requires that researchers do not use certain populations for research that may perpetuate the belief that there are biological differences between racial and ethnic populations, but it also requires that these populations can participate in beneficial biomedical research.
- *Equity* is a dimension of justice that reflects not only fairness in the distribution of the benefits and burdens of biomedical research, but also the fairness and unfairness of the social systems that affect health and in which biomedical research is conducted (Yearby, 2017, 2021; see also NASEM, 2023b). A commitment to equity calls for researchers to recognize and redress their biases regarding the populations they study and the power differentials between them. It also requires researchers to consider whether their study will further perpetuate or exacerbate unfairness in social systems.
- *Inclusion* is similarly a dimension of both justice and respect for persons. Inclusion requires recognition of the identities, strengths, needs, and lived experiences of members of racial and ethnic minority communities and populations, particularly as these groups see themselves, and works to create productive and respectful partnerships (NIMHD, 2024).

A COMMON UNDERSTANDING OF RACE AND ETHNICITY

The committee is comprised of members from a variety of disciplines—medicine, biomedical research, social sciences, and more. Race and ethnicity are defined and used differently across fields such as clinical practice and sociology. To assess the current use of race and ethnicity in biomedical research and to provide guidance for future use, it was necessary to grapple with the terms "race" and "ethnicity" and develop a common understanding of these concepts as well as their relationship to racism. Although there are many existing definitions of race and ethnicity, they are not necessarily consistent with one another; for example, some definitions treat the concepts as largely interchangeable while others highlight key differences between the two concepts. Thus, the committee consulted recent National Academies reports[1] on related topics as well as the broader scientific literature to develop a shared understanding of these terms.

Defining race and ethnicity can be elusive because the concepts are dynamic, highly contextual, and multidimensional, incorporating social, political, and geographic factors. Race is, to borrow a term from computer science, an *overloaded* word, indicating that the word has multiple meanings that depend on the context. The social context and related factors give meaning and vibrancy to the definition of race, affecting how race is conceptualized and operates in real life (Duany, 1998; Leeman, 2018). Even the words "race" and "ethnicity" are entangled. For instance, the U.S. 2020 census offered two categories for ethnicity, Hispanic/Latino and Not Hispanic/Latino (U.S. Census Bureau, 2021). Yet, many people with Latin American ancestry consider their *race* to be Hispanic/Latino. In addition, many people identify with a race or ethnic category that was not among the options included in the census. It should be noted that the 2024 revisions to the Office of Management and Budget (OMB) standards on race and ethnicity have combined race and ethnicity under one question, further enmeshing these concepts (see the following section, U.S. Office of Management and Budget Race and Ethnicity Categories). Failing to recognize the political context of race can also have far-reaching implications. American Indian or Alaska Native, for instance, has been a single racial category on the last three U.S. censuses, but that does not recognize an inherent complexity— that each of the 574 federally recognized Tribes is an independent nation and political body (Cherokee Nation, 2024; Library of Congress, n.d.).

Race and ethnicity are also difficult to define in a research context. Different academic disciplines do not share a common history or usage of the terms, which have evolved over time (Hammonds and Herzig, 2009; Morning, 2011; Roberts, 2012). Sociology has long defined race as a social construct; however, other fields have been slower to arrive at this conclusion (Morning, 2007). Anthropology, for example, historically had a concept of race rooted in shared physical characteristics or features that has since developed to incorporate other social and cultural aspects, in turns critiquing and reinforcing race science over time (Baker, 1998; Bashkow, 2020; Gravlee, 2009; Jobson, 2019; Morning, 2007). For these reasons, the committee discussed the meaning of race and ethnicity as part of their deliberations.

In brief, the committee defined *race* as a sociopolitical construct conceived to describe and categorize people hierarchically (Box 2-1). Race is not valid as a biological concept; race is a dynamic social division that has been used to include or exclude

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[1] *Advancing Antiracism, Diversity, Equity, and Inclusion in STEMM Organizations: Beyond Broadening Participation* (2023); *Using Population Descriptors in Genetics and Genomics Research: A New Framework for an Evolving Field* (2023); *Federal Policy to Advance Racial, Ethnic, and Tribal Health Equity* (2023).

BOX 2-1
Definitions of Race, Ethnicity, and Ancestry

Conceptual definitions describe the meaning underlying the term as an idea.

- *Race*: a sociopolitical construct conceived to describe and categorize people hierarchically. Race has been used to include or exclude individuals and groups; it is a dynamic social division that varies across historical, political, and geographic contexts.
- *Ethnicity*: A socially and politically constructed term used to describe people from a similar national or regional background who share common national, cultural, historical, and social experiences (NASEM, 2023c). An ethnic group is often defined based on a belief in shared ideas, values, behaviors, heritage, or language. Ethnicity also varies across historical, political, and geographic contexts.
- *Ancestry*: A person's origin or descent, lineage, "roots," or heritage, including kinship (NASEM, 2023a).

individuals and groups, and it varies across historical, political, and geographic contexts. Historically, race has been used to create and justify advantage or disadvantage for some groups over others. *Ethnicity* can be defined as a socially and politically constructed term used to describe people from a similar national or regional background who share common cultural, historical, and social experiences. An ethnic group is often defined based on a belief in shared values, behaviors, heritage, or language. Ethnic categories also vary across historical, political, and geographic contexts (see "Ethnicity" in Chapter 5 for more). Lastly, both race and ethnicity are intertwined with the concept of *ancestry*—that is, a person's origin or descent, lineage, "roots," or heritage (NASEM, 2023a). All three concepts are part of a family of descent-associated descriptors that attempt to represent aspects of common origin (NASEM, 2023a).

The definition of race provides a connection to the systems, institutions, beliefs, and processes that underpin racism. Racism, one form of discrimination, is rooted in a belief in innate differences between groups of people. Understandings of race based on physical features, including perceived inherent and biological differences, date to colonialism and the Transatlantic slave trade and are inextricable from the history of the United States. Yet, the history of race can be traced farther into the past. Historians note that the term race (raza) was first used with this connotation during the Spanish Inquisition, when a belief in "limpieza de sangre" (blood purity) led Spanish rulers to question the loyalty of Jewish and Moorish converts to Catholicism (Fredrickson, 2002). While a comprehensive review of the origins of race and racism are beyond the scope of this report, it is important to recognize how this history has shaped scientific knowledge and medical practice to this day. Racism can manifest in various forms, including structural, institutional, and interpersonal racism (see Box 2-2). Beyond interpersonal

BOX 2-2
Definitions of Racism[1]

"Racism is an organized social system in which the dominant racial group, based on an ideology of inferiority, categorizes and ranks people into social groups called 'races' and uses its power to devalue, disempower, and differentially allocate valued societal resources and opportunities to groups defined as inferior" (Williams et al., 2019, p. 106).

There are various forms of racism, which can operate at multiple levels (Jones, 2000), including, but not limited to, the following:

- *Structural racism* has been defined in a number of ways, including as "the macrolevel systems, social forces, institutions, ideologies, and processes that interact with one another to generate and reinforce inequities among racial and ethnic groups" (Gee and Ford, 2011, p. 3) as well as "the totality of ways in which societies foster [racial] discrimination, via mutually reinforcing systems... (e.g., in housing, education, employment, earnings, benefits, credit, media, health care, criminal justice, etc.) that in turn reinforce discriminatory beliefs, values, and distribution of resources" (Berkman et al., 2014, p. 69), reflected in history, culture, and interconnected institutions (Berkman et al., 2014; Krieger, 2014). This definition is similar to the "über discrimination" described in Reskin, 2012 (see also Dean and Thorpe, 2022 for discussion differentiating structural racism from other similar terms). Structural racism is perpetuated by law and policies that structure systems in a discriminatory way (Bailey et al., 2021; Dawes, 2020; Yearby, 2020).
- *Institutional racism* refers to policies and practices within and across institutions that, intentionally or not, disadvantage members of minoritized racial and ethnic groups (Roundtable on Community Change, 2017; see also NASEM, 2023d) and can operate through seemingly "race-neutral" policies and practices that impose disproportionate harms among racial and ethnic groups (Haney Lopez, 1999).
- *Interpersonal racism* refers to direct discriminatory interactions between individuals, which includes intentional actions of discrimination (DOJ, n.d.; Krieger, 2014).
- *Intrapersonal or internalized racism* occurs when individuals of socially constructed racial and ethnic groups accept stereotypes about themselves and those who share the same racial identities, while believing that members of other racial groups are superior, which can be harmful to their psychological well-being and physical health (Priest and Williams, 2018).

[1] This is a non-exhaustive list of the various forms and types of racism.

acts of discrimination or prejudice, racism can persist through systems and processes that reinforce inequity among racial and ethnic groups (Gee and Ford, 2011; Jones, 2000).

Among various forms of racism, scientific racism is particularly salient to this report. A pernicious ideology that sought to legitimize racism and White hegemony via the guise of pseudoscientific methods and evidence, scientific racism emerged in Western science as the ideas of evolutionary theory and the scientific impulse to categorize came together and resulted in the false notion that humans could be divided into distinct biological groups that could be ranked hierarchically. For instance, in the 19th century, notable physicians tried to identify the physical characteristics of Black individuals that could "serve to distinguish him from the white man" (Tidyman, 1826). Such spurious differences included thicker bones (Cartwright, 1851) and skulls, less sensitive nervous systems, and diseases intrinsic to darker skin (Tidyman, 1826). (See Chapter 3 for additional examples and discussion.) This type of biased research has long been embedded in the biomedical evidence base, shaping medical knowledge and practice, and it continues to affect science and medicine today. An assessment of publications from 1950—2000 found that biological theories of race and biological essentialism (e.g., that there are "African" and "White" genes) have evolved but persisted in biomedical and life science journals, despite the prevailing belief that the scientific community has moved away from these notions (Obasogie et al., 2015; see also Jones et al., 2024).[2] These purportedly "scientific" attitudes normalized the use of race to stratify groups of people and compare their risk of disease development or prognosis.

While the focus of this report is not on the origins of scientific racism or other forms of racism, the committee recognizes the importance of this history and its enduring implications. Indeed, other scholars have written extensively on these topics, and readers interested in a more comprehensive assessment of these topics, including the various forms and evolution of racism, are encouraged to consult the following reference list:

- Bonilla-Silva, E. 2021. *Racism without Racists: Color-blind Racism and the Persistence of Racial Inequality in America*. Rowman & Littlefield.
- Feagin, J. 2013. *Systemic Racism: A Theory of Oppression*. Routledge.
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[2] See a recent series of articles published by *The New England Journal of Medicine* exploring the history of mistreatment of groups of people on the basis of their race, ethnicity, religion, gender, and physical or mental conditions: https://www.nejm.org/recognizing-historical-injustices (accessed October 16, 2024).

- Keevak, M. 2011. *Becoming Yellow: A Short History of Racial Thinking*. Princeton, NJ: Princeton University Press.
- Morning, A. 2011. *The Nature of Race: How Scientists Think and Teach About Human Difference*. Berkeley, CA: University of California Press.
- National Academies of Sciences, Engineering, and Medicine. 2023. Chapter 2 The Historical and Contemporary Context for Structural, Systemic, and Institutional Racism in the United States. *Advancing Antiracism, Diversity, Equity, and Inclusion in STEMM Organizations: Beyond Broadening Participation*. Washington, DC: The National Academies Press.
- Roberts, D. 2011. *Fatal Invention: How Science, Politics, and Big Business Re-create Race in the Twenty-first Century*. New York: The New Press.
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Moving from Concepts of Race and Ethnicity to Measurements

Adding to the complexity of working with race and ethnicity, definitions of these constructs can be framed in a conceptual way or, alternatively, in the context of operationalizing (measuring) them. Distinct from conceptual definitions that describe the meaning of each term (such as those in Box 2-1), operational definitions explain how the concept is measured or how a variable might be defined in a research context. An operational definition delineates how a concept, such as race, was measured—for example, that race was measured by allowing participants to choose among a set of labels to answer a question about their racial identity. Operational definitions will, of necessity, vary across studies and contexts. In the United States, one of the most well-known operational definitions of ethnicity was the former federal definition, consisting of only two categories—Hispanic/Latino or Not Hispanic/Latino, until OMB released its revisions in March 2024.

The process of moving from the identification and definition of a relevant concept to its measurement is a key step in research methodology. Researchers often do this implicitly or without thinking much about it, but it is worth making the process explicit to highlight how a single concept can be measured in different ways. Take, for example, the concept of weight. Weight can be defined as the force acting on an object due to gravity; this is an abstract definition. The concept of weight is made concrete (operationalized) in how it is measured. For example, weight is often measured by putting an object on a scale. When determining the weight of a person, weight can also be assessed through self-report, which might be an estimate of how much that person thinks they weigh. Weight can also be described in different units, such as pounds or kilograms. Each of these are measures of weight, but they will not necessarily be equally well suited to different situations.

The same kind of methodological thinking is relevant when measuring concepts like race, ethnicity, nationality, or ancestry. People's nationality can be measured by the passport they carry, the place of their current residence, or their self-reported identification.

Similarly, ancestry can be measured in multiple ways, such as using genetic assessments of similarity or social perceptions of ancestry through genealogical records or family lore. Depending on the research question or context, some measures may be more appropriate than others. For example, genetic measures of relatedness may help identify allelic similarities (or differences) that have associations with particular illnesses, but social measures of ancestry may be more appropriate for understanding how particular health beliefs or practices are passed down in families.

Focusing on the decision to use a particular measure or set of measures helps identify many of the key debates that surround the use of race in science and medicine. Should a measure of race be self-reported or recorded as perceived by others? Is it better proxied by measuring visible, physical characteristics such as skin tone, or is it more closely related to ancestry? Should it be measured as an individual characteristic, or is it (also) a part of the social context in which people live? Today, most large-scale datasets used for health research rely on self-reported measures of race that draw on a set of categorical distinctions that have been defined by the government, but which are sometimes contested through political processes. This type of measure has been criticized for not reflecting how people actually identify themselves in their everyday lives (Atkin and Minniear, 2023) and for implying that race is something one *is* rather than a social position that is negotiated through interactions as part of a broader system of hierarchy and inequality. Self-reported race is also often uncritically applied, as when a measure intended to ensure inclusion during study recruitment is later treated by default as a relevant measure of "difference" during analysis (Bentz et al., 2024) or inappropriately interpreted as causal (Holland, 2001; Kaufman, 2008; VanderWeele and Robinson, 2014). Taking these critiques seriously, more recent work has focused on understanding race and racialization not as a static individual characteristic but as a dynamic process that hinges on racial appearance or treatment by others (Rose, 2023; Saperstein and Penner, 2012; Vargas et al., 2019), has been built up historically (Hudson, 2021; Nagata et al., 2024; Wrigley-Field, 2024), and is reflected in highly unequal contexts (Brown and Homan, 2024; O'Brien et al., 2020; Tan et al., 2022; Torche and Sirois, 2019). Although this does not render measures of racial self-identification irrelevant, it suggests their use should be carefully considered and explicitly matched to a particular purpose.

U.S. OFFICE OF MANAGEMENT AND BUDGET RACE AND ETHNICITY CATEGORIES

Background of the OMB Categories and the Census

In 1977, the U.S. Office of Management and Budget (OMB) Statistical Policy Directive No. 15 created federal standards for reporting race and ethnicity data to provide information needed for enforcing civil rights laws (OMB, 1977, 1997). The four race categories and two ethnicity categories soon became known popularly as "the OMB categories" (see Box 2-3). Directive 15 was updated in 1997 to include five race categories, two ethnicity categories, and the option to report more than one race. In 2024, the OMB categories were updated to include seven combined race and ethnicity categories.

BOX 2-3

United States Office of Management and Budget Categories for Collection of Race and Ethnicity

The concepts of race and ethnicity are operationalized in different ways depending on the context. In the United States, the Statistical Policy Directive No. 15 (Directive 15) describes categories for collecting race and ethnicity data. The categories described in Directive 15 are popularly known as "the OMB categories" and are often used interchangeably with race and ethnicity in the United States.

1997 OMB Categories

OMB's 1997 Directive 15[1] included separate race and ethnicity questions. The policy states that these are the minimum categories for data collection and encourages collecting more detailed information.

Race (five minimum categories)
- American Indian or Alaska Native
- Asian
- Black or African American
- Native Hawaiian or Other Pacific Islander
- White

Ethnicity (two minimum categories)
- Hispanic or Latino
- Non-Hispanic or Latino

2024 Revisions to the OMB Categories

OMB's 2024 revisions[2] combine collection of race and ethnicity information into a single question. The policy requires collecting more detailed race and ethnicity information by default, with the possibility of applying for exemption. The specific subcategories represent the six largest population groups in the United States within each minimum category, along with the option to select "Another group."

Directive 15 provides a minimum set of categories for federal agencies to use in collecting and reporting data on race and ethnicity. The categories have been widely used across government agencies to the extent that the categories have become ubiquitous and synonymous with the conception of race in the United States. Appearing in multiple contexts, the OMB categories have purposes across federal agencies and sectors, including in the census and for inclusion purposes in federally funded research.

Every 10 years, the U.S. Census Bureau collects information about the country's population. The OMB categories and census categories are often believed to be one and the same, but they are, in fact, distinct. The Census Bureau must use the OMB categories at a minimum but is ultimately accountable to Congress. As such, the census

Race and/or ethnicity (seven minimum categories)

- **American Indian or Alaska Native**[3]
    - Examples[4]: Navajo Nation, Blackfeet Tribe of the Blackfeet Indian Reservation of Montana, Native Village of Barrow Inupiat Traditional Government, Nome Eskimo Community, Aztec, Maya
- **Asian**
    - Detailed categories: Chinese, Asian Indian, Filipino, Vietnamese, Korean, Japanese
- **Black or African American**
    - Detailed categories: African American, Jamaican, Haitian, Nigerian, Ethiopian, Somali
- **Hispanic or Latino**
    - Detailed categories: Mexican, Puerto Rican, Salvadoran, Cuban, Dominican, Guatemalan
- **Middle Eastern or North African**
    - Detailed categories: Lebanese, Iranian, Egyptian, Syrian, Iraqi, Israeli
- **Native Hawaiian or Other Pacific Islander**
    - Detailed categories: Native Hawaiian, Samoan, Chamorro, Tongan, Fijian, Marshallese
- **White**
    - Detailed categories: English, German, Irish, Italian, Polish, Scottish

[1] https://transition.fcc.gov/Bureaus/OSEC/library/legislative_histories/1195.pdf (accessed October 16, 2024).

[2] https://www.federalregister.gov/documents/2024/03/29/2024-06469/revisions-to-ombs-statistical-policy-directive-no-15-standards-for-maintaining-collecting-and (accessed October 16, 2024).

[3] The American Indian or Alaska Native category does not have required detailed categories under the 2024 standards. A write-in field should be provided.

[4] This list of examples is verbatim from Directive 15. However, it should be noted that Aztec and Maya are not among the list of 574 federally recognized American Indian Tribes and are not American Indian under the legal definition (see "Indigeneity" in Chapter 5 for further detail).

may also include additional categories or questions, but only as needed by government agencies or as legislated by Congress. For instance, the specific breakdown of the Asian categories and the inclusion of "Some Other Race" were mandated by Congress for the last census in 2020 (Mathews et al., 2020). To provide recommendations for changes to the content of census questions, the Census Bureau runs content tests to evaluate different wording and formatting for the questions.

The census offers a prime example of how the categories have evolved over U.S. history. "The list of racial groups on the U.S. Census, for example, has changed nearly every decade since the first enumeration in 1790, with categories like 'mulatto,' 'Mexican,' and 'Hindu' appearing and disappearing (Lee, 1993; Prewitt, 2005)" (NASEM, 2023a, p. 73;

see also Figure 2-2 in NASEM, 2023a). Further demonstrating how racial and ethnic categories evolve, Italian, Jewish, and Irish population groups were commonly considered to be racial groups in the early 20th century (NASEM, 2023a; see also Jacobson, 1999). The names of categories also evolve, reflecting changing attitudes and politics of the day; for instance, "colored" became "Black", then "Negro" became common for a time, and the term later evolved to "Black or African American" in the 2020 Census.[3] Thus, race and ethnicity categories are not static, and, indeed, OMB convened the Federal Interagency Technical Working Group on Race and Ethnicity Standards to revise Directive 15. In 2023, OMB held a public comment period on initial proposals for revisions. In 2024, OMB published revisions to Directive 15 which included adding the geographically defined category of Middle Eastern or North African, combining the race and ethnicity questions into a single question stem, requiring data collection for more detailed subcategories, and updating specific terminology to provide greater consistency and clarity of the minimum category definitions (OMB, 2024).

Requiring the collection of more detailed subcategories unless an agency applies for an exemption marks a significant departure from the previous standards. For each of the minimum race and ethnicity categories, the OMB standards include six detailed subcategories, based on the largest subpopulations in the United States, and an option to select "Another group" or complete a write-in field. The policy suggests offering a write-in box whenever possible to enable greater self-identification. It should be noted that there are not standard subgroups for the category American Indian or Alaska Native, so offering a write-in field will be necessary. As in previous iterations of the OMB standards, any additional detailed categories used must be able to "roll up" into the set of seven minimum categories. Although effects of this change remain to be seen, it is an attempt to respond to a core criticism of the minimum categories—that they aggregate many different groups and fail to capture information distinct to various populations. For example, the Native Hawaiian and Pacific Islander category represents over 20 ethnicities, each with its own language, history, and culture.

Nomenclature for American Indians and Alaska Natives

The minimum OMB categories include American Indian or Alaska Native, but Indigenous people of the United States are unique among racial or ethnic minority groups in the United States because Tribes are sovereign nations with distinct legal status. Related considerations that affect collaborations with Tribal nations for research purposes are covered in Chapter 4. It is also important for health practitioners, researchers, and the public to understand the terms used to designate and distinguish between the First Peoples found in northern North America. *Indigenous* is used broadly and will be used in this report when speaking about people who had been on this continent for millennia before European colonization and during early contact with European colonizers. Because relationship to place is foundational to the concept of indigeneity, the discussion of indigeneity in this report focuses primarily on the U.S. context. At times

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[3] https://www.pewresearch.org/social-trends/feature/what-census-calls-us/ (accessed August 27, 2024).

Indigenous will be used inclusive of First Peoples across Canada and the U.S. Indian is the actual legal term in both Canada[4] and the United States today. In Canada, there are three groups denoting populations indigenous to what is now Canada: First Nations, Metis, and Inuit. In the United States, in modern vernacular the term *Native* encompasses any persons with close heritage and lineage to current or historical Tribes, even though—through the vast purposeful interference by the U.S. federal government—they may have lost any connections to their heritage groups and are not enrolled members of their Tribes. In fact, they may not know their Tribes. And in fact, their Tribes may no longer exist in the eyes of Congress. Native will also encompass self-identified Indigenous peoples whether enrolled or not. There are finely nuanced distinctions among these terms. The term "American Indian"—and, at times, "American Indian or Alaska Native" (AIAN)—indicates enrolled members of one of the 574 federally recognized Tribes in the United States. Today many AIAN choose to directly be identified by their Tribe's name rather than a blanket "global" indication of Indigeneity. Even this can be confusing as anglicized Tribal names are increasingly being rejected for the names in the Tribes' own language. Some examples are *Dine'* as opposed to Navajo, *A:Shiwi* instead of Zuni, and *Anishinaabe* not Chippewa. Thus, it is important to take into account a Tribe's and an individual's descriptor preferences when referring to a population.

DEFINING BIOMEDICAL RESEARCH

Biomedical research is by nature broad and multidisciplinary, drawing on expertise across fields of biology, medicine, epidemiology, social sciences, behavioral sciences, and many other disciplines. In the context of this report, *biomedical research* is scientific research across biological, social, and behavioral disciplines that pertains to human health, ranging from preclinical methods to population health. The committee's definition is intentionally broad, encompassing many related subfields—human physiology, clinical epidemiology, biomedical informatics, comparative effectiveness research, and numerous others (see Box 2-4). This expansive definition is intended to be inclusive and to avoid reinforcing scientific silos among disciplines while emphasizing areas of research that are most germane to human health and so may involve race and ethnicity. Importantly, the behavioral, social, and biomedical sciences often influence one another, and much of biomedical research operates at their intersection. Thus, this definition acknowledges the interaction of biological and social factors. Of note, although genetics and genomics research may fall under the umbrella of biomedical research, the committee did not focus specifically on these fields because they were addressed by a 2023 National Academies report (NASEM, 2023a). See Chapter 4 for a brief summary.

Biomedical research operates along a translational spectrum, ranging from basic or discovery science to translational research to clinical trials and implementation science. This research gives rise to a range of medical applications including pharmaceuticals, biotechnology, diagnostics, surgical interventions, clinical tools, and medical devices.

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[4] *Indian* means a person who pursuant to this Act is registered as an Indian or is entitled to be registered as an Indian; (*Indien*), Indian Act R.S.C., 1985, c. I-5, Definitions.

BOX 2-4
What is Biomedical Research?

General definition: Biomedical research is a subset of scientific research, that incorporates many disciplines within biology and medicine which all probe the nature of life, but do so at many different levels of organization, from the atomic to entire communities of organisms (Flier and Loscalzo, 2017).

Report definition: Biomedical research is scientific research across biomedical, behavioral, and social disciplines that pertains to human health, ranging from preclinical methods to population health.

These would all be included under this umbrella of biomedical research. The extent to which this encompasses early-stage bench science, including work with mammalian animal models, is more ambiguous because some preclinical methods fall within scope of this definition while others do not. For example, human-derived cell lines (e.g., HeLa cells), human organoids, and preclinical computational modeling using databases of human samples would all have bearing on human health and might be considered within scope. In contrast, non-human experiments (e.g., with *C. elegans*, a common model organism) would not likely have direct relevance to issues of race, ethnicity, and human health. Therefore, this report is primarily concentrated on the bulk of research downstream of preclinical models and further along on the translation spectrum.

Artificial intelligence (AI) is increasingly being used in biomedical research applications and in medicine as AI underpins a growing set of data science methods and clinical decision tools that are intended to aid medical professionals in their care of patients. The tools are employed in medical imaging, surgery, health monitoring, personalized treatment, and disease diagnostics (Raz et al., 2022; Varghese et al., 2024). AI-based methods are also used preclinically in, for example, drug development and genomics analysis. Although not the primary focus of this report, AI will likely play an increasingly large role in biomedical research, health care, and other related sectors, and is, thus, considered in the relevant research contexts throughout the report. In addition, the committee notes that the roles and impacts of AI in the clinic and biomedical research are a rapidly moving target. Though an in-depth examination of AI in health care is beyond the scope of this report, investigation of the impact of AI in this space is ongoing (e.g., Lee et al., 2024; Li et al., 2022; Ratwani et al., 2024).

The consideration of medical devices and medical instrumentation, in many cases, is distinct from the evaluation of how clinical diagnostic and decision-making tools incorporate racial and ethnic biases. Many of these devices, especially ones that employ optical sensors, use light readings to make assessments but historically have often not accounted for how optical physics interacts with attributes that are typically associated with race and ethnicity, such as skin pigmentation. Notably, these differences can affect how accurately the devices work and the outputs that the devices deliver. Medical devices are discussed in several places in the report and offer a specific use case for the committee's recommendations.

INTERACTION OF SOCIAL CONTEXT AND BIOLOGY WHEN USING RACE AND ETHNICITY IN BIOMEDICAL RESEARCH

As discussed in earlier sections of this chapter, race and ethnicity are dynamic, contextual, and difficult to define. In addition, biomedical research is intrinsically complex and interdisciplinary. The intersection of these domains presents unique challenges and potential pitfalls, such as oversimplification and misinterpretation of research findings.

Studies of human health involve social and environmental context in addition to biology. Race and ethnicity have long been assumed to be useful approximations of social context and are often used as proxies for other variables, ranging from socioeconomic status and environmental exposures to experiences of discrimination. It is widely understood that these social factors affect health, but they can be easily overlooked or obscured by an excess focus on race and ethnicity. It is important to recognize that race itself does not cause health differences; rather, factors such as social determinants of health, racism, and discrimination affect biological systems and health (see Chapter 3, section "Health Disparities and the Study of Racism" and Chapter 5). This complex interaction of biological and social factors can be difficult to tease apart.

Moreover, deep-seated misconceptions about race and ethnicity continue to affect science today and make these issues all the more challenging. The historical tendency in Western science to use categorization to understand the world essentialized race and reinforced the erroneous idea that people could be grouped into distinct categories (Hammonds and Herzig, 2009; Morning, 2011). Exacerbating the confusion, differences in physical appearance—such as skin color, which is commonly viewed as synonymous with race—are partially explained through genetic inheritance. But equating this biological phenotype with race is a misconception. Skin color is, in fact, a complex trait resulting from the contributions of many genes and the environment. Variation in skin color does not follow a clear distribution based on racial and ethnic categories (Jablonski, 2021), and the seeming connection between race and biology falls apart completely when examining complex traits and genetic variation (see Chapter 5, sections "Skin Color and Pigmentation" and "Genetic Markers and Ancestry"). Genetics research has made clear that human genetic variation is continuous, refuting the existence of distinct human races (Duello et al., 2021; Jorde and Wooding, 2004; NASEM, 2023a; see also Fullwiley, 2024 and Nelson, 2016). In addition, though there may be epidemiological differences in disease prevalence, fundamental molecular and cellular mechanisms are the same across racial and ethnic groups and are, moreover, often shared across species. Despite the accumulation of these lines of evidence over decades, it has been difficult to root out old beliefs, including the misattribution of biological differences to race, and their lasting impact on science and medicine.

This chapter began by laying a foundation of ethical and scientific principles for the committee's work. It defined race and ethnicity and introduced the OMB system for collection of race and ethnicity data in the United States. The chapter concluded with a discussion of the nuances that arise when bringing together biomedical research with race and ethnicity. Subsequent chapters will explore this complexity in more detail. The next chapter examines current uses of race and ethnicity in biomedical research, beginning with a general overview and then assessing examples throughout the areas of race correction in clinical practice, medical devices, secondary data use, and emerging AI applications.

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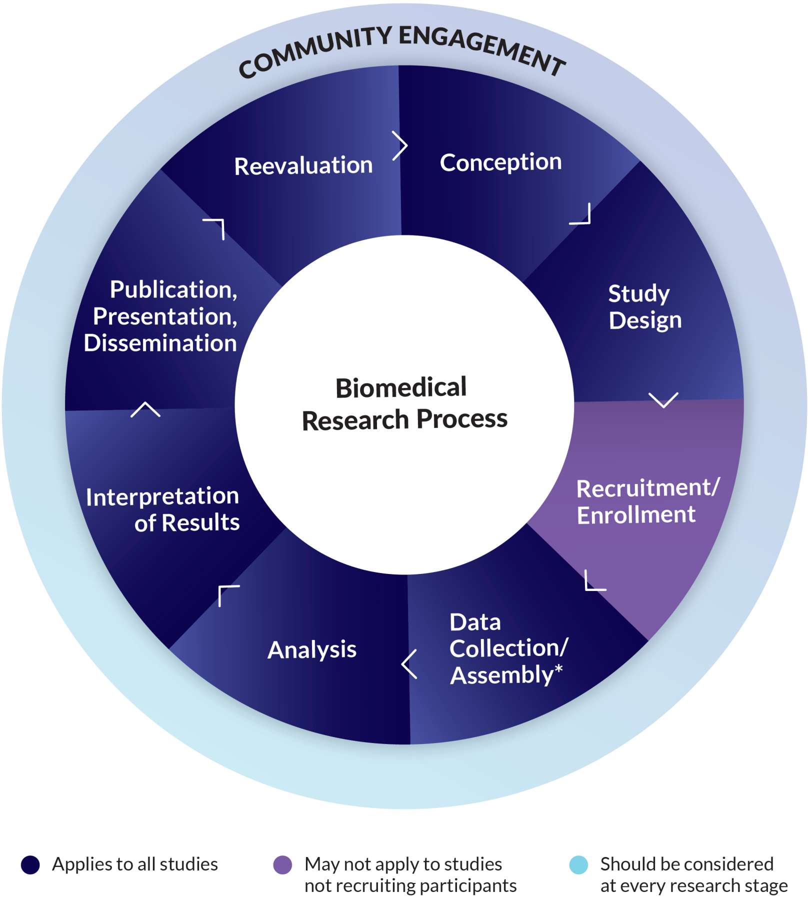
3

Current Use of Race and Ethnicity in Biomedical Research

The previous chapter defined race, ethnicity, and biomedical research and concluded by discussing the complexity of their intersection. Building on those conceptual foundations, this chapter begins with an overview of the uses of race and ethnicity in the biomedical research process. The remainder of the chapter considers more specific applications of the use of race and ethnicity and the consequences of their use in biomedical research, clinical practice, and the development and use of medical technologies. Given that biomedical research is often conducted using existing datasets, this chapter also examines race and ethnicity in secondary data and potential biases in these datasets that can affect downstream applications, including those using artificial intelligence. Lastly, the chapter discusses the study of health disparities, which are a primary impetus for the continued use of race and ethnicity in biomedical research.

Because biomedical research is a broad space encompassing many disciplines, it is helpful to examine its operations through a general framework. The biomedical research process can be viewed as a cyclical assembly of steps (Figure 3-1). Every research study starts with a question to be answered or a problem that needs solving, from which the study originates at the conception stage. The study design stage determines the overall approach to addressing the question of interest. If the study involves human participants, the study design is followed by recruitment and data collection. Although it is common in biomedical research to concentrate on community engagement efforts as part of study design or recruitment, community engagement and partnership can occur at and benefit every stage of the research process cycle. Observational studies that make use of existing data may skip recruitment and directly assemble the study dataset after the study design. After analyzing the study data, researchers interpret the results and determine how thoroughly the research question has been answered. Results are then disseminated through journal publications, conferences, presentations, and more. The final stage in the research process cycle is an evaluation of the preceding steps to assess



*Researchers conducting observational studies with existing data may enter the cycle here but should consider data provenance and prior stages.

FIGURE 3-1 Research process cycle. Research consists of several stages in what can be thought of as a cyclical process. There may be some variations to this approach. For instance, not all studies recruit and enroll participants. It should be noted that community engagement can and does occur throughout the process, including conception, study design, recruitment, and more.

lessons learned, what new questions have arisen from the study, and how to feed new information into subsequent studies.

An important additional consideration is the implementation of biomedical research findings to improve existing practice. Implementation efforts often aggregate results across multiple studies and take into account a variety of other considerations. Developing clinical practice guidelines, for example, may identify and synthesize evidence across relevant literature. In cases such as clinical trials, the creation of medical software, and the development of medical devices, implementation will involve applying the drug, therapy, algorithm, model, or device in the health care setting. Analogously, in fields such as biosocial research, social epidemiology, and public health research, implementation may include applying an intervention that takes into account economic, behavioral, and social determinants of health. The science of implementation—details of which are beyond the scope of this report—is an evolving field that uses methods and strategies to integrate evidence-based practices, interventions, and policies into routine health care (Bauer and Kirchner, 2020). Principles of implementation science, however, may be useful in the earlier stages of biomedical and clinical research to engineer health equity (Baumann and Cabassa, 2020; Reese et al., 2024).

FUNCTIONS OF RACE AND ETHNICITY IN BIOMEDICAL RESEARCH

Considering the range of studies that fall under the heading of biomedical research, it can be helpful to group kinds of biomedical research into broad categories to assess how race and ethnicity are included in those studies. Table 3-1 defines research strategies according to translational stage. Depending on the question being asked and on the relevant sub-discipline(s), biomedical research leverages data from various modalities throughout these translational stages. These modalities include human molecular data, clinical indicators, electronic health records (EHR), claims and billing data, public health data, and more. Given the many modalities for conducting biomedical research and the many reasons that race and ethnicity data may be collected and used, there is significant variation in how the information is recorded, if it is recorded at all.

This section describes different types of biomedical research, how race and ethnicity are often used currently, and the relevance of race and ethnicity to each type of research study. Of not, race is often used as a proxy for other concepts that might more specifically address the research question of interest, so what race attempts to represent in different types of biomedical research is highly context dependent (see Chapter 5).

Basic science (T0) uses laboratory-based techniques, such as preclinical cell and animal models, to investigate biological mechanisms. In general, race and ethnicity are less relevant for characterizing most fundamental biological phenomena, such as in developmental biology, because these biological mechanisms (e.g., DNA replication, mitosis) are shared among humans and often across species. Currently, in this

TABLE 3-1 Types of Biomedical Research Study.

Translational Stage	Definition/Example
T0: Basic and applied science research	Foundational, laboratory-based inquiry (e.g., preclinical and animal studies); defining biological mechanisms
T1: Translation to humans	Proof-of-concept research; Phase I clinical trials
T2: Translation to patients	Phase II clinical trials; Phase III clinical trials
T3: Translation to clinical practice	Phase IV clinical trials; clinical outcomes research
T4: Translation to community	Population-level outcomes research

SOURCE: Adapted from Blumberg (2012).

type of basic science research, race and ethnicity are commonly not considered, and the constructs have lower relevance to research focused only on understanding fundamental biology (see further discussion in Chapter 6, "Basic Science and Early-Stage Biomedical Research").

Translational research (T1–T4) uses basic science to inform biomedical innovation, with the goal of improving wellness, health, and health care. Early-stage translational research (T1) focuses on developing proof of concept or determining the efficacy and utility of an intervention, such as a drug that has been shown previously to have desirable biological effects in cultured cells or in an animal model. These studies are performed under ideal or highly controlled circumstances. T1 research includes small Phase I clinical trials that test a specific intervention; however, not all T1 research is done with a clinical trial. This translational stage also encompasses exploratory research with human participants or human-derived samples to evaluate new assays, characterize a condition, or validate a hypothesis; these studies do not affect treatment decisions for patients, so they are not clinical trials (NIH, 2017). Race and ethnicity are sometimes used in such studies to ensure a diverse sample of participants is recruited, and clinical trials are likely to have strict reporting requirements. Even so, researchers may, though not always, predicate these research efforts on biomedical circumstances that would not vary by race. Thus, the relevance of race and ethnicity to T1 research depends on the specific research questions and ranges from low to moderate.

Interventions that advance to the next research stage (T2) then receive subsequent evaluation for effectiveness, suitability, and utility in "real world" circumstances involving different people with varied history, contexts, resources, values, and preferences. In this type of research, collecting race and ethnicity data is typically required for recruiting diverse sample populations. Sometimes these constructs are also used as imperfect proxies to understand how implementation, resources, values, and preferences affect intervention effectiveness. As the social context becomes increasingly relevant to these research questions, the relevance of race and ethnicity to the research context increases as well.

Research at stages T3 and T4 may also highlight considerations of comparative effectiveness. The impact and import of a given treatment potentially vary between and within race and ethnicity groups. Consequently, it is important to consider variation regarding social factors within and between race and ethnic groups that might affect outcomes. As research is translated to patients and clinical practice, patients' and clinicians' values and preferences may differ between and within race and ethnic groups. Consequently, collecting data on race and ethnicity can clarify treatment effects. Even though race and ethnicity may not themselves be the underlying mechanism for differences (see Chapter 5), there can be a role for collecting the data, as is often required. Collecting race and ethnicity information may be useful to clarify whether diffusion of innovation varies by the race and ethnicity of care teams and patients. For example, this information could be used to study whether the innovations reach racially or ethnically diverse care teams, whether these teams adopt these innovations, and whether racially and ethnically homogeneous care teams implement care innovations in racially and ethnically diverse patient groups. These types of inquiry help ensure that all groups are positioned to benefit equally from treatment innovations. Therefore, in these lines of research race and ethnicity can be highly relevant.

The social constructs of race and ethnicity can serve multiple functions in biomedical research, depending on the category of research and the goals of the particular study. In addition, within a single study race and ethnicity can serve various purposes across different stages of the research process. For instance, racial and ethnic categories may be used in formulating the research question and study design, in recruitment to ensure a diverse sample of research participants, during data analysis to stratify data and evaluate interactions, and then to make inferences based on the analysis. In addition to these general functions, the social categories of race and ethnicity have sometimes been used as an input variable in the subset of biomedical research that is used to construct clinical algorithms and decision-making tools (see subsequent sections in this chapter for more information about race correction).

Research that Uses Results from Translational Biomedical Research

Beyond the translational research spectrum, there are other research domains that draw from the findings of biomedical research. Though a detailed examination was outside the scope of this study, it is important to recognize the impact that biomedical research has in these areas. According to a 2009 Institute of Medicine report, "comparative effectiveness research is the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care. The purpose of comparative effectiveness research is to assist consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels" (IOM, 2009). Comparative effectiveness research typically prioritizes patients' values and preferences in decision making. Race and ethnicity are sometimes treated as imperfect proxies for patient awareness, resources, values, or preferences related to decisions. In current practice, race and ethnicity may also influence whether or how clinicians or organizations provide or frame treatment options. Consequently, careful consideration of issues related to race and ethnicity is highly relevant in this research domain.

Implementation science is the study of the conditions facilitating the systematic uptake of proven effective interventions. This research domain helps translate biomedical research into effective practice under real-world conditions. Race and ethnicity, along with a range of other demographic information, could be relevant in identifying a diverse sample of patients and communities to determine how best to deliver an intervention to meet their needs (Bodison et al., 2015; Mensah, 2019).

Quality improvement is a means and method to systematically monitor and measure how to augment the performance of evidence-based practice. Quality improvement focuses on whether a health care facility executes effective care in a patient-centered manner and seeks strategies to deliver that patient-centered care more efficiently. Examining whether and how interventions reach all patient groups requires that race and ethnicity data be collected.

HISTORY AND CURRENT PRACTICES OF RACE CORRECTION

Race correction, also known as race norming or race adjustment, is the practice of developing clinical algorithms or practice guidelines that adjust their outputs based on a patient's race or ethnicity (Vyas et al., 2020). Physicians use these tools and guidelines, which often collect information related to symptoms, medical and family history, and other personal details along with race and ethnicity, to inform their clinical decisions and make assessments regarding an individual's risk of developing certain medical conditions (Doris Duke Foundation, 2023; Vyas et al., 2020). In addition to clinical algorithms and guidelines, adjustments based on race and ethnicity can also be hardwired into medical equipment (Lujan and DiCarlo, 2018).

The notion that a person's racial or ethnic identity determines their susceptibility to disease has been attributed to a historic belief that there are inherent biological differences between members of different racial and ethnic groups. Thomas Jefferson, for example, noted "a difference of structure in the pulmonary apparatus" between enslaved individuals and European colonists, while Samuel Cartwright, a prominent physician of the time, argued that there was a 20 percent deficiency in the pulmonary function of Black people (Braun, 2014; Hammond and Herzig, 2009; Lujan and DiCarlo, 2018). Thus, slavery and forced labor were perpetuated under the assumption that they would help revitalize the health of Black Americans who were allegedly more prone to disease than their White counterparts (Lujan and DiCarlo, 2018). The practice of adjusting or correcting for an individual's racial or ethnic identity became ingrained throughout various subfields in medicine, ostensibly to achieve greater precision in predicting a patient's risk level. Despite recent changes (e.g., the development of a race-free calculator to assess kidney function), race correction persists in medicine. It is not a simple matter, however, to remove race or ethnicity from clinical tools, algorithms, and guidelines. How to properly address the relationship between race and ethnicity and health outcomes without exacerbating existing health disparities is an area of active research (see Chapter 5 for a reconceptualization of the relevant variables and Chapter 6 for this committee's recommendations). Table 3-2 lists examples of race correction that were or are currently used in medicine.

Examples of Race Correction in Clinical Practice

Pulmonology

Spirometers are medical devices used to diagnose respiratory disease by measuring the volume of air let out after a deep breath (Anderson et al., 2021; Braun, 2014). Most of these devices apply a correction factor of 4–6 percent smaller lung capacity for Asians and 10–15 percent smaller lung capacity for Black individuals (Anderson et al., 2021). These corrections are hardwired into the software of spirometers and are automatically applied to their outputs, often without much awareness or consideration from the physicians using these instruments (Anderson et al., 2021; Lujan and DiCarlo, 2018; Wright et al., 2022). There is no standardized correction factor for mixed-race individuals (Anderson et al., 2021). Furthermore, this example of race correction perpetuates the

TABLE 3-2 Examples of Clinical Calculators and Tools that Incorporate Race Correction.

Specialty	Clinical Algorithms with Race and Ethnicity	Exemplars
Cardiology	1. Atherosclerotic cardiovascular disease (ASCVD) risk calculator 2. Eighth Joint National Committee (JNC 8) hypertension guidelines 3. Get with the Guidelines—Heart Failure	Get with the Guidelines–Heart Failure Risk Score
Endocrinology	1. Body mass index (BMI) risk for diabetes 2. Fracture risk assessment tool (FRAX) 3. Osteoporosis risk score	
Infectious Diseases	1. COVID-19 positive risk of severe COVID-19 2. Denver HIV risk score 3. Predict hospitalization risk for COVID-19 positive	
Nephrology	1. Kidney donor risk index (KDRI) 2. Kinetic estimated glomerular filtration rate (keGFR) 3. MDRD and CKD-EPI GFR equation	
Obstetrics	1. Anemia in pregnancy 2. Vaginal birth after Cesarean (VBAC) 3. Risk for miscarriage at 12–24 weeks	Different diagnostic criteria for detecting anemia among pregnant Black women Vaginal birth after Cesarean (VBAC) algorithm
Oncology	1. Breast Cancer Surveillance Consortium (BCSC) risk calculator 2. CanRisk (ovarian cancer model) 3. Colon cancer survival calculator	
Pulmonology	1. Expected peak expiratory flow 2. Spirometry reference value calculator	
Surgery	1. Cardiac risk index for infrainguinal bypass 2. Cardiac risk index for open abdominal aortic aneurysm repair 3. The Society of Thoracic Surgeons short-term risk calculator	Society of Thoracic Surgeons' risk calculator estimates the likelihood of experiencing complications or death during heart surgery
Urology	1. STONE score 2. Urinary tract infection calculator (UTICalc)	STONE score Risk of developing UTI in Black children

SOURCES: clinicalalgorithmswithrace.org (2023); Visweswaran et al. (2023) CC BY 4.0.

notion of innate biological differences, or race science, that has historically been used to rationalize the oppression of racial and ethnic minority groups. The European Respiratory Society and the American Thoracic Society have stated that adjustment factors for race are not appropriate and are discouraged (Diao et al, 2024; Stanojevic et al., 2022). The Global Lung Function Initiative in 2022 replaced race-based equations with new equations that do not incorporate race but instead use a weighted average across race groups. Comparing the previous race-adjusted equations with the race-neutral equations, a recent study reported that both classes of equations provided similarly accurate predictions of respiratory outcomes (e.g., respiratory symptoms, new-onset disease, and death from respiratory causes) but assigned different disease classifications, occupational eligibility, and disability compensation for millions of people (Diao et al., 2024). Despite similar performance in accuracy, these revised classifications had broad clinical, occupational, and financial implications that differed across racial and ethnic groups (Diao et al., 2024). This may be due to small differences related to lung-function thresholds or differences in sensitivity and specificity that are not accounted for when examining accuracy overall, emphasizing the importance of comprehensively evaluating potential tradeoffs (Diao et al., 2024).

Nephrology

Black Americans are almost four times more likely to develop end-stage kidney disease than White Americans (NIDDK, 2023), and they face other disparities in kidney disease progression (Ahmed et al., 2021). The contributing factors are not completely understood, but social determinants of health (Nicholas et al., 2015; Norton et al., 2016; Powe, 2021) and a higher prevalence of genetic variants that are associated with increased risk for kidney disease (Drawz and Sedor, 2011; Freedman et al., 2018; Friedman and Pollak, 2020) likely play a role in this disparate burden of disease. Powered by the social justice movement following the murder of George Floyd and other young Black people, medical communities responded with a heightened awareness of health and health care inequities (Powe, 2022), and trainee contributions were instrumental to galvanizing change in nephrology (Hefron et al., 2022). One area of focus became equations for estimating glomerular filtration rate (GFR), a key measure of kidney function, and specifically the use of race as a categorical variable in the equation.

In 1998, Camille Jones and colleagues at the U.S. National Institutes of Health (NIH) used the National Health and Nutrition Examination Survey to show that Black men and women at all ages had higher serum creatine levels than their White counterparts and argued that there should not be one level of normality until this finding was clarified (C. Jones et al., 1998). With a gold standard of directly measured (rather than estimated) GFR, Levey et al. found a correlation of higher serum creatinine levels among Black people, and this finding was replicated in both U.S. and European datasets (Inker et al., 2021; Pottel et al., 2023). These observations led to the incorporation of race into the Modification of Diet in Renal Disease (MDRD) estimated GFR (eGFR) equation in 1999 (Levey et al., 1999) and subsequently in 2009 in the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) eGFR equation (Stevens et al., 2008). Beginning in 2017, the Beth Israel Deaconess Medical Center in Boston officially removed the race coefficient and provided a range of estimated values with and without the correction factor because of concerns that the eGFR overestimated the kidney function of Black individuals and might deprive Black persons with chronic kidney disease of the opportunity to obtain a timely kidney transplant (Hoenig et al., 2022).

Several other medical centers began to do the same, by removing the race coefficient from the calculation without fully characterizing potential effects (Powe, 2020). The National Kidney Foundation and American Society of Nephrology formed a task force in 2020 to reassess the use of race in the calculation of eGFR. The task force used a rigorous process to recommend a newly developed CKD–EDI race-free equation using serum creatinine as well as greater use of cystatin C, a biomarker for kidney function that does not vary by race (Delgado et al., 2022). The new equation changing eGFR for all patients does not include race in the calculation and reporting, and special consideration was taken to ensure that the potential consequences do not disproportionately affect any one group of individuals. This equation was rapidly adopted by medical centers and laboratories across the United States as well as by the Organ Procurement Transplant Network (Genzen et al., 2023).

Obstetrics

In the field of obstetrics, an individual's race and ethnicity can influence their risk assessment for certain conditions and what treatment or procedures are recommended. For example, the Institute of Medicine recommended different diagnostic criteria based on race for detecting anemia among pregnant women (IOM, 1993). Until recently, this guideline was supported by the American College of Obstetricians and Gynecologists (Brown et al., 2022). Moreover, the commonly used vaginal birth after cesarean (VBAC) algorithm applies two different correction factors for Black and Hispanic individuals in order to calculate the likelihood of successfully giving birth vaginally after undergoing a cesarian section in a previous pregnancy (O'Brien and Clare, 2023). The correction factors assigned to patients from either of these backgrounds result in outputs that predict a lower likelihood of a successful VBAC, meaning that these patients are systematically less likely than White patients to attempt a vaginal delivery, which is typically less risky than a cesarian delivery (O'Brien and Clare, 2023; Wright et al., 2022). Although other social factors, including insurance type and marital status, were also associated with the likelihood of successful VBAC, these were not included in the 2007 calculator (Vyas et al., 2019). Moreover, these correction factors can be traced back to a long history of race science and descriptions of anatomical differences that deemed the pelvises of White women more suited to childbirth than those of Black and Hispanic women (Vyas et al., 2019). More recently, a race-free VBAC calculator was developed (Grobman et al., 2021) and was shown to be accurate in a diverse cohort of patients at an urban medical center (Adjei, et al., 2023). However, knowledge of the new race-free calculator is not widespread (Cron et al., 2024), and it will take a concerted effort to challenge misplaced beliefs about the role of race and ethnicity in this area of medicine.

Cardiology

The American Heart Association Get with the Guidelines–Heart Failure Risk Score predicts the risk of death for patients admitted to the hospital for a heart condition (Peterson et al., 2010; Vyas et al., 2020). This score assigns three additional points to non-Black individuals, while Black patients are automatically categorized as lower risk. The Society of Thoracic Surgeons' risk calculator estimates the likelihood of experiencing complications or death during heart surgery and includes information about patients' race and ethnicity because of differences in surgical outcomes between different groups (Shahian et al., 2018; Vyas et al., 2020). Using this calculator, the risk of death for a White patient undergoing an isolated coronary artery bypass is 0.492 percent but jumps by almost 20 percent if the patient's race was changed to "Black/African American" (Shahian et al., 2018; Vyas et al., 2020), thereby reducing the likelihood that this procedure would be recommended for Black patients. A new sex-specific, race-free equation PREVENT that predicts risk of cardiovascular events was recently introduced (Khan, 2023).

Hematology

Approximately two out of three people with African or Middle Eastern ancestry in the United States have the Duffy null phenotype (Doris Duke Foundation, 2023), a non-expression of the Duffy antigen on red blood cells, which can manifest as chronic neutropenia in otherwise healthy individuals. This condition is known as benign ethnic neutropenia, but individuals with this phenotype are often mislabeled based on their race or ethnicity as suffering from neutropenia, a condition that involves a deficiency in a specific type of white blood cell, which increases susceptibility to infection and can indicate underlying bone marrow dysfunction (American Cancer Society, 2023; Atallah-Yunes et al., 2019; Doris Duke Foundation, 2023). Patients with benign ethnic neutropenia are not at increased risk of infection (Atallah-Yunes et al., 2019), but misdiagnosis may subject them to unnecessary medical testing, exclude them from clinical trials, and prevent them from receiving appropriate chemotherapeutic drugs (CMSS, 2023; Doris Duke Foundation, 2023).

Pharmacogenomics

Pharmacogenomics is a specialty that examines how a person's genetic variants influence their response to a drug for the purpose of choosing a more individualized therapy (Goodman and Brett, 2021). Racial and ethnic categories are often used in this field to stratify genetic risk based on the assumption that these categories can adequately identify populations that have a high or low prevalence of specific genes, thereby enabling physicians to refer high-prevalence groups for additional testing and care (Goodman and Brett, 2021). However, pharmacogenetic screening based on race or ethnicity can be limiting or even misleading. For example, the American College of Rheumatology recommended that individuals who identify as Southeast Asian or African American test for the HLA-B*5801 allele before taking allopurinol, a medication for gout, because of studies demonstrating a higher prevalence of this allele in these groups (FitzGerald et al., 2020; Goodman and Brett, 2021). The presence of the HLA-B*5801 allele has been associated with allopurinol-induced severe cutaneous adverse reactions, which can be deadly. The limitations of this guideline, however, are exemplified by the vast amount of genetic variation present within certain racial, ethnic, or geographic populations, which can exceed the variation across these groups. Data from Switzerland attest to this fact; despite Switzerland's smaller size and lower racial and ethnic diversity compared to the United States, HLA-B*5801 frequencies vary considerably throughout the country, making race and ethnicity poor proxies for capturing this variability (Goodman and Brett, 2021).

U.S. Food and Drug Administration (FDA) product labeling contains prescribing information for certain drugs that includes race-adjusted indication, dose, and monitoring (Clinical Algorithms with Race, 2023; Visweswaran et al., 2023). For example, initial dosage for warfarin[1] is influenced by several factors including age, race, genetics, and body weight, among others, and dosage for omeprazole[2] is indicated by race because of a correlation to CYP2C19 genotype. Some of the justification for using race in the context of prescribing medication is based on pharmacokinetics or pharmacogenetics studies where associations were made with racial groups. However, because genetic variation within racial and ethnic groups can be greater than the variation across such groups, race or ethnicity-based pharmacogenetic decision making can be limited by intrapopulation genetic variation along with the sociopolitical nature of race and ethnicity categories themselves (Goodman and Brett, 2021; O'Brien et al., 2021). As discussed in Chapter 5, though race is sometimes used to assess patients' disease risk, race is not a substitute for unmeasured biological indicators of disease risk and, in the case of pharmacogenomics, relying upon race can be limiting for assessing dosage or adverse drug events.

Consequences of Race Correction and Considerations for Future Practice

As the examples in the previous section make evident, there are many potential consequences of applying race correction in clinical algorithms and decision-making tools (Siddique et al., 2024). The evidence base that resulted in race correction or adjustment in clinical algorithms and decision-making tools is based in part on beliefs that racial and ethnic groups are distinct and are biologically different. Algorithms that assess patients' risk for developing certain conditions and guide treatment protocols can direct attention or resources away from racial or ethnic minority groups (Vyas et al., 2020). Ahmed et al. (2021) explored how the race correction factor influenced the diagnosis and care of chronic kidney disease and found that over a third of Black patients who were part of the study would have hypothetically been reclassified to a more severe stage of the disease had race been removed from the CKD-EPI calculator. This algorithmic bias holds implications for Black patients' ability to enroll in care coordination programs, thereby limiting the resources available to them and potentially exacerbating their disease burden. The reliance of these clinical tools on variable and subjective categorizations such as race and ethnicity can also obfuscate

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[1] https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/009218s107lbl.pdf (accessed October 16, 2024).

[2] https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/019810s102,022056s019lbl.pdf (accessed October 16, 2024).

the role of social determinants of health (Lujan and DiCarlo, 2018). Factors like the high prevalence of food deserts in low-income neighborhoods, exposure to toxins in the environment, high rates of incarceration, and the physical and mental stress of experiencing racial discrimination may be far more consequential to health outcomes and are likely inadequately captured by simply checking “Black” or “White” in a clinical risk prediction tool (Lujan and DiCarlo, 2018). Research is underway to identify the impact of social factors on disease rather than using race as a proxy for factors that can be directly measured.

Adjustments based on race and ethnicity within clinical diagnostic tools can also lead to misdiagnosis or delayed diagnosis of certain conditions. The treatment of COVID-19, for example, has been complicated by the growing prevalence of restrictive ventilatory dysfunction in patients, a condition that is detected through spirometry (Anderson et al., 2021). Physicians could miss this diagnosis if they have become accustomed to associating certain racial or ethnic groups with having a lower lung capacity at baseline compared with other groups. Furthermore, these groups can be further disadvantaged in the health care system by having a higher likelihood of being recommended riskier or more invasive medical procedures. The application of the VBAC calculator illustrates this point; despite VBAC being associated with a range of positive maternal health outcomes, such as decreased morbidity and a lower risk of future complications, Black women are less likely to be recommended for VBAC and to experience these benefits on account of their racial identity, exacerbating existing disparities in maternal morbidity and mortality (O’Brien and Clare, 2023). Thus, the rationale behind including a patent’s racial or ethnic identity as a means of individualizing medical intervention does not always translate to how these tools are implemented in everyday clinical practice and can result in more harm than good in some cases.

Given the controversies surrounding the use of race correction in clinical algorithms and tools, there have been efforts in some scientific and medical disciplines to discontinue this practice. The NYC Coalition to End Racism in Clinical Algorithms (CERCA), for example, has encouraged health systems, hospitals, medical schools, and clinicians in private practice to retire the use of race correction in at least one algorithm at their facilities within 2 years (O’Brien and Clare, 2023). In addition, a joint task force established by the National Kidney Foundation and the American Society of Nephrology decided that race correction should no longer be applied to GFR calculations (Delgado et al., 2022). Health systems across multiple universities, including the University of Washington, the University of California San Francisco, the Beth Israel Deaconess, and Vanderbilt University Medical Center, removed race from their eGFR calculator (Cerdeña et al., 2020).

Preventing the harmful consequences of race correction on health outcomes is not as simple, however, as removing the race variable from clinical algorithms; each tool and context is different and needs comprehensive examination. There are tradeoffs because race correction can have beneficial effects as well, such as when race is intentionally included to counteract a known disparity that may be tied to bias (X. Zhang et al., 2018). A recent report from the Agency for Healthcare Research and Quality found heterogeneous effects of clinical algorithms on health disparities, regardless of whether the algorithms explicitly include race or ethnicity as an input variable; the report identified five algorithms that may reduce racial and ethnic disparities, 13 algorithms that may worsen disparities, and one with no effect on disparities (Siddique et al., 2024). Results can be complicated even for a single clinical tool—while removing race from eGFR calculations will, for Black patients, increase their addition to the kidney transplant list and the likelihood of being diagnosed with chronic and severe kidney disease, it may reduce their access to other treatments such as chemotherapy and potentially decrease their eligibility for clinical trials (Tipton et al., 2023). Moreover, how algorithms are implemented in the real world can also impact disparities (Siddique et al., 2024). These tradeoffs may also vary across different racial and ethnic minority groups, as demonstrated in a prediction model for lung cancer screening eligibility that tested the potential effects of removing race from the calculation and found that disparities might improve for Hispanic and Asian groups but could worsen for Black populations (Landy et al., 2023). (See Chapter 4, "Lessons from Clinical Guidelines and Algorithms," for proposed strategies to mitigate negative effects of race correction.) This section underscores how some current clinical practices can be traced back to a history of race science. The examples of race correction discussed here refer primarily to mathematical correction factors (e.g., applying a percentage decrease to a result) or are based on traditional statistical methods and calculations (e.g., regression analyses) (see Igo, 2007 and Zuberi, 2003 for background on race in statistics). Looking toward the future, artificial intelligence (AI) will undoubtedly reshape how clinical algorithms are both developed and implemented. The rapidly expanding use of AI in research and health care is bringing even greater awareness to potential bias in datasets and clinical algorithms (see subsequent section Race and Ethnicity in Clinical AI Algorithms for further discussion).

RACE AND ETHNICITY IN MEDICAL DEVICES

Skin color and pigmentation are relevant to the design and function of some medical devices that use optical technology. Failing to test these devices with a broadly representative population can result in data that are not equally reliable across the full spectrum of skin tones, contributing to differential performance of these technologies and health disparities, which may reflect larger inequities in health outcomes. When optical devices do not work accurately for people across the full range of human skin tones, this is at times referred to as "racial bias" in the design and engineering processes. However, it is important to note that skin color and race should not be conflated in seeking to improve these technologies in the future. Medical devices that produce racially biased results include pulse oximeters, transcutaneous bilirubinometers, and photoplethysmographic sensors, which use optical technology to measure blood oxygen levels, serum bilirubin levels, and heart rate and rhythm monitoring, respectively, as well as forehead thermometers, which use infrared technology to measure body temperature. Examples of the biased outputs from these devices are shown in Table 3-3.

TABLE 3-3 Examples of Medical Devices with Differential Performance across Racial and Ethnic Groups.

Device	Racial Differences
Photoplethysmographic sensor	Photoplethysmographic sensors in wearable devices used to detect atrial fibrillation have been linked to poor performance on darker skin tones, which is similar to the issue that affects pulse oximeters (Merid and Volpe, 2023).
Pulse oximeter	Skin pigmentation can affect light absorption, and research indicates that pulse oximeters overestimate blood oxygen levels in people with darker skin. Pulse oximeters are two times less likely to detect abnormally low concentrations of oxygen in Black patients in the ICU, which can lead to missed hypoxemia (Holder and Wong, 2022).
Temporal artery (forehead) thermometer	Temporal temperature measurement was associated with a lower likelihood of detecting fever in Black patients than oral temperature measurement, but not in White patients (Bhavani et al., 2022). This discrepancy, combined with commonly used fever cutoffs, may cause fever to go undetected in Black patients. Research has shown that skin emissivity may influence temperature measurement variability, but its relationship to pigmentation needs further investigation (Bhavani et al., 2022).
Transcutaneous bilirubinometer	Transcutaneous bilirubinometers are used for detecting neonatal hyperbilirubinemia, and research shows that transcutaneous bilirubinometry measurements are correlated with blood-based total serum bilirubin measurements better in lighter skin color babies than darker skin color babies (Varughese et al., 2018).

SOURCES: Adapted from clinicalalgorithmswithrace.org (2023). Content from Bhavani et al. (2022); Holder and Wong (2022); Merid and Volpe (2023); Varughese et al. (2018).

Pulse Oximetry: A Case Study of Race and Ethnicity in Biomedical Research and Medicine

As a window into larger questions of why diverse representation remains important to consider in biomedical research and medical device design, the pulse oximeter offers a useful case study. In recent years, the pulse oximeter has become commonly pointed to as "poster child" (McFarling, 2022) for the need for more diversity in science and medicine, including during the design and engineering phases of health technologies as well as during safety assessments. Pulse oximeters estimate blood oxygen saturation via color sensing, assessing the shade of iron-containing hemoglobin—which is a cooler color when desaturated with oxygen and a warmer red color when fully saturated.[3] Because the light emitted from "wearable" devices passes through not only blood but also surrounding skin and tissues, optical readings can be affected by melanin and other chromophores in the skin. This is why diversity in safety testing groups and calibration

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[3] https://www.howequipmentworks.com/pulse_oximeter/ (accessed October 16, 2024).

matters so much, yet it historically has often been inadequate—with important exceptions. Decades ago, physicians at the University of California, San Francisco Hypoxia Lab realized they were testing a color-sensing device on mostly White populations and noted many years' worth of overlooked reports of unequal errors. Their follow-up study showed that pulse oximeter devices in hospitals at the time of their research indeed did not meet FDA safety thresholds for people of color (Bickler et al., 2005; Feiner et al., 2007). At the time, there was little public response.

During the early COVID-19 pandemic, optical devices were increasingly emphasized in homes as well as clinics, positioned as "biomarkers" to be used in triage, and played a role as gatekeepers to resources such as admissions to emergency departments and supplemental oxygen. Putting this reality together with the history of concerns about such devices, a network of social scientists again brought this issue to the attention of physicians (Benjamin, 2019; Moran-Thomas, 2020; Valley, 2023), including a team that examined the issue for the first time using meta-data across major hospitals. Published in the *New England Journal of Medicine*, this team's study showed that errors were three times as likely for Black hospitalized patients as for White patients (Sjoding et al., 2020). A wave of follow-up studies found that a disproportionate number of Black hospitalized patients experienced "occult hypoxemia" (Valbuena et al., 2022)—a new designation created to capture the clinical significance of seemingly small discrepancies in device accuracy (Sjoding et al., 2023). Other researchers found that these errors correlated with Black hospitalized patients receiving less oxygen supplementation in intensive care units (Gottlieb et al., 2022). Further studies revealed that disparate device discrepancies were associated not only with delayed treatment but also with sequelae such as higher rates of consequent organ dysfunction and mortality for Black hospitalized patients (Wong et al., 2021). Notably, while the categories "Black" and "White" were used as proxies at the time that these hospital data were collected, other studies have shown such inaccuracies have implications across the spectrum of skin tone variability (Feiner et al., 2007) and will require ongoing attention and nuance around self-identification and skin tone in the future. Oximeter inaccuracies—leading to "hidden hypoxia" being three times more common among Black patients than White patients (Sjoding et al., 2020)—were also found among hospitalized children (Andrist et al., 2022) and, more subtly, among preterm infants (Vesoulis et al., 2022).

Problems with Other Optical Sensing Devices

As noted in Table 3-3, inaccuracies have also been identified in other optical sensing devices, including infrared thermometers (Bhavani et al., 2022), heart monitors (Bent et al., 2020), and bilirubinometers (Varughese et al., 2018). An expanded crowd-sourced list is currently underway.[4] There is growing concern that errors in devices' direct inputs into algorithms can interact with—and cause unequal errors—in the artificial intelligence (AI)-mediated algorithms now becoming increasingly prominent across hospital

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[4] https://clinical-algorithms-with-race.org/devices (accessed October 16, 2024).

computing systems (Zou and Schiebinger, 2021). As part of broad movements toward decentralized care, there is increasing emphasis on at-home wearable device measurements, often without sufficient attention to equity and accuracy for all device wearers. There is also a general push toward "surrogate measures" that substitute long-standard lab readings (e.g., highly accurate blood tests) for wearable readings from devices such as oximeters (Carvalho et al., 2022). This shift is occurring in a range of algorithms used in triage, which worryingly can incorporate measurements known to be racially biased into the computing used across health care systems. Engineers are now working to create novel solutions to these issues and to imagine more equitable optical devices (Harling et al., 2023; McFarling, 2022), but sustained attention is needed across many sectors in order for more equitable designs to be realized at market scale. With unequal optical device hardware changing slowly and the computing and AI systems that use their inputs changing quickly, present systems are not yet capable of ensuring equal safety.

Lessons Learned

These examples illustrate what can be missed by failing to consider racial and ethnic diversity in medical device design and testing. Overlooking characteristics like skin tone can lead to discrepancies in device performance and health outcomes. Caution is warranted, though, before simply eliminating the consideration of race, which can be used to address bias and inequities. Rather, characteristics like skin pigmentation, which do not universally correlate to specific racial or ethnic categories, must be taken into consideration. It is important to learn from history while trying to correct present errors. Pulse oximeter performance, for instance, cannot be easily fixed by a race-based correction factor because issues of skin color and race are distinct (Patwari et al., 2024). Some devices may need to be redesigned, requiring a greater investment than a quick fix might entail. More fully understanding device inaccuracies (Okunlola et al., 2022) can open the doors to opportunities for much-needed future innovations.

RACE AND ETHNICITY IN SECONDARY DATA ANALYSIS

Many biomedical studies rely on preexisting datasets to address specific research questions. These previously collected datasets, or *secondary data*, can be reused or reanalyzed in the service of new research questions in biomedical research. Broadly, secondary data used in biomedical research can be legacy data, administrative claims or financial health care records, and electronic health records (EHRs). Race and ethnicity can be captured in secondary data in myriad ways, including through self-identification, via census or administrative data, from surrogate markers, from clinician and researcher determinations, or by a combination of any of these methods. Each type of secondary data has unique considerations for use as well as notable limitations.

Legacy data is made up of research data derived from past studies, such as clinical trials, genetic and genomic studies, and epidemiological studies. These datasets typically remain static after the completion of a given study. While having access to a wealth of data from previous research can help spur the development of new studies and generate new insights on a similar topic, there are major challenges that accompany the reuse of race and ethnicity research data. One limitation is the longstanding history of underrepresentation of racial and ethnic minority groups in clinical trial and genomic datasets. For example, an analysis of genomics studies through the middle of 2021 found that 86.3 percent of participants were of European descent, 5.9 percent were East Asian, 1.1 percent African, 0.8 percent South Asian, and 0.08 percent were Hispanic/Latino (Fatumo et al., 2022). A review of 20,692 U.S.-based studies in ClinicalTrials.gov from 2000 to 2020 demonstrated a similar pattern, with White individuals making up the majority of the 4.76 million trial enrollees (Turner et al., 2022).

In addition to the lack of representation of minority populations and the resulting limited generalizability of study findings, many clinical trial datasets are missing race and ethnicity data altogether. For example, only 43 percent of the 20,692 clinical trials reviewed by Turner et al. (2022) reported any race or ethnicity data. Furthermore, the methods used to collect the race and ethnicity data may be ambiguous or questionable, particularly for datasets that are decades old. These datasets are prone to aggregating data into categories like "Other" but with little or no explicit rationale. Thus, researchers who want to use legacy datasets have to contend with race and ethnicity data that are potentially inaccurate, incomplete, or of problematic origin.

Administrative claims data, or data collected from health care transactions, are generated from billing and payment records related to medical services, including insurance claims submitted to Medicare, Medicaid, and private insurance companies. As with legacy data, administrative claims data contain incomplete race and ethnicity information, due to nonreporting or misreporting. In addition, the data may be further complicated because the racial and ethnic categories of some people in the datasets change over time. This latter problem is seen in the Medicare enrollment database, which obtains race and ethnicity data from the Social Security Administration. When individuals were applying for social security numbers from 1935 to 1980, the only racial categories available were White, Black, or Other, whereas in 2024, there are seven racial and/or ethnic categories (Nead et al., 2022). There is also a lack of standardization in how states and hospitals collect this information. Medicaid claims data, for example, are collected on a state-by-state basis, with most states opting to collect self-reported race and ethnicity, yet often filling in missing or incomplete data based on a person's name, language, and geographic location or by matching with data from other states (Nead et al., 2022). Given these limitations in race and ethnicity data within administrative claims data, researchers intending to use this type of data will likely need to navigate the vast amount of geographic and temporal variability in existing race and ethnicity datasets.

EHR data consist of large datasets collected from multiple hospitals. The use of race and ethnicity information from EHR data poses similar challenges to those found in other secondary data types, because the data often vary across hospitals and institutions and are often incomplete. EHR systems are widely used in the United States to capture data on clinical encounters. As of 2021, 96 percent of all non-federal acute care hospitals and nearly four in five office-based physicians had implemented a certified EHR system (Office of the National Coordinator for Health Information Technology, 2023). Originally, the primary purpose of EHRs in the United States was to support clinical care, financial billing, and insurance claims. Data collected in EHRs are now extensively used for secondary purposes such as clinical research, improving health care practice, and large-scale analyses for the creation and validation of predictive algorithms. Federal agencies such as the FDA have been empowered by legislation such as the 21st Century Cures Act to increase the use of real-world evidence based on real world data, such as EHR and administrative claims data. Statistical and AI methods are increasingly applied to EHR data to study patient cohorts for various clinical and research applications, such as phenotype extraction, precision medicine, intervention evaluation, and disease prediction, detection, and progression. Examples of federally funded, privately funded and community-based initiatives that are collecting EHRs of millions of individuals include the Patient-Centered Outcomes Research Institute's PCORnet,[5] the National COVID Cohort Collaborative,[6] TriNetX,[7] Epic Cosmos,[8] NIH All of Us research program,[9] VA Million Veteran Program,[10] the Observational Medical Outcomes Partnership,[11] the NIH-funded ENACT network,[12] the Consortium for Clinical Characterization of COVID-19 by EHR,[13] and the University of California Health Data Warehouse.[14]

EHRs contain a wide range of data types that characterize the health conditions of individuals. These data types include demographics, vital signs, medications, diagnoses, procedures, laboratory test results, clinical imaging results, and clinical notes. Demographic data often include race and ethnicity, which are ascertained in various ways: patients complete forms as part of the registration process, which are then transcribed into the EHR by a registration clerk, or registration clerks enter responses after asking patients about their racial and ethnic identification. Given the different methods that can be employed when collecting this information, the extent to which data are missing or erroneous can also vary. The most widely used standard for gathering and classifying racial and ethnic data by health care systems was adopted from the Office of Management and Budget (OMB) standard created in 1997 for the 2000 U.S. Census. Health Level Seven International, the organization that developed the standard that health care systems use most frequently to send and receive health records, subsequently adopted the OMB classification system from 1997 (see Box 2-3) (Cook et al., 2022). Of note, these standards reflect the 1997 OMB system and may yet be updated per the 2024 OMB revised system.

Many studies have documented that race and ethnicity are frequently missing in EHRs and that, when present, they are often of inconsistent quality (Klinger et al., 2015;

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[5] https://pcornet.org/ (accessed October 16, 2024).

[6] https://covid/cd2h.org/about (accessed October 16, 2024).

[7] https://trinetx.com/ (accessed October 16, 2024).

[8] https://cosmos.epic.com/ (accessed October 16, 2024).

[9] https://allofus.nih.gov/ (accessed October 16, 2024).

[10] https://www.mvp.va.gov/ (accessed October 16, 2024).

[11] https://fnih.org/observational-medical-outcomes-partnership-omop/ (accessed October 16, 2024).

[12] https://www.enact-network.us/ (accessed October 16, 2024).

[13] https://covidclinical.net/ (accessed October 16, 2024).

[14] https://ctsi.ucla.edu/uc-health-data-warehouse-uchdw (accessed October 16, 2024).

Polubriaginof et al., 2019). The National COVID Cohort Collaborative examined EHRs from 6.5 million patients from 56 health care institutions in the United States and found that about 21 percent of the race data did not conform to current standards and that about 12 percent of all records were missing race or ethnicity data (Cook et al., 2022). The extent and nature of nonconformance differed according to race and ethnicity, with vulnerable populations and patients of color being disproportionately represented in both the nonconforming and misclassified data. Of note, no patients with race listed as American Indian or Alaska Native (AIAN) were available in the dataset because NIH was in consultation with Tribal leaders and scholars to ensure human protections for research involving the AIAN community and withheld the data of AIAN patients (Cook et al., 2022).

Sources of Biases in EHR Data

Biases in EHR data can stem from a variety of sources; the main sources of biases in EHR data are described below (Chen et al., 2024; Gianfrancesco et al., 2018). Although not unique to EHR data, these potential sources of bias are common in EHR datasets used for biomedical research. Moreover, it is important to recognize bias-driven limitations that could affect study results across racial and ethnic groups. Because EHR data are used routinely in the development, training, and validation of AI algorithms and machine learning (ML) models, failing to correct for the biases in EHR datasets can introduce problems into AI and ML tools.

Selection bias (also known as sampling bias or population bias) arises when the EHR data of individuals or groups used in an analysis are not representative of the larger population, yielding results that cannot be generalized to the larger population. For example, an AI model for forecasting sepsis mortality that is trained on EHR data from a single hospital in a specific geographic region may not generalize well to a broader population such as the entire United States.

Information bias (also known as measurement bias) arises when there are inaccuracies or incompleteness in data entries in the EHR. Incorrect or biased measurements can affect the performance and validity of the analyses. For example, race data in EHRs are acquired through a combination of patient self-report, administrative data entry by health care practitioners, and, in some cases, demographic data transfers from other systems such as insurance databases. Discrepancies in race data in EHRs occur as a result of the heterogeneity of data collection across the 5 Ws (who, what, where, when, and why) (Yemane et al., 2024).

Confounding bias (also known as association bias) arises when a variable, not accounted for in the study design, influences both the predictor and outcome variables, leading to a spurious association between them. In a study predicting patient readmissions, for example, there could be a confounding bias in the data due to socioeconomic status, as those with lower socioeconomic status may have less access to health care resources, contributing to worse medical conditions. In this case, socioeconomic status influences both the input medical problems and the model predictions (Chen et al., 2024). These associations may not be accounted for in EHR data.

Implicit bias refers to unintentional prejudices captured within EHR data due to subjective factors influencing data collection and recording processes. This type of bias may manifest due to health care provider perceptions, patient–provider interactions, or systemic health care practices that influence the way information is recorded in EHRs. For example, studies have shown that pain assessment and management can vary significantly based on patient demographics such as race (Hoffman et al., 2016). AI models trained on these data can potentially perpetuate disparities in the treatment of pain.

Modeling bias (also known as algorithmic bias) arises when the assumptions, selection of variables, or the design of a model create or amplify the bias in the EHR data. Such bias can occur due to imbalanced or misrepresentative training data, erroneous assumptions made by the model, lack of regulation in model processing, and so on (Chen et al., 2024; Norori et al., 2021). For example, an algorithm that predicts future health care needs based on prior health care costs underestimated the needs of Black patients compared with White patients (Obermeyer et al., 2019).

RACE AND ETHNICITY IN CLINICAL DECISION-MAKING TOOLS

Clinical practice guidelines, clinical algorithms, and clinical care pathways are crucial evidence-based practice facilitators. The Institute of Medicine defined clinical practice guidelines (CPGs) as "statements that include recommendations, intended to optimize patient care, that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options" (IOM, 2011). CPGs guide recommendations for addressing a clinical condition, as they contain a thorough analysis of research evidence, including a benefits and risk assessment for each recommendation; CPGs also include a detailed justification for the recommendation. Often, expert consensus primarily drives recommendations when evidence is insufficient or absent.

Clinical algorithms are typically mathematical formulas, prediction models, flowcharts, or regression equations that assess multiple input variables to discern an outcome probability, such as disease, or a risk estimate of a clinical outcome (Tipton et al., 2023). Investigators employ such algorithms for a variety of clinical purposes (e.g., screening, risk prediction, diagnosis, prognosis, treatment planning, and resource allocation; Table 3-4) (Tipton et al., 2023). Traditional statistical methods (e.g., regression analysis) inform most of the algorithms that clinical investigators currently employ in clinical practice. However, investigators increasingly derive novel algorithms via AI methods, including machine learning.

Clinical care pathways are decision tools that clinicians use to guide evidence-based health care (Busse et al., 2019). Pathways translate clinical practice recommendations into clinical care processes while accounting for the institution's unique culture and environment. Pathways are often institution-tailored implementations of CPGs or clinical algorithms. However, care teams occasionally predicate their guidelines on data derived exclusively in-house.

TABLE 3-4 Examples of Clinical Algorithms.

Algorithm	Description
Calculator	Mathematical formula or regression equation, such as the formula for calculating current osteoporosis status and predicting future fracture risk associated with osteoporosis.
Flowchart	A branching decision tree, such as a diagnostic flowchart for determining the etiology of chest pain.
Lookup table	Enables quick reference of data, such as a table containing energy and nutritional content of various foodstuffs.
Nomogram	A graphical tool used for a specific calculation, such as a nomogram of height and weight measurements that can be used to find the surface area of a person.

SOURCE: Content adapted from Visweswaran et al. (2023) CC BY-NC-ND.

Race and Ethnicity in Clinical Practice Guidelines and Clinical Practice Pathways

Many medical professional associations as well as federal agencies, such as the CDC and FDA, and volunteer committee-based organizations, such as the U.S. Preventive Services Task Force and the National Academies of Sciences, Engineering, and Medicine, have developed clinical practice guidelines. Currently, there is scant evidence clarifying the extent to which CPGs incorporate race and ethnicity and any subsequent impact. A systematic review of U.S.-based pediatric CPGs found that race was frequently used in ways that could negatively affect health disparities (Gilliam et al., 2022). The study examined 414 pediatric CPGs and found that 126 (30 percent) incorporated the use of race or ethnicity phrases with 175 occurrences throughout background, recommendations, or future directions (Gilliam et al., 2022). Race was used in a potentially detrimental manner in about 50 percent of instances across 73 CPGs, and in a beneficial way in about 29 percent of instances across 45 CPGs. Potential harmful uses included reinforcing negative stereotypes, conflating race as a biological or genetic risk factor, and normalizing the majority group (Gilliam et al., 2022). Uses of race with potentially positive effects included describing health disparities, inclusivity, and cultural humility.

Even less is known about the extent to which clinical care pathways incorporate race and ethnicity and their resulting effects. A review of clinical care pathways at Boston Children's Hospital found that 8 (6 percent) out of 132 pathways included race, ethnicity, or ancestry terms (Rosen et al., 2023). Applying a structured framework to evaluate the use of race, ethnicity, and ancestry in these pathways led to the removal or alteration of terms in each instance—in 6 pathways race, ethnicity, or ancestry were eliminated, and 2 pathways were amended (Rosen et al., 2023).

Race and Ethnicity in Clinical Algorithms

When developing clinical algorithms, race and ethnicity are often included based on group-level differences observed in population studies. However, extrapolating group-level differences based on race or ethnicity to determine an individual's risk is misguided. For a clinical variable to serve as a predictor of an individual's risk level, it must be regularly assessed, ordered, and explicitly related to the outcome of interest. For example, the level of LDL cholesterol is a variable that is consistently measured in blood tests, it is ordered (increasing concentrations correlate with increasing risk), and it is related to the risk of developing cardiovascular disease. In contrast, race and ethnicity, as well as other social variables, are not consistently measured and are not ordered (e.g., these are nominal variables, with no inherent ranking); the relationship of these variables to clinical outcomes is indirect and ambiguous with many potentially relevant factors.

The rationale to include race and ethnicity as input variables in statistical algorithms is often motivated by observed differences in clinical outcomes between racial and ethnic groups in the studies that developed these algorithms. Vyas et al. (2019), for example, reviewed race-based algorithms in eight clinical specialties and noted this same justification for the inclusion of race and ethnicity as input variables across these different algorithms. However, little, if any, evaluation was done in these studies to assess potential downstream race- or ethnicity-based harms of using such algorithms.

Another persistent challenge with the use of clinical algorithms is that the race and ethnicity values used as inputs for these tools are often heterogenous and unstandardized. For example, one study identified a total of 49 distinct race or ethnicity values in clinical algorithms incorporating race or ethnicity information, the most common of which were White, Black, Other, Asian, Caucasian, East Asian, Mixed, and South Asian (Visweswaran et al., 2023). Almost all of these algorithms use a single race variable, and only a few of them use variables for both race and ethnicity. Some of the algorithms that were examined rely on overly broad race categorizations, such as White/non-White or Black/non-Black, which are inadequate for capturing the full complexities of how patients choose to identify themselves in a clinical context. Some algorithms use just two racial categories, Black or White, and such algorithms are unusable for other research or clinical cases. Thus, these algorithms often employ different sets of race and ethnicity values at varying granularities and with very little consistency, making it challenging to evaluate their current use and develop guidance to inform their future use.

Race and Ethnicity in Clinical AI Algorithms

Clinical algorithms[15] developed using standard statistical methods typically rely on statistical models that are designed to identify patterns and relationships in the data. These models are often based on well-established statistical principles and assumptions, and they typically require researchers to specify the relationship between the variables of interest. In contrast, clinical algorithms developed with AI use computer algorithms that learn relations from the data automatically without being guided by human researchers.

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[15] In the AI literature, algorithms are the methods or procedures used to process data, while models are the outputs of these algorithms that represent learned patterns and relationships. However, in the medical literature, models are frequently referred to as algorithms.

AI is particularly useful for analyzing large, complex datasets with many variables as it can detect complex patterns and relationships in the data that may not be apparent to human researchers. The explosion of data obtained from EHRs as well as data from personal health devices, coupled with advances in computation, is driving the integration of AI throughout the health care ecosystem. AI models are used to predict risk prior to surgery, to assist in emergency department triage, to read medical images, and to evaluate treatment options, along with numerous other uses (Ahmad et al., 2021; Mueller et al., 2022; Rajpurkar et al., 2022). Despite evidence that these models can improve care, there is also growing concern about the presence of bias within these algorithms and their ability to exacerbate existing inequities in the health care system.

While bias in general, and racial bias in particular, is not specific to AI-derived models, the automated nature of AI makes it challenging to evaluate and mitigate bias without explicitly looking for such effects. Bias can enter at any point in the developmental life cycle of an AI model. Moreover, since AI models are often derived from structured and unstructured EHR information that inadequately represents all the demographic factors and social determinants that can affect an individual's health, the racial and ethnic bias present within these large datasets can be baked in and reinforced by these tools in clinical practice.

The potential for these algorithms to encode and perpetuate bias is exemplified in medical imaging. Current AI technologies, particularly deep learning, are well suited to imaging data, and are increasingly used to process and interpret medical images, such as X-rays, CT scans, and MRIs. AI models can assist in diagnosing conditions, from lung diseases to brain tumors, and have now achieved expert-level performance. However, the models can also display differential performance across subgroups. For example, AI models developed to diagnose pathologies from chest X-rays demonstrated significant underdiagnosis in patients who were Black, female, or of low socioeconomic status (Seyyed-Kalantari et al., 2021).

In addition to radiology, deep learning models have been developed in other medical specialties that use medical images. AI models in dermatology have shown promise in diagnosing skin conditions. However, a systematic review of deep learning models for various skin diseases, including acne, psoriasis, eczema, and rosacea, highlighted the risk of model bias and need for diverse training data (Choy et al., 2023). Others have reported similar limitations in models that are trained predominantly on images of lighter skin tones and less accurate diagnoses for individuals with darker skin (Daneshjou et al., 2022; Groh et al., 2024; Venkatesh et al., 2024), adding to a body of work showing a lack of diverse images of skin tone in dermatology (Alvarado et al., 2021; Lester et al., 2020). Similar results have been shown in AI models in ophthalmology (Burlina et al., 2021) and cardiology (Puyol-Antón et al., 2022). Underdiagnosis can result in delayed care for a patient, placing them at higher risk for extended illness, worse outcomes, and higher health care costs.

Multiple studies have found that AI models can develop surprising abilities, such as extracting demographic information (e.g., age, sex, and self-identified race) from medical images (Eng et al., 2021; Gichoya et al., 2022; Yi et al., 2021), even though they are not typically developed to explicitly identify the race or ethnicity of a patient from a medical image (Gichoya et al., 2022). For instance, Gichoya and colleagues (2022) showed that AI models could accurately detect a patient's self-reported race from a variety of medical imaging modalities (see also Coyner et al., 2023). How these models can do this remains elusive; no specific features were identified to be responsible for the results. While the ability of an AI model to detect self-reported race from medical images is not meaningful on its own, it is important in the larger context in which AI models are being employed in health care. The apparent ease with which the models learn to identify self-reported race raises the concern that a model may use that information to make race-based interpretations or predictions that could be biased or erroneous, resulting in unfair treatment of patients based on race (Gichoya et al., 2022). This possibility is especially concerning because clinical radiologists examining the same images would be unable to discern race and without additional information, would be unable to audit the veracity of the model's output.

There are several ways that bias could enter the model and contribute to these results. Increasingly, chest X-ray datasets are labeled automatically using natural language processing (NLP) methods (Seyyed-Kalantari et al., 2021). NLP-based methods have been shown to be biased in other health care settings (H. Zhang et al., 2020), and while these labelers have been validated overall, their performance in various subpopulations is untested. Second, the model's labels are extracted from EHR data, which likely contain biases (see "Sources of Biases in EHR data) that are carried over into the model. This is a form of bias amplification, in which the model outputs amplify biases or errors that exist in the training data (Seyyed-Kalantari et al., 2021). Third, datasets that are too small or lack diversity in racial and ethnic populations may develop biases that favor the dominant populations within the data, leading to inaccurate or unfair predictions for underrepresented groups (Gianfrancesco et al., 2018). Fourth, AI models that extract demographic information such as race and ethnicity may use this information as proxies rather than relying on more relevant factors, resulting in bias (Yang et al., 2024).

Research efforts focused on preventing and removing bias in AI models are emerging throughout the AI and ML community. A variety of fairness metrics have been created to assess fairness across racial and ethnic groups to determine whether an AI model disproportionately penalizes particular racial or ethnic groups (Caton et al., 2024). Furthermore, achieving fairness often involves tradeoffs with overall model performance (accuracy) (Caton et al., 2024). If the model is only to be used in a single setting, the best way to obtain a model that is fair while maintaining performance is to optimize for fairness locally (Ghassemi, 2024). Researchers using training data from a single hospital manipulated their model to be more fair and were able to achieve better measures of fairness across demographic groups without a significant loss in model performance (Ghassemi, 2024). However, these optimization results did not hold when the model was evaluated in a new setting, such as analogous data from a different hospital in a different location. In this scenario where a model will be used in a variety of different settings, prior work has shown that if the only goal is to maximize overall performance, one should select the model with maximum performance on the training domain. However, researchers have shown that this strategy often results in models with degraded fairness during implementation (Ghassemi, 2024). Instead, researchers have found that selecting models which encode minimal demographic information is a more promising strategy which allows for optimal fairness and performance transfer to new hospitals (Ghassemi, 2024). These case studies demonstrate that reducing race- and ethnicity-based bias associated with AI and ML models and improving patient health outcomes for underserved populations require that different strategies be evaluated and employed based on several factors, meaning that there is no single solution that can address these complex problems. The use of AI in biomedicine and health care is a dynamic, active area of research. Although further exploration was out of scope of this committee,[16] future research will be needed to understand best practices that promote fairness and mitigate performance differences across racial and ethnic groups.

HEALTH DISPARITIES AND THE STUDY OF RACISM

The previous sections describe a number of ways that race and ethnicity are used in biomedical research and thereby affect clinical practice. Given the limitations and biases described, some might wonder what role race and ethnicity serve in biomedical research. This is a question that the committee contemplated over the course of its work. One area the committee examined in its analysis is health disparities. Race and ethnicity have long been used in the study of health disparities and of racism as a driver of persistent health inequity. Racism in health care is evidenced by policies and clinical practice guidelines that use race and ethnicity as a factor to determine a different standard of care that disadvantages members of racial and ethnic minority groups compared with White individuals. For example, a study on prescribing practices for hypertension medication found that providers were using race-based guidelines to determine the treatment regimen for Black patients, which limited Black patients from receiving the full range of appropriate medications for hypertension (Holt et al., 2022). The study further showed that there was more variation in hypertension control within each racial group (Black and non-Black) than between racial groups (Black versus non-Black) (Holt et al., 2022). Racism in U.S. health policy has also been associated with health disparities experienced by American Indian and Alaska Native people (Solomon et al., 2022). Governmental policies that have "sanctioned inequitable systems of housing, education, employment, health care, environment, and infrastructure" have been associated with lower life expectancy and higher rates of alcohol-related deaths for American Indian and Alaska Native people (Solomon et al., 2022). (See Chapter 5 for more information about structural racism.)

Evidence increasingly indicates that racism, not race, drives health disparities, including, for example, in neuropsychiatry (Carter et al., 2022), asthma (Martinez et al., 2021), and COVID-19 outcomes (Khazanchi et al., 2020; Sabatello et al., 2021). This appears to be in part because racism drives other factors, like socioeconomic status, that influence health. However, socioeconomic status alone does not account for enduring health disparities (Phelan and Link, 2015; Williams et al., 2019b). Research has shown that, independent of socioeconomic status, racism influences health, likely due to inequalities in power, prestige, freedom, neighborhood context, and health care

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[16] For discussion of existing guidance, see also Chapter 4, section "Guidance for Race and Ethnicity in Clinical AI Algorithms."

(Phelan and Link, 2015). Therefore, racism (defined in Box 2-2) can have direct and indirect effects on health. In addition, racism limits equal access to not only health care but also to participation in biomedical research when beneficial. For instance, Jones (2002 and 2018) notes how racism determines how opportunity is structured, unfairly disadvantaging some individuals and communities while unfairly advantaging others. At the same time, racism appears to have harmful effects on health across racial and ethnic groups, including White populations (Williams et al., 2019a), reducing the health, strength, and potential of the whole society. This evidence contributed to the formulation of the committee's approach described in Chapter 5 and the development of its recommendations provided in Chapter 6.

CHAPTER SUMMARY AND CONCLUSIONS

Biomedical research comprises many disciplines that include a range of scientific approaches, from basic science to clinical trials to population-level investigations. Thus, the committee examined the common features of the research process as a framework for their analysis. As presented in this chapter, race and ethnicity are commonly used (and sometimes misused) throughout the research process—from study design, to recruitment, analysis, and interpretation of results. The next chapter will build on this framework and assess existing guidance for appropriate use of race and ethnicity in research. This chapter also examined the history of race correction and some of the consequences of this practice that are still seen in science and medicine today. Addressing issues of biased data, misguided approaches, and erroneous assumptions will take effort. Evidence shows that rooting out harmful effects is not simple and that it is important to be wary of unintended consequences. Therefore, based on the evidence presented in this chapter, the committee concluded:

> *Conclusion 3-1: The incorporation of race and ethnicity into clinical decision-making and care requires nuanced appraisal and consideration to mitigate potential harm to racial and ethnic minority groups and individuals. Issues of race correction or adjustment are not straightforward because removing race can have beneficial, neutral, or harmful effects which vary within and between racial and ethnic populations and contexts.*
>
> *Conclusion 3-2: Future efforts to investigate and improve the use of race and ethnicity in clinical algorithms will benefit from a nuanced and context-dependent approach that prioritizes the differential impact that these tools can have on racial and ethnic minority groups who have been harmed by clinical algorithms and other clinical practices.*

The evidence presented in this chapter underscored the need for caution in the use of race and ethnicity in biomedical research. The chapter closed with a brief introduction to the evidence from health disparities research that racism, not race, drives health disparities. The persistence of health disparities is a key reason for the continued use of race and ethnicity in research. The following chapter reviews existing guidance on race and ethnicity in biomedical research.

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4

Existing Guidance on Using Race and Ethnicity in Biomedical Research

Many partners in the biomedical research enterprise, including federal governmental agencies, professional societies, journals, and other institutions have published guidelines outlining changes they want to see in the use of race and ethnicity for clinical practice guidelines, clinical algorithms, clinical trial enrollment procedures, data reporting, and more. This chapter reviews some of these current guidelines and identifies gaps that remain. This existing guidance served the committee both in its deliberations and in developing its recommendations and their rationale, which are presented in Chapters 5 and 6. Before discussing specific guidance, it is worth noting some of the large gaps in guidance that exist. One area where the committee struggled to find guidance for the use of race and ethnicity is in earlier translational stages (T0 and T1) of biomedical research. As discussed in Chapter 3, race and ethnicity may be less relevant to the research questions at these early translational stages compared with later translational stages (T2–T4). However, there may be instances, particularly in T1, where there may be human participants involved in research and guidance for how to collect and use race and ethnicity data would be beneficial. The committee also struggled to find specific guidance for the use of race and ethnicity for biobanks, which may hold health samples and health information for thousands of human samples.

GUIDANCE FOR USING POPULATION DESCRIPTORS IN GENETICS AND GENOMICS RESEARCH

The 2023 National Academies report *Using Population Descriptors in Genetics and Genomics Research: A New Framework for an Evolving Field* (“population descriptors” report), provided detailed guidance on the use of descriptors such as race, ethnicity, and ancestry for investigators conducting research using genetics or genomics data. Recommendations relevant to the broader biomedical community provided in that report are summarized in Box 4-1. Readers conducting genetics and genomics

BOX 4-1
Using Population Descriptors in Genetics and Genomics Research

Requisites for Sustained Change

The population descriptors report included recommendations addressing long standing issues in genomics research: the use of typological thinking, analysis of environmental factors into examinations of genetic effects, and community engagement.

- Researchers should not use race as a proxy for human genetic variation. To eliminate typological thinking and establish new models that better reflect the complex reality of human genetic ancestry, researchers should avoid typological thinking when grouping people in genetics and genomics studies, refrain from using race as a proxy for human genetic variation and be sensitive to the connotations and impacts of the labels they do choose to use.
- Researchers should directly evaluate the environmental factors or exposures that are of potential relevance to their study, rather than rely on descriptors like race and ethnicity as proxies. A lack of information about environmental factors can cause descriptors to be used as proxies for environmental factors and result in the attribution of unexplained phenotypic variance between populations to unmeasured genetic differences. When measuring environmental factors is not feasible and population descriptors need to be used as proxies, then researchers should explain why these descriptors were chosen, how they are relevant, and how they are being used.
- Researchers should work in ongoing partnerships with study participants and community experts to integrate community perspectives into the research and to inform the selection and use of population descriptors. The legacy of community engagement by researchers in genetics is fraught with failure to respect communities and avoid harm. Successful community engagement takes effort and often requires creating a multidisciplinary research team, but these efforts are essential for success.

Best Practices for Researchers

The population descriptors report provided detailed practical guidance and tools for researchers who use descent-associated population descriptors in their genetics or genomics research while acknowledging that there is no single solution or approach that will work for all researchers in all situations.

- Researchers should first determine thoughtfully whether descriptors are needed at all for their study.
- Researchers should tailor their use of population descriptors to the type and purpose of the study, in alignment with scientific and ethical guiding principles, and explain how and why they used these descriptors.
- Researchers should disclose the process by which they selected and assigned group labels and the rationale for any grouping of samples. Where new labels are developed for legacy samples, researchers should provide descriptions of new labels relative to old ones.

Implementation and Accountability

Genetics and genomics research (and all research, truthfully) occurs within a complex research ecosystem. Institutions provide infrastructure and workforce, granting agencies provide essential funding, and professional societies and journals offer outlets for dissemination of results. All of these actors share responsibility for making lasting and meaningful change. Researchers cannot do this alone.

- Funding agencies, research institutions, journals, and professional societies should offer tools widely to their communities to facilitate the implementation of the report's recommendations. These tools should be publicly available, especially when they are supported by public funds.
- Funding agencies and research institutions should incentivize and reward investigators for fostering interdisciplinary collaborations among researchers with different areas of expertise to facilitate the inclusion of environmental measures and the engagement of diverse communities.
- Multidisciplinary advisory groups should be established to periodically evaluate the report's recommendations, best practices, and the implementation strategies established by funders, research institutions, professional societies, and journals.

research are encouraged, though, to read the population descriptors report for more detailed guidance.

As in this current report, the population descriptors report acknowledged that other parties in the broader genomics research ecosystem have critical roles in effecting change. Thus, the report provided specific guidance and recommendations for funding agencies, research institutions, research journals, and professional societies to assist in implementing the recommendations, establishing mechanisms of accountability, and creating an environment that will foster the recommended changes.

GUIDANCE FOR COLLECTING RACE AND ETHNICITY DATA IN CLINICAL TRIALS

Clinical trials are vital for testing new treatments aimed at reducing disease morbidity and mortality. Historically, trial populations did not represent the diversity of the general U.S. population, nor the diversity of the populations affected by the disease or condition under study. Clinical trials may encounter difficulties enrolling minoritized groups because trial recruitment may not be tailored to fit the needs of diverse groups. The underrepresentation of racial and ethnic minority populations has consequences, including limiting opportunities for equitable access to new therapies, threatening the efficiency of research, and limiting the generalizability of the results (NASEM, 2022).

Many populations remain underrepresented in trials for drugs approved by the U.S. Food and Drug Administration (FDA) (Martei et al., 2024), including Black, Hispanic, American Indian, and Alaska Native populations. As an example, Chen et al. (2021) conducted a review of clinical trials that led to the approval of 24 cardiometabolic treatments from 2006 to 2024 and found that only 2.9 percent of the 187,294 participants enrolled in these trials were Black (Chen et al., 2024; Martei et al., 2024). However, it is difficult to track the demographics of clinical trial participants in the United States. Although FDA guidance has encouraged the collection and reporting of participant age, sex, race, and ethnicity in clinical trials for many years (FDA, 2016), progress has been slow (Martei et al., 2024). For example, in a study that looked at more than 20,000 U.S.-based clinical trials, only 43 percent reported any race and ethnicity data (Turner et al., 2022). FDA “Drug Trial Snapshots” provides a helpful overview of the demographics of clinical trial participants in Phase III trials of approved drugs each year. However, this does not account for the many trials that never receive FDA approval nor earlier Phase I or Phase II trials. FDA Snapshots also does not track clinical trials for medical devices. Further, inconsistencies in reporting trail data to ClinicalTrials.gov make it difficult to examine race and ethnicity across a large number of clinical trials (NASEM, 2022).

Given the importance of enrolling diverse populations in clinical trials and research, a recent National Academies report examined strategies to improve the representation of underrepresented populations in clinical research and provided a series of recommendations to advance research with diverse populations (Box 4-2). Since the report was released, some of these recommendations have been implemented, including a

BOX 4-2
Improving Representation in Clinical Trials and Research

To improve research quality and to support greater health equity, it is important for all populations to have access and opportunities to participate in clinical research. In 2022, the National Academies released a report titled *Improving Representation in Clinical Trials and Research- Building Research Equity for Women and Underrepresented Groups*. The actions outlined in that report are critical for ensuring that diverse populations have the opportunity and access to participate in biomedical research and that the ethical principles outlined in Chapter 2 of this report are realized. This 2022 report concluded that improving representation in clinical research is urgent, requires investment, and is the responsibility of everyone involved in the clinical research enterprise. The report's epilogue describes a more equitable future emerging as a result of a paradigm shift that transfers power from investigators and institutions towards community members.

The 2022 report included 17 recommendations, which divide into several themes:

Reporting: Current data tracking and monitoring of the demographics of clinical trial participants are insufficient and do not provide a clear picture of who is participating in clinical research in the United States. Therefore, the committee recommended that the U.S. Department of Health and Human Services (HHS) establish an intradepartmental taskforce on research equity charged with coordinating data collection and developing better accrual tracking systems across federal agencies. The report also recommended that the National Institutes of Health (NIH) standardize the submission of demographic characteristics to Clinicaltrials.gov beyond existing guidelines so that trial characteristics are labeled uniformly across the database and can be easily disaggregated, exported, and analyzed by the public.

Increased Accountability: For new investigational drugs and devices, industry sponsors have a responsibility to ensure that the populations enrolled in those studies are representative of the population affected by the disease or condition under study. The report recommended that FDA use their existing authorities to ensure that studies are designed with representation in mind and that study teams are appropriately planning for enrolling appropriate populations in their studies. The report also recommended that the Office of Human Research Protections (OHRP) and FDA direct institutional review boards (IRBs) to assess and report representativeness as a measure of sound research design.

Federal incentives: Improving representation of underrepresented and excluded populations in clinical research requires an investment of money, time, and effort. To offset some of these costs and to incentivize industry to make

continued

BOX 4-2 Continued

these investments, the report recommended that Congress should establish a taskforce to study new incentives such as extended market exclusivity, tax credits, or fast-track criteria for new drug and device applications for trials that achieve representative enrollment. The committee also recommended that the Centers for Medicare & Medicaid Services (CMS) incentivize community providers to enroll and retain participants in clinical trials by reimbursing for the time and infrastructure that is required and that CMS expedite coverage decisions for drugs and devices that have been approved based on clinical development programs that are representative of the populations most affected by the treatable condition.

Remuneration: Reported barriers for diverse population participation in clinical research includes the lack of adequate reimbursement for expenses such as lost wages, transportation cost, housing and lodging costs, and more. Therefore, the report recommended that federal regulatory agencies, including the OHRP, NIH, and FDA, develop guidance to direct local IRBs on equitable compensation to research participants and their caregivers. This guidance should allow for differential compensation to research participants and their caregivers according to the time and financial burdens of their participation.

Education, Workforce, and Partnerships: Research suggested that engaging with community members can lead to more equitable study designs and increase participation of these community members in clinical research. Therefore, the report recommended that HHS should invest in building a community research infrastructure intended to improve representation in research. This funding should go to agencies such as the Health Resources Service Administration, NIH, Agency for Healthcare Research & Quality (AHRQ), Center for Disease and Control (CDC), and Indian Health Service to expand the capacity of community health centers and safety net hospitals to participate in and initiate clinical research focused on conditions that disproportionately affect the patient populations they serve. The committee also recommended that leaders of academic medical centers and large health systems should recognize research to advance community engaged scholarship as an area of excellence for promotion or tenure.

Congressional requirement that drug and device manufacturers must submit a diversity action plan to the FDA that details their plans to enroll a diverse population in the clinical trials. Although specific strategies to improve representation in clinical trials are outside of the scope for this committee, the committee wanted to highlight some of the findings of this report, which are critical for ensuring health equity and that all populations have the opportunity to contribute to clinical research.

In an effort to increase the diversity of clinical trial populations and broaden the eligibility criteria for clinical trial enrollment, FDA has advised sponsors "to consider patients with co-morbid illnesses such as chronic kidney, heart, and liver disease, prior or concurrent malignancy, and extremes of weight" (Martei et al., 2024, p. 387; see also FDA, 2020). In another strategy to increase diversity, adaptive designs would start with a more narrowly defined population and then expand trial eligibility to a broader population, based on interim safety data (FDA, 2020). This guidance has important implications for the inclusion of participants in trials since many underrepresented minority populations have higher rates of multiple overlapping comorbidities, e.g., heart disease and chronic kidney disease.

FDA DIVERSITY ACTION PLANS

To improve representation in clinical trials, the FDA introduced guidance in 2022 for inclusion of diversity action plans in study design (FDA, 2022). In December 2022, an omnibus appropriations bill, the Consolidated Appropriations Act 2023 (P.L. 117-328), was passed, including the Food and Drug Omnibus Reform Act of 2022 (FDORA). This act includes "provisions intended to promote diversity in clinical trial enrollment, encourage the growth of decentralized clinical trials, and streamline clinical trials" (Peloquin, 2023). Under this act, the FDA has the legal authority to mandate sponsors of Phase III or other major drug trials to specify enrollment goals by age, sex, race, and ethnicity (Martei et al., 2024). This requirement includes a "rationale for these goals, informed by disease prevalence or incidence among various demographic groups, and an action plan for meeting these goals including demographic-specific outreach and enrollment strategies, inclusion and exclusion practices, and diversity training for study personnel" (Martei et al., 2024, p. 387).

However, there are many challenges to operationalizing FDORA. One shortcoming is the lack of an enforcement mechanism if sponsors fail to meet the intended plan for recruitment. Although FDA could technically deny approval for a drug that does not meet recruitment targets, it is highly unlikely to delay approval and access for a safe and effective medication for this reason. Further, even after a drug is on the market, race and ethnicity data are not required for post-marketing studies and are rarely reported in postmarket databases, such as the Food and Drug Administration Event Reporting System (FAERS) (Muñoz et al., 2024).

Another set of challenges is the availability and source of the data used to inform the diversity action plans, limitations of the datasets used, timeliness of the data, and lack of data for rare diseases. Examples of currently available data that can inform diversity action plans include:

- Registries such SEER (the National Cancer Institute's Surveillance, Epidemiology, and End Results Program) or state cancer registries. The strengths are that these often have outcome data, but one of the limitations is they lag and are not available in real time.
- Real-world data, such as data based on health care administrative (insurance) and pharmacy claims as well as data from electronic health records or electronic

medical records. The large sample sizes available from these sources is a strength. However, these data also have many limitations—they are protected and limited to being collected at point of service, and they may be unstructured. Claims data often lack clinical outcomes/endpoints, and oftentimes people are lost to follow-up.

- Databases from companies such as Flatiron[1] have combined real-world data from multiple sources.

Sponsors of clinical trials are still seeking clarity to unanswered questions about diversity action plans. For example, if a sponsor recruits predominantly Black populations globally for a trial, how does that affect diversity action plans for drug approvals in the United States? Another challenge to reducing the burden of trials as stipulated in the diversity action plans is the absence of a national policy that provides safe harbor to the sponsors for the financial reimbursement of out-of-pocket expenses associated with participating in clinical trials (travel, lodging, lost wages, childcare/eldercare costs, etc.). There is also a tension between sponsors' time pressures to bring drugs to market and operationalizing diversity action plans.

GUIDANCE FOR COMMUNITY AND PARTICIPANT ENGAGEMENT IN BIOMEDICAL RESEARCH

In recent years, there has been a growing recognition of the importance of collaborating with communities throughout the research process. Community engagement can be defined as "the process of working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting the well-being of those people" (CDC, 1997, p. 9). Moreover, as noted by Bergstrom and colleagues, community engagement is not only a set of methods confined to a particular study but rather "a way of communication, decision making, and governance that gives community members the power to own the change they want to see, leading to equitable outcomes" (Bergstrom et al., 2012, p. 4).

Although an extensive review of best practice in community engagement is outside the scope of this report and merits further consideration, collaborative decision making throughout the research process is critical for improving the use of race and ethnicity, given how these concepts are interwoven with identity, social context, environmental exposures, and health. The health of individuals and communities is affected by socioeconomic, lifestyle, and behavioral factors as well as by the physical environment and the political and legal landscape (Hanson, 1988; IOM, 2002). Community engagement has been an important strategy for achieving racial and ethnic representation in research (e.g., Beech and Heitman, 2024); the goal is to engage community members in the process of designing protocols, including procedures for collection and use of race and ethnicity data, that meet their needs and that account for the barriers they face to participation. Inclusive community involvement throughout the research process can also increase the relevance, quality, generalizability, and dissemination of health research

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[1] https://flatiron.com/ (accessed October 16, 2024).

(Hood et al., 2010). Community representatives and patient advocates can play a role in identifying and prioritizing research questions that are important to specific populations, provide insight and networks to aid dissemination of research results, and contribute to translating research findings into practice and policy (Hood et al., 2010). Racial and ethnic populations are not a cultural monolith, so including perspectives from a range of community members can increase research relevance to the broader community.

As part of their work, the committee sought to hear community perspectives on the use of race and ethnicity in biomedical research and hosted a moderated discussion with invited panelists. (See Appendix A for the agenda and session objectives.) Panelists discussed their experiences with the collection and use of race and ethnicity data during different phases of biomedical research and how to build trust and stronger partnerships between scientists and communities. The session emphasized the importance of partnering with communities to better address race- and ethnicity-related issues in biomedical research and highlighted several important themes. First, panelists highlighted that race and ethnicity are social constructs that are challenging to define but have meaning for people's lives. The panelists emphasized the role of race and ethnicity for their own identities and the importance of seeing people like them and their communities in biomedical studies, further underscoring the importance of diverse representation in research. Moreover, when asked about their motivations for participating in studies, panelists named contributing data that could improve health among their communities as well as sharing information about their racial and ethnic identities for research purposes. For example, one panelist said, "[I was] following the footsteps of my mom and knowing that all of the different things that she had been involved [in] . . . was helping others in our community. My getting involved again [in clinical trials] was mainly because of the limited amount of participation from African American males particularly getting involved in research or practices in which the community as a whole could be better served" (Donald Adams, Jr., in remarks to the committee on March 14, 2024).

Second, panelists emphasized the importance of balancing qualitative methods with standardized measures of race and ethnicity to capture more granular information about an individual's identity and about the heterogeneity of populations. Racial identity may be fluid and may shift as a result of life experiences and the social context individuals are in. Although most people use categorical descriptors to identify their race or ethnicity, these classifications are more complex and fluid for some individuals (Croll & Gerteis, 2019). Collecting additional information about racial and ethnic identities allows researchers more accurately reflect the complexity of these classifications (Saperstein, 2012). However, panelists did note that we still need standardized approaches to asking about race and ethnicity in medical research settings to minimize misclassification, which can further exacerbate problems.

Lastly, understanding the narrative of what makes people who they are and what is important to communities can improve biomedical research, increase the quality of data about race and ethnicity, and illuminate unexpected and rewarding lines of inquiry. However, doing this work requires deep engagement with communities and research participants that cannot be episodic or transactional. As panelists noted, partnerships that are equitable support long-term, longitudinal relationships that are built on trust and future collaboration is predicated on continuous engagement and follow-through after the study. Building relationships with communities requires consistent engagement and an understanding of a community's culture, viewpoints, and history (NASEM, 2022). These relationships take time to build but can be broken in an instant. Building and maintaining these relationships therefore requires an investment of resources and time that many academic researchers find challenging, given the limitations of grant budgets and timelines. Industry-sponsored research faces similar challenges of maintaining funding for community sites in the time between one study ending and another study beginning. Another challenge is that in order to get IRB approval, every party engaged in research, including staff from a community organization, must undergo the required human subjects protection training (Anderson et al., 2012). This may be challenging for those in community organizations to complete in a timely manner. Although outside of the scope of this report, these are real challenges for conducting and funding community engaged research that require attention.

Despite these challenges, the committee identified community partnership as a key strategy for implementing the report's recommendations, especially in later stages of translational research (T2-T4), and for improving the use of race and ethnicity in future biomedical research. For those engaging in this work, how to conduct this engagement and where to begin will depend on the context of the study, the experience of the researcher and their institution working with the surrounding community, and what resources have already been built within the community. Although most academic medical centers have a long history of community service, a more comprehensive approach to community engagement in research would lead to more discoveries and healthier communities (Wilkins & Alberti, 2019). The following section outlines some strategies for doing this work and some examples of successful community engagement. (See Chapter 6 for more information on the role of community engagement in the committee's recommendations.)

Operationalizing Community Engagement

From a pragmatic perspective, community engagement exists on an engagement continuum, ranging from outreach to shared leadership (CDC, 2011; see also Table 4-1). On one end of the engagement spectrum, communication is primarily unidirectional, with communities only informed about current research and results (Hood et al., 2010). In the middle of the spectrum, engagement transitions toward bidirectional communication, and communities are engaged in important, but limited, research processes, such as recruiting research participants (Hood et al., 2010). On the other end is community-based participatory research (CBPR), which consists of shared decision-making governance and leadership to facilitate equal involvement of community partners and researchers (Hood et al., 2010; Paskett et al., 2003). CBPR not only increases community understanding of important research topics but also enables researchers to understand and address community priorities and to implement culturally sensitive research approaches (NIMHD, 2024). Moving from left to right along this spectrum of engagement increases transparency and dialogue between community members and researchers and requires greater time, effort, and financial investment from study teams.

TABLE 4-1 Community Engagement Continuum: A Comparison of Levels of Engagement.

Level of Engagement	Outreach	Consult	Involve	Collaborate	Shared Leadership
Definition	Interaction with the community where information flows from a researcher or research entity to the community	An information-seeking practice that incorporates community input on research design, implementation, or dissemination in the decision-making process	The involvement of multiple interested parties by researchers towards achieving goals established by the researcher	The formation of partnerships between researchers and stakeholders to achieve a common goal	Consensus-driven research process based on a strong system of relationships, reciprocity, and trust; final decision-making is at the community level
Goal or Objective	Provide the community with information about research studies or results	Inform communities about research proposals or results; community feedback informs researchers' decision-making	Obtain more participation from communities on research issues via community-led organizations	Form partnerships and work together on each aspect of research study from development to solution	Work together as equals on accomplishing a mutually agreed-upon research goal
Methods	Information or materials distributed via email, phone calls, mailing lists, community visits, presentations at community events, announcements, listening sessions, or media interviews	Surveys, questionnaires, facilitated discussions, focus groups, interviews, social media engagement, email blasts, newsletters, websites, SMS mobile, community input sessions, advisory boards	Involve partners and interested parties to obtain feedback or input on research	Partners and other interested parties share responsibility with researchers for achieving the study goals	Researchers and community partners create a common agenda and research aims together Shared framework for performance measurement and continuous communication

Continued

TABLE 4-1 Continued

Level of Engagement	Outreach	Consult	Involve	Collaborate	Shared Leadership
Examples for Use of Race and Ethnicity	Researcher provides community participants with information about why race and ethnicity are being collected and how the data will be used	A researcher seeks input from community advisory board on a research proposal to design the protocol for collecting race- and ethnicity-related data	A researcher seeks the help of community-led organizations to reach diverse populations for input on a research study of racial or ethnic health disparities	A researcher partners with a community organization to help identify and screen participants for a study about a health issue important to the community	A research team and community work together to identify a health problem important to the population; the community and study team co-design the research aims, protocol, and procedures
Examples of Specific Research Studies or Programs	**Recruitment of Three Generations of African American Women into Genetics Research (Taylor, 2009):** Participants were recruited using methods such as advertisements, presenting to churches, and outreach to HBCU sororities	**NIH *All of Us***: Research program that supports and recommends that awardees establish community or participant advisory boards to provide input on issues like recruitment methods and design of promotional messaging and engagement materials	**NIH Community Engagement Alliance (CEAL)**: A research network designed to work with community-based organizations to strengthen partnership through community-engaged research to address racial, ethnic, and socioeconomic health disparities	**Jackson Heart Study**: A 20-year prospective community-based cohort that successfully enrolled 5,306 African Americans by mobilizing community support and engagement through partnerships	**Wisconsin Alzheimer's Institute**: Organization committed to health equity for people living with dementia; primary goal was to support the community; community members initiated their participation in research
Pros	Expedient, less costly Quick, broad dissemination of research results Potential for subsequent relationship building	Develops connections Increases transparency and trust between researchers and community	Community involvement increases the potential for change Increases cultural sensitivity and humility among researchers	Builds more lasting and collaborative relationships, given increased commitment from community partners—in the form of time or other resources	Builds strong trust and long-lasting relationships Organizational structures may facilitate the sustainability of the initiative beyond the initial project

Cons	Limited public/community input or influence Could be perceived as impersonal or intrusive Risk of failing to reach deeper levels of engagement	Additional time and resources required to collect, analyze, and disseminate community input Not incorporating community feedback exposes researchers to criticism and could perpetuate problems	Requires more time and effort from community members	More labor intensive for researchers Relinquishing power to community partners can be difficult; researchers have less control of the process and may have to accept unanticipated outcomes	Takes time, consistency, flexibility, and focus from both research and community partners Better suited for broader issues that call for significant investment and participants of varying skills

NOTES: See Appendix B for an extended version of this table. This table is a general guide, and there may be other considerations for specific populations, such as American Indians. See text for more information about best practices.
SOURCE: Some content adapted from the CDC Principles of Community Engagement and New York City Department of Health and Mental Hygiene Community Engagement Framework and associated resources[2] (CDC, 2011; NYC Dept of Health and Mental Hygiene, 2017).

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[2] https://www.nyc.gov/site/doh/health/health-topics/race-to-justice.page (accessed July 10, 2024).

Successful Examples of Community Engagement

Developing relationships with communities means engaging with community members in meaningful and sustained ways throughout the research process. The Patient-Centered Outcomes Research Institute (PCORI) articulates this approach as its foundational expectations for research partnerships, which it requires from researchers who apply for funding.[3] The expectations include team diversity and representation to mirror the community, early and ongoing engagement with partners (including decision making), dedicated funds for engagement and partner compensation, training and capacity building for the team, shared decision-making with partners, and ongoing review and assessment of engagement. PCORI sees these as "building blocks for meaningful, effective, and sustainable engagement with patients, communities, and other partners in research." The strategies are intentionally general because the elements of community engagement should be tailored to the specific context based on goals of the community, researchers, and project, which may mean taking into account community preferences, cultural beliefs, values, and historical background. PCORI offers a number of illustrative examples of its expectations in action.[4]

PCORI-funded studies are more likely to directly engage participants and include contributions from this engagement in research design decisions (Forsythe et al., 2019). Further, a review of PCORI-funded studies found that this community engagement is "important to patients and clinicians, recruitment and retention of study participants, data collection processes, interpretation of results, and dissemination." PCORI also continues to monitor and evaluate their progress in advancing the National Priorities for Health, which will help researchers evaluate which aspects of PCORI's approach are most effective for engaging community members in biomedical research.

A second example is the Jackson Heart Study of cardiovascular disease among African Americans in the Jackson, Mississippi, metropolitan area. It is a 20-year prospective community-based cohort study that successfully enrolled 5,306 African American participants by mobilizing community support and engagement through partnerships with over 100 churches, government agencies, and community-based and nonprofit organizations (Addison et al., 2021). The Community Outreach Center (CORC), which was created to maintain trust and community engagement throughout the study, utilized community health education activities, health promotion, and health prevention messages within the Jackson community. Due to the efforts of the CORC, the Jackson Heart Study recruited the largest cohort of African Americans to participate in a study on cardiovascular disease and maintained high retention, with 85 percent of participants returning from the first exam to the second exam. The study also developed an extensive media campaign that was channeled through trusted community leaders, which began at least one year prior to the inception of the study (Addison et al., 2021; Martei et al.,

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[3] https://www.pcori.org/engagement/engagement-resources/engagement-research-pcoris-foundational-expectations-partnerships (accessed May 10, 2024).

[4] https://www.pcori.org/engagement/foundational-expectations/in-action (accessed July 10, 2024).

2024). This large community-based cohort study now includes a biospecimen and data repository as well as a registry for the recruitment of Black participants into ancillary clinical trials (Martei et al., 2024). Furthermore, the approach could potentially be adapted to build cancer survivorship cohorts for management of long-term cardiovascular outcomes (Martei et al., 2024).

In another example, a pivotal cluster-randomized trial of blood pressure reduction used a nontraditional health care setting to develop and test a blood-pressure control program for Black men. The study enrolled a total of 319 Black male participants with hypertension across 52 Black-owned barbershops (Victor et al., 2018). The intervention group saw a 95 percent retention rate, achieved by using "multiple blood pressure screenings, ID cards, follow-up calls at 3 months, culturally specific health sessions, and payments to offset the costs of generic drugs and transportation to pharmacies" (Martei et al., 2024, p. 388; Victor et al., 2018).[5]

Collaborating with Indian Tribes on Biomedical Research Studies

Working with American Indians and Alaska Natives (AIANs) on research studies requires additional considerations that are absent when working with other communities. Some of these are the result of the longstanding sovereignty of Indian Tribes within the boundaries of what is now the United States and their resulting governmental structures. This sovereign status is a defining feature of American Indian Tribes. Other reasons stem from the sharply different frames of reference of Western science and Indigenous knowledge.

Differences in Viewpoint

It is critical that researchers become aware and sensitive to the culture, belief systems, history, and priorities of the American Indian or Alaska Native group with which they would like to work (Hiratsuka et al., 2012). Few non-native researchers possess such an awareness, especially a deep understanding of the continuing effect of American colonialism on the people they seek to include in their study. Emphasizing this point, a speaker shared with the committee, "If you want to study a native community, you will have to actually come to our world. You have to assimilate to us instead of the other way around. You have to leave your perspectives and beliefs at the door and be open to our perspectives and beliefs" (Audie Atole in remarks to the committee on March 14, 2024).

Biomedical researchers may find it challenging to understand non-Western scientific paradigms that undergird Indigenous knowledge and how to integrate that knowledge into a study. There is an entrenched Western mindset that Indigenous worldviews of studying natural phenomena and human health, which have developed over centuries (even millennia in some cases), are deficient and primitive (Beauchamp and Childress,

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[5] https://www.cedars-sinai.org/newsroom/update-cedars-sinais-la-barbershop-study/ (accessed July 10, 2024).

2001; Deloria Jr., 1999; Jonsen et al., 1998). "Native peoples tend to see their cultures as encompassing systems of knowledge and understanding that are fundamental to the continuation of the Tribe itself. Any harm to culture is perceived as a direct harm to the ability of the Tribe to continue into the future" (Tsosie, 2007, p. 402). Traditional knowledge and stories are intellectual property and sources of a Tribe's collective wealth passed down across generations (Cruikshank, 1992; Harding et al., 2012; Tsosie, 2002). As with any sovereign nation, a Tribal government has a responsibility to safeguard its Tribe's cultural, intellectual, and spiritual inheritance along with the rights and resources of its people and place.

Consent from the Tribal Government

Biomedical researchers must understand that each Indian Tribal government is the only entity authorized to represent and make decisions on behalf of that Tribe. There are 574 distinct and federally recognized Tribes or Tribal entities afforded sovereignty within the United States today.[6]

Many Tribes have legally enforceable codes that set forth whether and how research will be done in their Nation, on their land, and with members of their Tribe (Carroll et al., 2022). For example, the Ho-Chunk Nation's Tribal research code establishes an application and permitting process that is overseen by the Tribal institutional review board (IRB) and is "designed to protect individuals, communities and the Nation itself from improper research procedures" (Ho-Chunk Nation, 2005, p. 2). The Ho-Chunk Nation's code also protects the rights of individuals who are members of the Tribe; secures ownership of and provides protections for the Nation's data; and ensures "appropriate Nation and community participation in the design and evaluation of research, and appropriate local opportunities in employment in all research projects permitted . . . within the Ho-Chunk community" (Ho-Chunk Nation, 2005, p. 2). Researchers who want to work with the Ho-Chunk Nation—or with many other Tribes—must apply for a permit either through the Tribe's IRB or through the U.S. Indian Health Service (in addition to any academic or institutional IRB). A Tribal IRB considers potential adverse impacts to the Tribe, the Tribe's government, and Tribal individuals and does so with knowledge and a viewpoint that an academic IRB may lack (Around Him et al., 2019); thus, the two review processes are complementary.

When Tribes do not have IRBs, there are still cultural and formal protocols that must be followed by researchers (Garba et al., 2023). Often it is a matter of getting in front of the Tribal council and head of the Tribe, who function as the de facto IRB—something that can take months. Sometimes an approval is also needed from a cultural head in addition to the governmental body. Therefore, before approaching Tribes about

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[6] https://www.federalregister.gov/documents/2021/01/29/2021-01606/indian-entities-recognized-by-and-eligible-to-receive-services-from-the-united-states-bureau-of (accessed July 10, 2024).

permission to carry out reservation-based research, researchers should learn about the Tribe and its protocols, laws, codes, beliefs, and structures.

"[T]ribal needs may not accommodate research timelines, which are often too short (short-term or one-time federally funded initiatives) or too long (publication-heavy research without actual remedies for the community). It is rare that a federally funded initiative is timely and sustained, that the grant is received when needed by the Tribe, and that the Tribe is ready with adequate staff and processes in place" (Harding et al., 2012, p. 7).

With 78 percent of AIANs living off reservation, urban-based AIAN research has its own set of "protocols" that are distinct from reservation- or Nation-based research. There are several urban centers around the country that have some institutional body—whether formal or informal—where researchers can find out about procedures and protocols for seeking to carry out research, including what to avoid. These bodies may be able to assist in or have a mechanism for granting community assent and access (e.g., Metropolitan Urban Indian Directors,[7] National Urban Indian Family Coalition,[8] Seattle Indian Health Board[9]).

Data Sovereignty and Intellectual Property Rights

Researchers may face challenges centering on trust, data ownership, and sovereign rights. Although research is trending toward more open-source approaches, this may be at odds with the values and rights of Indigenous populations (Garrison and Carroll, 2024). Differences may include conceptions of how knowledge may be generated, used, and shared as well as who owns both the material and information collected for a study and the data, analyses, and disseminating documents generated from those collected materials. This necessitates that a material and data sharing agreement (MDSA) be crafted collaboratively and then agreed to and signed by all parties (Harding et al., 2012; see also Hayward et al., 2021). All parties will benefit, and trust will be built when material and data-sharing issues are discussed and resolved early in the study's lifecycle.

Here the complementary perspectives of academic and Tribal IRBs can be useful. An awareness of and sensitivity to past and ongoing abuses of Tribal material and information underscore why an MDSA is needed (Chadwick et al., 2019; Claw et al., 2021; Garrison and Carroll, 2023). Tribes may want the MDSA to include language that defines how Tribal information can be used in publications. They may want it to provide clarity about intellectual property rights in the context of studies involving participants who are members of sovereign nations. The MDSA will likely confirm that all materials and information remain the property of the Tribe, and they are not to be shared with a third party without Tribal permission or used for anything other

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[7] https://muidmn.org/committees (accessed October 16, 2024).

[8] https://www.nuifc.org/ (accessed October 16, 2024).

[9] https://www.sihb.org/ (accessed October 16, 2024).

than permitted research. Furthermore, all materials will be returned to the Tribe at the conclusion of the study. Developed by the Indigenous Data Alliance,[10] the CARE Principles for Indigenous Data Governance[11] can provide guidance for researchers engaging in this work. With a foundation of Indigenous worldviews, the CARE principles are collective benefit, authority to control, responsibility, and ethics (Carroll et al., 2022).

Informed Consent

Entry into a Tribal nation or an Indigenous community requires time on site and introduction to key members relevant to the envisioned study well before the research is set to begin. Once a relationship with the Tribe or community is established, researchers should consider partnering with or have on the research team one or two trusted members of the Tribe or community. Someone who "speaks the language" of both Indigenous and Western science can facilitate collaborations that build mutual trust and respect (Hatch et al., 2023). It is important for researchers to communicate the risks, consequences, and benefits of consenting to participating in a research study, by offering participants clear and concise descriptions of the purpose of the research, the use and storage of the information collected, and any potential issues of anonymity (Harding et al., 2012). There will likely need to be confidentiality agreements "signed by university research personnel who have access to project material and data. These forms are held by Tribal researchers under secured conditions so that they know who has access to the data and for what purpose" (Harding et al., 2012, p. 9).

Strategies for Success

Partnering with Tribal nations entails time and commitment to overcome unexpected barriers or roadblocks, including potential geographic and logistical challenges that are unique to each Tribe (Jones et al., 2019; Laveaux and Christopher, 2009). Each Tribe has distinct protocols for research approvals, and researchers often underestimate the time required to meet them. While perhaps time-consuming, Tribal approval processes allow time for cultural immersion, demonstrating trustworthiness and commitment, and developing relationships (Jones et al., 2019). Essential to productive collaborations with Tribal nations, relationship building benefits from cultural sensitivity, humility, and openness to personal growth (Jones et al., 2019). Taken a step further, understanding Tribes' priorities could also result in changes to the research questions or study design.

Some research studies have used a version of community-based participatory research (Laveaux and Christopher, 2009) or coproduction, and the outcomes benefited

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[10] https://www.gida-global.org/whoweare (accessed October 16, 2024).

[11] https://www.gida-global.org/care (accessed October 16, 2024).

equitably both the Indian Tribe and the academic researchers (Woodbury et al., 2019). Some examples are:

- The Center for Braiding Indigenous Knowledges and Science,[12] which is not biomedical research, but has been funded by the NSF at $30 million for 5 years.[13]
- The Center for Indigenous Health Research and Policy,[14] which focuses on cardiovascular and related confounding diseases, like diabetes and obesity, and behavioral and environmental changes to reduce their prevalence, especially by expanding access to healthy foods and tapping into traditional cultural practices.
- The Confederated Tribes of the Umatilla Indian Reservation and Oregon State University collaborated to address Tribal exposures to polycyclic aromatic hydrocarbons and assess ways to improve community health. As part of the process, they collaborated on the formation of a model material and data sharing agreement and a confidentiality agreement (Harding et al., 2012).

Other resources, including extramural grant opportunities, can be found through parts of the federal government that focus on biomedical research with AIAN populations, such as the NIH Tribal Health Research Office, NIH Native American Research Centers for Health, HHS Indian Health Service, HHS Office of Minority Health, and Environmental Protection Agency's Science to Achieve Results (STAR) tribal environmental health research program.

GUIDANCE ON THE COLLECTION OF RACE AND ETHNICITY INFORMATION IN ELECTRONIC HEALTH RECORDS

As noted in Chapter 3, electronic health records (EHRs) are now the standard method for collecting and retrieving patient and patient-related information. EHR systems have become extremely sophisticated, and multiple commercial systems are in use by healthcare systems across the United States and the globe. EHR data are now used in biomedical research studies and in the training and validation of AI algorithms. Yet despite repeated calls for standardizing EHR data collection on race and ethnicity, such standardization requirements do not exist (IOM, 2003; NASEM, 2024). A 2018 report by the Agency for Healthcare Research and Quality said, "Given variations in locally relevant populations, no single national set of additional ethnicity categories is best for all entities that collect these data" and recommended tailoring the more granular ethnicity groups based on locally relevant categories chosen from a national standard set of options (AHRQ, 2018). Since then, some have explored the use of imputation models to expand the granularity in ethnic and racial categories for Hispanic, Asian, Native Hawaiian, and Pacific Islander populations (NASEM, 2024). It should be noted that

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[12] https://www.umass.edu/gateway/research/indigenous-knowledges (accessed October 16, 2024).

[13] https://www.umass.edu/news/article/umass-amherst-partnering-indigenous-communities-launch-30m-nsf-center-braiding (accessed October 16, 2024).

[14] https://medicine.okstate.edu/cihrp/ (accessed October 16, 2024).

the revised U.S. Office of Management and Budget (OMB) standards now recommend collecting more granular data as well (OMB, 2024).

The U.S. Office of the National Coordinator for Health Information Technology is building standardized data elements that are being evaluated ahead of becoming required elements in EHR systems. EHR systems are currently required to support not only the OMB categories for race and ethnicity but also the more granular CDC Race and Ethnicity Code Set representations of race, ethnicity, and Tribal affiliation (NASEM, 2024).[15]

GUIDANCE FOR RACE AND ETHNICITY IN CLINICAL PRACTICE GUIDELINES

Several organizations, such as the U.S. Preventive Services Task Force (USPSTF), the Agency for Healthcare Research and Quality (AHRQ), and the American Academy of Pediatrics (AAP), have issued guidance on the use of race and ethnicity in clinical practice guidelines. The USPSTF creates evidence-based clinical practice guidelines to guide the delivery of clinical preventive services. In 2021, the USPSTF acknowledged that systemic racism is a root cause of health disparities in preventive care and made a commitment to promote antiracism and health equity in its preventative care recommendations (Davidson et al., 2021). Its recommendations and next steps include the following:

1. “Consider race as a social, not a biological construct
2. Promote racial and ethnic diversity in membership and leadership and foster a culture of inclusivity
3. Commission a report to understand how systemic racism undermines the benefits of evidence-based clinical preventive services
4. Iteratively update methods to overcome health inequities experienced by populations affected by systemic racism
5. Communicate gaps created by systemic racism in all dissemination efforts
6. Collaborate with its partners and experts to reduce the influence of systemic racism on health” (Davidson et al., 2021, p. 2406; Doubeni et al., 2021).

In December 2023, AHRQ developed a health equity framework for incorporating a health equity lens that spans the entirety of the USPSTF recommendation-making process (J. Lin et al., 2023, 2024). The report provides an equity framework for each phase of the USPSTF guideline development: “(1) topic nomination, selection, and prioritization, (2) development of the work plan, (3) evidence review, (4) evidence deliberation, (5) development of the recommendation statement, and (6) dissemination of recommendation(s)” (J. Lin et al., 2023, p. 5).

The AAP released a policy statement in June 2022 to tackle the eradication of race-based medicine as a component of a larger effort to deconstruct the structural and

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[15] https://www.healthit.gov/isa/representing-patient-race-and-ethnicity (accessed May 12, 2024).

systemic injustices responsible for racial health disparities (Wright et al., 2022). The following recommendations were adopted:

- "AAP will critically examine all policies and practice guidelines for the presence of race-based approaches in their development and deconstruct, revise, and retire, if necessary, all policies and practice guidelines that include race assignment as a part of clinical decision-making.
- The AAP will critically examine all policies and guidelines currently under development as well as consideration of all such future documents to ensure the exclusion of race assignment as part of clinical decision-making.
- The AAP will leverage the "Words Matter" document to ensure that all authors, editors, presenters, media spokespersons, and other content contributors recognize race as a social construct only and desist from any use, or its reference, as a biological proxy" (p. 5-6).

Application of the AAP framework to a clinical pathways library at Boston Children's Hospital established several recommended practices, including: (1) "define race, ethnicity, and ancestry rigorously; (2) assess the most likely mechanisms underlying epidemiologic associations; (3) consider whether inclusion of the term is likely to mitigate or exacerbate existing inequities; and (4) exercise caution when applying population-level data to individual patient encounters" (Rosen et al., 2023, p. 1-2). This process, and those framed by the USPSTF and AHRQ, could serve as a useful model for other organizations looking to reevaluate how race and ethnicity are incorporated into clinical pathways.

GUIDANCE FOR RACE AND ETHNICITY IN CLINICAL ALGORITHMS

Despite the potential of clinical algorithms to exacerbate existing health disparities, there are very few studies that evaluate the disparity effects of using clinical algorithms. In addition, some algorithms are proprietary, or created by private companies such as EHR vendors or payers, and even less is known about their development and impact on racial and ethnic disparities. One of the few existing resources that tackles this subject in a comprehensive manner is a recent report by the AHRQ that reviewed the literature to examine the effect of 18 statistical algorithms on racial and ethnic differences in access to care, quality of care, and health outcomes (Tipton et al., 2023). The review found that algorithms sometimes perpetuate or exacerbate disparities and at other times reduce racial and ethnic disparities. Rarely do the algorithms have no discernable effect on disparities. An important conclusion from the AHRQ report is that the quality of the evidence was found to be weak in terms of rigorous study designs (Powe, 2024). Most studies suggesting deleterious effects were designed as simulations, modeling what might happen when an algorithm is used in care. Such studies are susceptible to biases. Few used randomized clinical trials or pre-post implementation designs to examine outcomes.

Tipton and coauthors (2023) also reviewed the literature for mitigation strategies used to address potential race-based harms from algorithms and identified six types of mitigation strategies, which are summarized in the AHRQ report:

- removing a race or ethnicity input variable from the algorithm
- replacing race or another input variable with a different measure
- adding an input variable
- recalibrating the algorithm with a more representative patient population
- stratifying algorithms to assess patients of different racial and ethnic groups separately
- using different statistical techniques within algorithms

The authors concluded, "It is unclear from the current evidence base if certain types of strategies are generally more effective than others" (Tipton et al., 2023, p. 30). Employing mitigation strategies to influence health outcomes can have mixed results, improving one outcome while worsening another. For example, most studies showed that omitting race from the estimated kidney function test (eGFR) led to an increase in diagnoses of chronic and severe renal disease in Black patients (Delgado et al., 2022). Thus, the removal of race and ethnicity values from this algorithm can result in earlier interventions to treat chronic kidney disease and increase the referral of Black patients for kidney transplants. However, omitting race from eGFR may also exacerbate disparities related to clinical trial eligibility or cancer therapy access because Black patients are classified as having more severe kidney disease (Tipton et al., 2023; see also Figure 3 in Siddique et al., 2024).

In a report summarizing a meeting sponsored by the Doris Duke Foundation and others in June 2023, the Council of Medical Specialty Societies also observed that the consequences of using race as a variable in research studies can vary considerably and can be beneficial (e.g., if race is included in an intentional, well-considered effort to reduce inequities); neutral/have no impact; or harmful (e.g., if including race perpetuates disparities or the misconception of innate biological differences between racial groups) (CMSS, 2023). According to the report, the "path to improving health equity will likely differ for each algorithm" (CMSS, 2023, p. 4). The best option for a particular algorithm may be to exclude race altogether; to replace race with an alternative variable, such as measures of social determinants of health; to stop using the algorithm and replace it with one that promotes equity; or to continue to include race as it is currently being used (CMSS, 2023). For this reason, there is likely not a one-size-fits-all solution to the persistent problems surrounding the use of clinical algorithms that incorporate race and ethnicity data.

GUIDANCE FOR RACE AND ETHNICITY IN CLINICAL AI ALGORITHMS

Bias in AI Algorithms

Sources of AI bias can appear throughout the developmental life cycle of AI algorithms (Cary Jr. et al., 2024; see also Box 4-3). To address racial and ethnic bias in the development and use of healthcare algorithms, AHRQ and the National Institute on

BOX 4-3
Sources of Bias in AI Algorithms

Problem formulation/specification: The development of a predictive model necessitates specifying the overall goals, actions available for decision making, and, in the case of predicting an outcome of interest, clearly defining an outcome that is likely to be complex and ambiguous. For example, Obermeyer et al. demonstrated that a health care model used to identify patients with complex health needs was racially biased because the outcome was specified using health care costs as a proxy for illness burden. Because of unequal access to health care, the model unfairly predicted that members of groups with less health care access were healthier than they were (Obermeyer et al., 2019).

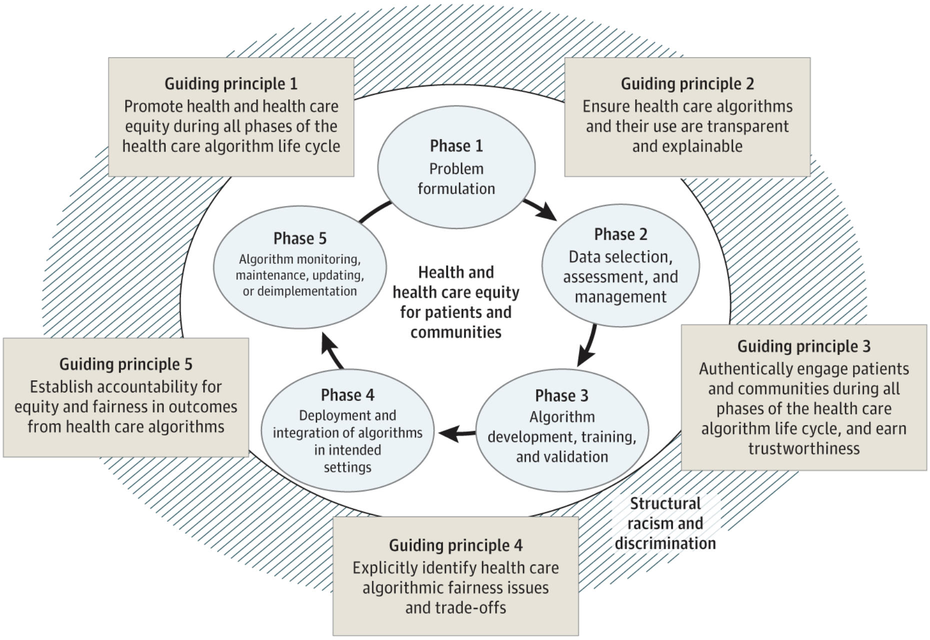
Data: Following problem specification, model derivation typically entails applying a statistical or artificial intelligence (AI) method to a dataset of historical cases in order to discover useful patterns. Biases in the data will be captured in the model because model derivation methods aim to capture statistical features of the input dataset. For example, if there is systemic racism in health care access and delivery, historical EHR data will encode these biases and lead to discriminative predictive models (Gijsberts et al., 2015). Moreover, historical data may not reflect the current context, potentially missing key information.

Modeling: Given a dataset, derivation and validation of a model is done to optimize model performance relative to some success criteria which are technically encoded as an objective function. Typically, the objective function focuses on pure overall predictive performance by maximizing accuracy. Since fairness is not explicitly accounted for in the objective function, such optimization may lead to models that have lower accuracy in a specific group or groups.

Implementation: Biases can emerge during the implementation, often called deployment, of a model. This can occur, for example, when the implementation context differs significantly from the historical context of the training data, resulting in poor performance in groups that were underrepresented in the training data. Furthermore, biases can arise from a failure to recognize the limitations of a purely predictive model, whose predictions may be insufficient for interventions that require causal information.

Monitoring: Biases can appear at any point after model deployment, even if the model was fair during initial deployment. Vigilance is thus essential on an ongoing basis. New bias may develop because the data used to train the model may no longer be representative of the real-world population as time passes. For example, new racial groups may emerge on which the model was not trained and on which it performs poorly. Another reason is changing societal norms and legislation—that is, a model that was considered fair during initial deployment may become unfair as social and ethical standards evolve.

Source: Adapted from Anderson et al. (2024).



Guiding principles apply at each phase to mitigate and prevent bias in an algorithm.
Operationalization of the principles takes place at 3 levels: individual, institutional, and societal.

FIGURE 4-1 Developmental life cycle of an algorithm and guiding principles to mitigate and prevent bias.
SOURCES: Chin et al., 2023, CC-BY-ND; Matheny et al., 2020.

Minority Health and Health Disparities convened an expert panel that developed guiding principles to mitigate or eliminate the impact of bias at each phase of the algorithm life cycle (Figure 4-1; Chin et al., 2023).

The AI Program in the FDA's Center for Devices and Radiological Health has identified major regulatory science gaps and challenges in clinical AI algorithms. One of the focus areas of program activity is "to develop methods to measure and quantify algorithmic bias, reduce performance difference among subpopulations, and ensure generalizability" (FDA, 2023). Presumably, this will include consideration of the use of race and ethnicity as input variables and assessment of performance on racial and ethnic subpopulations.

Reporting Guidelines and Repositories for AI Algorithms

As research in health AI algorithms has progressed, reporting guidelines have been developed to assure scientific validity, clarity of presented results, reproducibility, and adherence to ethical principles. Some of these guidelines (Box 4-4), such as SPIRIT-AI and CONSORT-AI, are extensions for AI of existing guidelines that were developed for biomedical research studies. More are under development, such as STARD-AI,

BOX 4-4
Reporting Guidelines for AI Algorithms

SPIRIT-AI is the AI-specific version of the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) and provides guidelines for reporting clinical trial protocols for AI interventions (Cruz Rivera et al., 2020).

CONSORT-AI is the AI-specific version of the Consolidated Standards of Reporting Trials (CONSORT) and provides guidelines for reporting randomized trials of AI interventions (Liu et al., 2020).

FUTURE-AI provides guidelines based on six guiding principles for AI research: fairness, universality, traceability, usability, robustness and explainability (FUTURE). The fairness guideline calls for maintaining the same performance across subgroups of individuals of different ethnicities (though not across different races) (Lekadira et al., 2021).

HUMANE (Harmonious Understanding of Machine Learning Analytics Network) provides a checklist of 60 questions with binary, multiple choice, or free-text responses to assess the reporting quality of medical AI studies (du Toit et al., 2023).

MI-CLAIM (Minimum Information about Clinical Artificial Intelligence Modeling) provides reporting guidelines for clinical AI models (Norgeot et al., 2020).

MINIMAR (Minimum Information for Medical AI Reporting) provides minimum reporting standards for medical AI applications (Hernandez-Boussard et al., 2020).

CLAIM (Checklist for Artificial Intelligence in Medical Imaging) provides reporting standards for medical-imaging AI studies (Mongan et al., 2020).

RQS (Radiomics Quality Score) is an assessment tool for evaluating the methodological quality of radiomics—quantitative approach to medical imaging—studies, including those that use AI (Lambin et al., 2017).

STARD-AI is the AI-specific version of the Standards for Reporting of Diagnostic Accuracy Studies and provides guidelines for reporting diagnostic accuracy of AI models. It is under development (Sounderajah et al., 2021).

TRIPOD-AI is the AI-specific version of the Transparent Reporting of a Multivariable Prediction Model of Individual Prognosis or Diagnosis and provides reporting guidelines for studies developing, validating, or updating diagnostic and prognostic AI models. It is under development (Collins et al., 2021).

PROBAST-AI is the AI-specific version of the Prediction Model Risk Of Bias Assessment Tool and provides guidelines for assessing the risk of bias and applicability of diagnostic and prognostic AI models. It is under development (Collins et al., 2021).

TRIPOD-AI, and PROBAST-AI. Of the currently published guidelines, commentary on the use of race and ethnicity is limited. Only FUTURE-AI calls for the evaluation of AI across ethnic categories, though not across racial categories.

Two repositories for clinical practice guidelines are an extensive free repository maintained by the ECRI Guidelines Trust[16] and the repository maintained by Guideline Central.[17] An online database of clinical statistical algorithms with race-based guidelines, medications with race-based guidelines, and medical devices with differential racial performance is available (Clinical Algorithms with Race, 2023). The FDA also maintains a database of AI and machine learning-enabled medical devices,[18] including approved AI algorithms.[19]

GUIDANCE ON THE REPORTING OF RACE AND ETHNICITY DATA IN PUBLICATIONS

Publication in medical and science journals is an important avenue through which the use of race and ethnicity in research can be improved. The language used and the ways race and ethnicity are discussed reflect the care with which the concepts were considered throughout the research process. Clear descriptions of how and why race and ethnicity were used in a study promote transparency, openness, and replicability—principles of sound science introduced in Chapter 2. While the inclusion of race and ethnicity in health research has increased over time, these terms are almost never clearly defined (Martinez, 2023a). Less than 50 percent of articles across disciplines and only approximately 30 percent of medical and epidemiological publications had any justification regarding their use of race and/or ethnicity (Martinez, 2023a, 2023b). There is a lack of standardized practice around the use of race as a study variable and inconsistency in how researchers conceptualize and report on race in biomedical publications (Boyd et al., 2020).

There have been many attempts to establish guidelines directed towards researchers, journal editors, and reviewers to standardize practices for discussing the use of race and ethnicity data. In a recent article, nine biomedical journal editors provided guidance for using race, ethnicity, and geographic origin as proxies for genetic ancestry groups when publishing study results (Feero et al., 2024). Although focused on genetics, the authors encouraged researchers throughout the biomedical community to embrace these best practices, which would help to ensure scientific accuracy and the interpretability of published research across biomedical research disciplines. Among existing reporting guidelines, a few common themes have emerged, including:

- Explain why race and ethnicity are being used as study variables.
- Define race and ethnicity as they are used in the study.

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[16] https://guidelines.ecri.org/ (accessed August 27, 2024).

[17] https://www.guidelinecentral.com/guidelines/ (accessed August 27, 2024).

[18] https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices (accessed August 27, 2024).

[19] https://medicalfuturist.com/fda-approved-ai-based-algorithms/ (accessed August 27, 2024).

- Describe how race and ethnicity data were collected.
- Avoid using race or ethnicity as explanatory variables for observed health disparities.
- Use clear, consistent, and inclusive language in reporting on race and ethnicity.

It is important that researchers have a clear understanding of the objectives of the study they are developing, select the most appropriate variables needed to carry out these objectives, and use them consistently (Lu et al., 2022). According to the International Committee of Medical Journal Editors recommendations, "Authors should define how they determined race or ethnicity and justify their relevance" and if they choose to not collect this data, they should explain their reasonings behind this decision (ICMJE, 2023, p. 7). The *Journal of the American Medical Association* (*JAMA*) states that if "race and ethnicity categories were collected for a study, the reasons that these were assessed should be described in the Methods section" (Flanagin et al., 2021, p. 623). Moreover, researchers should note if the collection of these data was a requirement by a funding agency (Flanagin et al., 2021). Employing race and ethnicity as study variables without any clear reasoning for doing so implies that these categories are a "primary, natural, and neutral means of grouping humans" (Bhopal, 1997, p. 1751; see also Kaplan and Bennett, 2003), a practice that should be avoided.

When race and ethnicity are used as study variables, researchers will need to define these terms as they are used in their study (Boyd et al., 2020). In their guidance on race and ethnicity reporting, JAMA offers some discussion of definitions that could be of use to researchers as a starting point (Flanagin et al., 2021). To avoid conflating race with ethnicity, JAMA suggests that researchers use "race and ethnicity" as opposed to "race/ethnicity" in their publications (Flanagin et al., 2021). Journals and funding agencies can encourage researchers to carefully appraise their use of these terms by setting requirements for the inclusion of precise definitions of these constructs in their submissions (Lu et al., 2022) and ensuring clear descriptions in the methods sections of articles (Feero et al., 2024).

Researchers will need to describe in the methods section how race and ethnicity data were collected. If self-report was used to assign participants into racial or ethnic categories, researchers should specify if they were given a fixed set of options to choose from or if the questions were open-ended (Kaplan and Bennett, 2003). Some journals consider self-identification with an option to write-in the desired response or select multiple categories to be the gold standard for collecting this type of data. When assignments to racial or ethnic categories were made by research or health care personnel, it should be specified how these categories were attributed (AHA, 2021). Ultimately, researchers should do their best to collect data that capture as much of the multidimensional nature of an individual's identity as possible with the tools at their disposal (NHGRI, 2016; Roth, 2016). In doing so, they are better equipped to develop and execute studies that are more rigorous and transparent.

Other guidelines advise against treating race and ethnicity as explanatory variables for health disparities found between different groups. Rather, their use in health disparities research is appropriate "as [a way] . . . of examining the underlying sociocultural reasons for these disparities" (Rivara and Finberg, 2001, p. 119). An association between membership in a racial or ethnic group and a higher incidence of a disease does not in itself establish causality (Kaplan and Bennett, 2003). Instead of using race and ethnicity as explanations for the existence of disparities in health, investigating other relevant factors, including racism and discrimination, socioeconomic status, social class, environmental exposures, and educational attainment, will likely provide more meaningful results (Kaplan and Bennett, 2003; NHGRI, 2016). Several journals have advised that the collection of race and ethnicity data is best done in conjunction with all relevant social and structural factors that influence the research question (AHA/ASA, 2021; Flanagin et al., 2021). Explicitly using terms like "structural racism" and "racial equity" in the study could be another important way to highlight the impact of racism on health outcomes and avoid misusing race and ethnicity data (Flanagin et al., 2021). Boyd and colleagues (2020) suggest that researchers name racism as a key determinant of health, identify what type of racism (interpersonal, institutional, internalized) is relevant, the mechanism by which it is operating, and examine additional forms of oppression that may exacerbate racism's effects (Boyd et al., 2020). By considering the multitude of social and environmental forces that impact the health of individuals and populations, researchers can avoid reinforcing the existence of a biological basis of race and get a clearer understanding of what drives differences in health outcomes between groups.

A number of journals provide style-based guidance on terminology, capitalization, and the use of inclusive language when describing racial and ethnic groups in biomedical publications. A few examples follow. Authors are advised to use language that is "neutral, precise, and respectful" when describing research participants and discouraged from using terminology that may be stigmatizing (ICMJE, 2023, p. 17). The term "White" is acceptable while "Caucasian" is not, because the latter is rooted in "racist taxonomies used to justify slavery" (Popejoy, 2021, p. 463). Descriptors like "Non-White" and "Other" homogenize populations or groups of study participants, thus obscuring meaningful data and reducing the power and validity of a research study. An exception to using "Non-White" or "Other" may be when it was an explicit preselected category in an existing database or research instrument (Flanagin et al., 2021). Grouping together different populations that are unrelated except for their being "non-White" can contribute to the assumption that whiteness is the reference category. It is preferable to identify the smaller population groups, whenever possible (AHA, 2021). Capitalizing the names of racial and ethnic groups and avoiding the use of pejorative terms like brown and yellow are recommended (Flanagin et al., 2021).

Remaining Challenges with Race and Ethnicity Reporting Guidelines

Despite the concordance among journals on many aspects of reporting on race and ethnicity in biomedical research studies, several challenges remain. One obstacle is the difficulty of maintaining and tracking adherence to these guidelines. Since the majority of the policies on race and ethnicity have been published in recent years, there is not yet much information on adherence to updated guidance documents (Martinez, 2023a). Notably, guidelines developed by the ICMJE and JAMA in 2004 have largely not been met (Martinez, 2023a). An examination of reporting of race and ethnicity in three JAMA network journals before and after the development of the 2021 AMA Style Guide found improvement in the reporting of measures, coding, and style-based polices but did not explore the impact of the guidance on how race and ethnicity are defined in publications and the justifications for their use (Flanagin et al., 2023). It was also unclear in their analysis whether the noted improvements in reporting occurred prior to submission, during peer review, or during the editing process following acceptance of the manuscript (Flanagin et al., 2023). Thus, in order for the biomedical research community to benefit from these guidelines and publish studies that employ race and ethnicity categories in a thoughtful manner, there need to be mechanisms in place to enforce these guidelines and a formalized way of measuring their impact.

A second challenge is the lack of standardization across journals and disciplines concerning the reporting of race and ethnicity in biomedical research studies (Lu et al., 2022). The distinctions between race and ethnicity as descriptors along with recommendations on when to use each term have not yet been consistently agreed upon (Lu et al., 2022). A scoping review of publications that offer guidance on the use of population descriptors like race and ethnicity in genomics research found that many of the guidance documents had definitions of "race" that differed from one another along the social–biological axis and offered conflicting opinions on how strictly these descriptors should be defined (Mauro et al., 2022). The extent of this widespread disagreement demonstrates that a lack of standardized definitions for these terms results in considerable confusion on their use (Mauro et al., 2022). The biomedical research community could benefit from ensuring that reporting guidelines for race and ethnicity in publications are clearly defined and enforced in a systematic manner (see Chapter 6 for recommendations).

Another limitation of publishing guidelines focused on race and ethnicity is the potential to inadvertently obfuscate the impact of racism on health disparities (see Chapter 3, "Health Disparities and the Study of Racism"). One way that this can be observed is in how frequently terms like *race* and *ethnicity* appear in publications, but not terms like *structural* or *systemic racism*. A PubMed database search conducted in 2020 turned up a mere 86 articles that included both race as a term and structural or institutional racism (Boyd et al., 2020). Furthermore, research on health disparities often posits the role of "environmental" or "social" factors without explicitly mentioning how racism is the underlying mechanism by which these factors have biological consequences (Boyd et al., 2020). This framing devalues racism as a social and political force that has a resounding influence on health and health care. In addition, without careful consideration of racism as a relevant contributor to health outcomes, researchers run the risk of incorrectly attributing health disparities to innate biological or genetic characteristics, thereby stigmatizing and alienating populations that are already marginalized within the biomedical research enterprise.

This section makes clear that useful guidance on reporting race and ethnicity data exists; however, gaps in implementation remain. Moreover, the time of publication is late in the research process, and reporting guidelines often focus on using the "right" language or terms. Although those are important, many issues related to the conceptualization and use of race and ethnicity occur in earlier in a study.

CHAPTER SUMMARY AND CONCLUSIONS

The committee set out to use the research process cycle introduced in Chapter 3 as a framework for analyzing existing guidance on the use of race and ethnicity in biomedical research. It quickly became apparent that there is a host of best practice information on reporting standards. There have also been efforts to provide guidance to improve representation in clinical trials, promote community engagement, standardize EHR data collection, and reexamine the use of race and ethnicity in clinical tools. But guidance is lacking for other stages in the research process, notably for earlier steps such as conception, leaving open the possibility of misuse.

> *Conclusion 4-1: There are gaps in guidance on the use of race and ethnicity in research studies, especially early in the research process. Some helpful guidance for recruitment and data collection exists, yet improvements and accountability are needed. Existing publishing guidelines are useful, but the biomedical research community could benefit from further standardization for reporting race and ethnicity in publications and enforcement in a systematic manner. In addition, guidance is needed on study design, engagement and partnership with communities and other invested parties, use of legacy data, data analysis, and interpretation of results.*

Some existing recommendations attempt to provide direction for considering race and ethnicity earlier in study design, suggesting, for example, the need to provide clear rationale for the use of race and ethnicity. However, these guidelines tend to lack detailed standards illustrating the kind of rationale required, allowing researchers to justify their approach without strong scientific reasoning. Furthermore, these guidelines can be difficult to enforce at the time of publication because publishing and disseminating results are downstream of many key points of decision making in the research process. These earlier junctures in study design and execution can be pivotal intervention points for improving the use of race and ethnicity in biomedical research.

Also based on their analysis of the existing guidance and the gaps identified, the committee provides the following conclusions:

> *Conclusion 4-2: Conducting biomedical research with American Indian or Alaska Native Tribes is distinct from working with other populations. Enrolled Tribal members have both a racial identity and citizenship within one of the 574 federally recognized Tribes. As Tribes are sovereign nations, soliciting entrance to the community may require demonstrated understanding of their history as survivors of relocation, reservation, assimilation, and termination federal policy. Members may be guarded toward participating in research. It is critical to recognize requirements for working with Tribal nations, including distinct IRB processes, data sovereignty, and approval for dissemination of results.*

Conclusion 4-3: There is a critical gap in guidance regarding the use of race and ethnicity in all phases of the development of clinical algorithms and biomedical AI models, including in problem formulation, data selection, algorithm development, deployment, and monitoring. There are inadequate reporting, regulatory, and legal standards for the use of race and ethnicity in clinical prediction models and other clinical decision tools. Additional investment in creating repositories and specific standards for assessment across racial and ethnic groups as appropriate could help close these gaps and promote transparency in clinical algorithms and biomedical AI models.

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5

Reconceptualizing the Use of Race and Ethnicity in Biomedical Research

This chapter provides conceptual underpinnings for the committee's recommendations provided in Chapter 6. The status quo approach to using race and ethnicity in biomedical research has generally relied on the U.S. Office of Management and Budget (OMB) race and ethnicity categories. This chapter opens with a summary of some of the limitations of using the OMB categories in biomedical research studies. The following section brings together several concepts introduced in previous report chapters in a discussion of the committee's path forward. Importantly, there are alternatives to using the OMB categories throughout the development and execution of biomedical research studies, and one way to improve and reconceptualize the use of race and ethnicity is to think critically about which concepts and measures are most relevant to a given research context. The majority of the chapter introduces strategies for replacing the use of race and ethnicity with other more meaningful concepts and measurements of social and biologic factors that affect people's health.

CURRENT USE OF THE OMB RACE AND ETHNICITY CATEGORIES IN BIOMEDICAL RESEARCH

Biomedical researchers in the United States who incorporate race and ethnicity information frequently collect, analyze, and report those data based on classification schemes set out in the OMB Statistical Policy Directive No. 15 (OMB, 1997, 2024). The OMB categories are used across federal government agencies and, having become ubiquitous, are also used by many nongovernmental institutions, such as health care systems (see Chapter 2 for background on the origin and evolution of the OMB categories). Though the OMB has stated that these categories are not anthropologically or scientifically based designations, in practice they are sometimes used in those ways, which can perpetuate misconceptions about race and ethnicity.

Misconceptions about the Use of the OMB Categories in Research

In an effort to ensure that diverse groups of people are recruited for research, funders such as the National Institutes of Health (NIH) often require the use of the OMB categories for reporting recruitment statistics.[1] It is worth repeating that although Directive 15 specifies that the categories should not be considered as scientific, biological, or anthropological in nature, their use in research contributes to their conflation with biological meaning and importance. More generally, the way in which people encounter the OMB categories in research and medicine lends them a perceived but misplaced importance (Epstein, 2008).

Misconceptions about the OMB categories continue to permeate scientific research and affect health outcomes. Directive 15 notes, "The categories represent a social–political construct designed for collecting data on the race and ethnicity of broad population groups in this country, and are not anthropologically or scientifically based" (OMB, 1997). "The racial and ethnic categories set forth in the standards should not be interpreted as being primarily biological or genetic in reference" (OMB, 1997). The NIH policy on reporting race and ethnicity data for participants in clinical research repeats these disclaimers about its more detailed definitions (NIH, 2001). These key distinctions for the use of the OMB categories were also noted in the 2023 NASEM population descriptors report (NASEM, 2023).

Researchers have long been able to collect information on additional categories, but more granular data are often not collected or are "rolled up" into the standard minimum OMB categories for reporting purposes. Directive 15 has always indicated that additional data may be collected. In 1977, the OMB stated, "In no case should the provisions of this Directive be construed to limit the collection of data to the categories described above" (OMB, 1977). This was reiterated in with the 1997 revisions. "This classification provides a *minimum standard* for maintaining, collecting, and presenting data on race and ethnicity for all Federal reporting purposes" (emphasis added) (OMB, 1997). Even though the OMB categories are a minimum set of categories and some agencies encourage collecting more granular data, the previous lack of a requirement to collect more detailed information implied that the standard OMB categories were sufficient. The 2024 standards now require agencies to collect more granular subcategories, though it remains to be seen how this standard will be implemented in biomedical research and what its effects may be. Furthermore, in practice, granular data must collapse or "roll-up" to the standard OMB categories. The Department of Health and Human Services, for example, collects the categories Asian Indian, Chinese, Filipino, Japanese, Korean, Vietnamese, and Other Asian, all of which roll up to the Asian OMB standard category (OMH, 2024).

As introduced in Chapter 2, the OMB revised Directive 15 in 2024. Among updates to terminology and other revisions, the OMB added the category Middle Eastern or North African (MENA), defined as "[i]ndividuals with origins in any of the original peoples of the Middle East or North Africa, including, for example, Lebanese, Iranian,

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[1] For example, see NOT-OD-01-053 and related policies for including women and members of racial and ethnic minority groups as participants in research: https://grants.nih.gov/policy/inclusion/women-and-minorities.htm (accessed October 15, 2024).

Egyptian, Syrian, Iraqi, and Israeli" (OMB, 2024, p. 22191). As such, MENA is defined with a combination of geography and national origin, reflecting an overall trend in the policy to predominantly define categories based on national origin (see Box 2-3). National origin is only one aspect of racial and ethnic identity, as will be further explored in this chapter. The full effects of implementing this system of categories remain to be seen for biomedical research but will depend on how the policy is operationalized for health research by government agencies such as HHS and NIH. Federal agencies, including NIH, are required to submit an Action Plan on Race and Ethnicity Data to OMB by September 28, 2025; these action plans will be made publicly available (OMB, 2024).

There is a prevailing misconception that reporting recruitment statistics according to the OMB categories means that the corresponding scientific analysis must be done with the same categories. Although funding organizations may require the use of the OMB categories for reporting purposes, additional categories or variables may be used in study design and analysis (NASEM, 2023). In their 2023 report, the National Academies Committee on the Use of Race, Ethnicity, and Ancestry in Genomics Research cautioned

> *against the use of typological categories, such as the racial and ethnic categories established by the U.S. Office of Management and Budget in Statistical Directive 15, for most purposes in human genomics research. While the use of these categories may be required of researchers under certain circumstances (for example, in describing participants in studies receiving federal funding), the fundamentally sociopolitical origins of these categories make them a poor fit for capturing human biological diversity and as analytical tools in human genomics research. Furthermore, use of these categories reinforces misconceptions about differences caused by social inequities* (NASEM, 2023, p. 104).

The continued use of the OMB categories in research contexts carries the risk of perpetuating these misunderstandings.

MOVING TOWARD RACISM-CONSCIOUS RESEARCH

An overemphasis on the OMB categories in research has been at the expense of rigorous investigation of other concepts related to race. Because it is frequently used as a proxy for other factors of interest, race often serves to collapse a wealth of information about individuals, communities, and health. While acknowledging how past harms and flawed research have affected the past and current evidence base in biomedical research, the committee's path forward is grounded in a recognition of the multiple dimensions—social, biological, environmental, behavioral—that affect people and their health, including racism (see definitions in Box 2-2).

For much of the past, race-based approaches in science and medicine essentialized race, reinforcing the belief that there are innate, race-based biological differences between groups of people. Numerous historical examples of race-based medicine continue today and contribute to harms and inequitable care (Vyas et al., 2020; Yearby, 2020). Some of these are examined in Chapter 3. For example, current practices of race adjustment in pulmonary function testing are tied to the erroneous belief that Black people have weaker lungs than White people, which served as a justification for slavery

(Braun, 2014; Scanlon and Shriver, 2010). These race-based adjustments prevent Black people from receiving equal access to care.

Recognition of the harms of race-based medicine have led some to call for a "race-neutral" approach—that is, taking race out of clinical care entirely. Race neutral, also known as "colorblind", policies or approaches disregard the role of structural discrimination, fail to account for differential effects on people and groups, and can worsen health inequities (Delaney et al., 2021; Okah et al., 2022; see also Bliss, 2012; Brown et al., 2023; Hatch et al., 2016). In response to arguments for race neutral approaches, others have suggested that race should continue to be used to track the impacts of racism on members of racial and ethnic minority populations (Geronimus, 1992; Krieger, 1999; Kuehn, 2024). As discussed throughout Chapters 3 and 4, there is no simple solution, as removing race without evaluating potential consequences can result in ignoring important social factors that influence health or even exacerbate disparities (Tipton et al., 2023).

Race-conscious medicine is an attempt to address this complexity. Race-conscious medicine emerged from a recognition of the historical role of race in perpetuating racism in science and medicine (Cerdeña et al., 2020; Hernandez-Boussard et al., 2023; Wright et al., 2022). Cerdeña and coauthors frame race-conscious medicine around race as a social and power construct that can be used to measure racism, rather than race, as the exposure leading to poor health outcomes (Cerdeña et al., 2020). Even so, the term *race-conscious medicine* can be misconstrued by seeming to emphasize race as an individual attribute of a patient. For instance, in clinical care, race-conscious medicine can be understood to mean having an awareness of race in order to narrow down likely risks of disease. Awareness of a patient's race is a criterion or heuristic that physicians have long been trained to use to assess disease probabilities. However, the attendant risk of race-conscious medicine is that relying too much on race in the care of patients can be misguided, reinforce racialized stereotypes, and continue to reify race as a biological variable (Braun et al., 2007; Fashaw-Walters, 2023; Khazanchi et al., 2023; Moscou and Baker, 2018; Olufadeji et al., 2021). Recognizing the practical concerns in clinical care, race-conscious medicine may continue to have a limited role as better tools are developed to identify and interrogate disease risk more directly and accurately.

Race consciousness acknowledges that race can play a role in health, not due to inherent biological differences between racial groups, but rather due to social determinants of health. While this is an important distinction, it does not engage with underlying drivers of structural inequities. Therefore, an alternative to *race-consciousness* is needed. Since much of the existing evidence base for race-based approaches is tied to the discriminatory belief that members of minoritized racial and ethnic groups are inferior to White people, perpetuating racism, the committee suggests the phrase *racism-conscious medicine and research*. A racism-conscious approach means acknowledging discriminatory historical and modern practices that have led to flawed research and clinical standards, making it challenging or impossible to disentangle from the current evidence base (see Box 5-1). As introduced in Chapter 2, racism occurs at multiple levels—not only in interpersonal acts of discrimination or prejudice but also in macrolevel systems and social structures. Biomedical research needs to be conducted with an awareness of

BOX 5-1
Defining Race-Based, Race-Neutral, Race-Conscious, and Racism-Conscious Approaches to Biomedical Research

These various approaches differ in how they handle the concept of race, ranging from explicitly incorporating it, to ignoring it, to acknowledging it in a nuanced manner that addresses broader social and structural determinants of health.

Existing Approaches

Race-based biomedical research explicitly incorporates race as a factor and is rooted in a mistaken presumption of biological differences across racial or ethnic groups. This approach essentializes race, reinforces racial stereotypes, and fails to integrate the numerous social and environmental factors that contribute to health outcomes.

Race-neutral biomedical research omits race as a factor, emphasizing that race is a social construct with no biological basis. Although the intention may be to avoid potential biases or oversimplifications by eliminating race as a factor, this approach risks overlooking or underestimating how societal factors related to race, such as racism, affect health outcomes.

Race-conscious biomedical research acknowledges that race can affect health outcomes, not because of inherent biological differences, but due to social, economic, and cultural factors. This approach involves designing studies, policies, or interventions that consider these broader social determinants of health, without reducing research participants to their racial identities; however, the term risks reifying race and being misconstrued as race-based in practice.

Committee's Suggested Approach

Racism-conscious biomedical research emphasizes how various forms of racism have contributed to health disparities and the need to address structural drivers of inequity directly to achieve equitable health outcomes.

the broader social system and structural inequities. Because science is systematic, there is an assumption that it is also neutral and bias free. However, this belief has allowed the scientific community to ignore racially discriminatory practices entrenched within it and the ways in which science has reinforced racism within society, including via invalid ascriptions of race made over time in scientific research. A fundamental shift in thinking is necessary to grapple with the mechanisms and social forces that affect health—giving rise to the committee's approach of racism-conscious research.

Racism-consciousness provides the first step in preventing the continued misuse of race —namely, acknowledgement and understanding of how discriminatory societal practices have influenced biomedical research—and allows researchers the opportunity to begin to rectify the harm caused by these practices. Pulse oximetry, as discussed in Chapter 3, offers an illustrative example. Failing to attend to how medical devices operated across different skin tones resulted in inaccurate measurements for many patients with darker skin. A University of Michigan study demonstrated that Black patients had nearly three times the frequency of occult hypoxemia undetected by pulse oximetry as did White patients (Sjoding et al., 2020). This has spurred racism-conscious research to identify technologies to more accurately measure hypoxemia that are not affected by or can adjust to skin color. Upholding the principle of equity requires correcting structural unfairness in social systems and distribution of benefits and burdens (see Chapter 2, "Guiding Principles"). Research that redresses health inequity requires an awareness and understanding of the systems and structures that create and perpetuate inequity.

As the research community moves toward an ideal of greater shared decision making in science and medicine, it will be critical to bring racial and ethnic minority communities and participants harmed by these practices into research decision making (Fashaw-Walters, 2023). This will mean fully contextualizing an individual, moving beyond race-consciousness to context- and person-consciousness in order to begin rectifying the historical and modern-day harms to build toward a better future.

Realizing this vision for the future of biomedical research will require articulating and measuring the other concepts and factors for which race is often a proxy (Box 5-2). These factors can all play a role in health. The following sections detail some of these

BOX 5-2
Race, Ethnicity, and Related Concepts

Race and ethnicity categories are often used as proxies for the true concepts or variables of interest. In addition to self-identified race and ethnicity, related concepts include:

- Relational aspects of race
- Structural racism
- Social determinants of health (e.g., environment)
- Ethnic and cultural practices (e.g., language, religion)
- Immigration status and degree of acculturation
- Indigeneity
- Skin color and pigmentation
- Known ancestry
- Genetic markers; genetic variation
- Social and stress-related biomarkers
- Other biomarkers and biological indicators

concepts and provide tools for considering them in research contexts. Building from the committee's conceptualization of racism-conscious medicine, the next sections continue with structural racism and social determinants of health. The chapter proceeds with ethnicity and indigeneity, which are closely entwined with race. Next the chapter distinguishes skin color from race and discusses the multidimensionality of race. One dimension of race is ancestry, so the chapter continues with a discussion of ancestry and multiracial and multiethnic identity. The chapter concludes with a discussion of the relationship between race, ethnicity, and biomarkers.

STRUCTURAL RACISM

Researchers using race may be using the construct as a proxy for social exposures that affect health, such as structural racism. In 2010, the federal government recognized that structural discrimination is one of the root causes of health disparities (Yearby, 2020a). Structural discrimination—meaning macro-level conditions such as residential segregation—limits the conditions and well-being of less privileged groups (including racial and ethnic minority groups, women, LGBTQIA+ individuals, older people, people with disabilities, people who have low incomes), which keeps these groups from reaching their full health potential (Williams and Mohammed, 2009; Yearby, 2020a). Policies and law (that is, the political process, standards, regulations, and guidance) are tools used to perpetuate structural discrimination by structuring systems in a discriminatory way, which has been associated with health disparities (Dawes, 2020; NASEM, 2024; Yearby, 2020a, 2020b). Figure 5-1 highlights how structural discrimination, such as racism, is associated with health disparities.

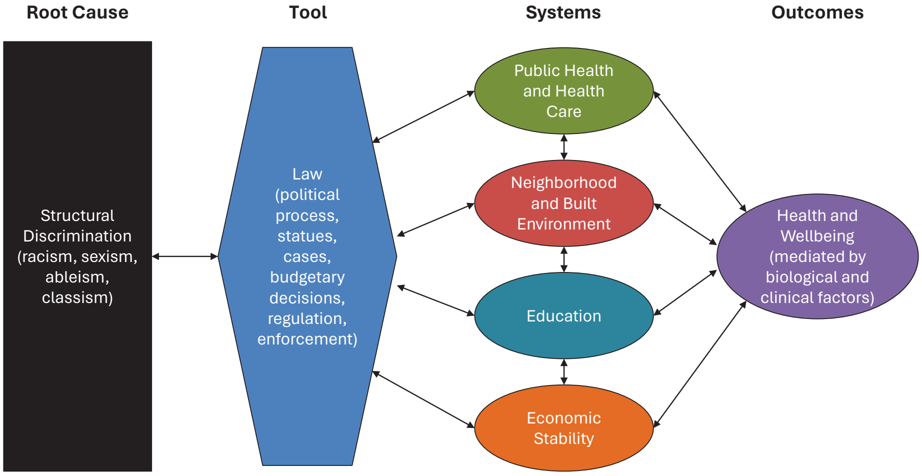

FIGURE 5-1 Social determinants of health framework.
SOURCE: Adapted with permission from Yearby (2020b). Structural racism and health disparities: Reconfiguring the social determinants of health framework to include the root cause. *Journal of Law, Medicine & Ethics* 48(3):518–526. © Cambridge University Press, reproduced with permission.

Structural racism is one form of structural discrimination. Structural racism has been defined as “the macrolevel systems, social forces, institutions, ideologies, and processes that interact with one another to generate and reinforce inequities among racial and ethnic groups. The term *structural racism* emphasizes the most influential socioecological levels at which racism may affect racial and ethnic health inequities. Structural mechanisms do not require the actions or intent of individuals” (Gee and Ford, 2011, p. 3). Structural racism also includes discrimination based on color and national origin.

In recent years, there has been an exponential increase in the term *structural racism* in health-related publications (Dean and Thorpe, 2022), partially due to growing interest in structural racism as a mechanism and driver of population health (Bailey et al., 2017). As much as structural racism can be challenging to define (Bailey et al., 2017; Dean and Thorpe, 2022), the concept has been difficult to measure, with the literature featuring a wide variety of approaches (Dean and Thorpe, 2022; Hardeman et al., 2022). With the variety of ways that structural racism can operate, there is no single optimal way to measure it (Jahn, 2022), but given the multidimensional and interactive qualities of structural racism, index measures consisting of multiple indicators may be best suited to capturing key nuances (Dean and Thorpe, 2022). Box 5-3 describes some possible strategies for measuring structural racism for epidemiological and biomedical research applications.

Given evidence for racism as a driver of health disparities (see Chapter 3), biomedical research could benefit from directly interrogating the role of structural

BOX 5-3
Possible Ways to Measure Structural Racism

- Index measures that aggregate multiple indicator variables (Adkins-Jackson et al., 2022; Jahn, 2022; Urban Institute, 2023)
- Latent construct approach or latent variable modeling (Adkins-Jackson et al., 2022; Brown and Homan, 2024; Jahn et al., 2023; Urban Institute, 2023)
- Psychometric evaluation to test measures for relevance over historical eras and life-course time (Adkins-Jackson et al., 2022; Szanton et al., 2022; Thorpe et al., 2019; Urban Institute, 2023)
- Consider
    - The level(s) at which racism is operating and how to be precise in measurement.
    - Developing measures with indicators that are specially targeted to how structural racism presents itself in specific contexts.
    - Developing structural racism measures for use at different levels of geography of exposure or unit of intervention.

See also Table 1 in Dean and Thorpe (2022).

racism. Structural factors include policies and practices from institutions, organizations, and systems and are distinct from interpersonal racism and implicit bias, which have typically garnered more attention (Carter et al., 2022; Gee and Ford, 2011; Weinreb, 2023). Increasing awareness of structural racism and how it works can lead to studying its effects in new ways in biomedical research. Pathways linking racism to health outcomes are complex and merit further investigation of how structural factors drive persistent health disparities. Not only is structural racism itself linked to poor health outcomes, but it also influences social factors, such as the social determinants of health, which are associated with individuals' health and well-being. As one example of this type of approach, Carlos et al. (2022) proposed social genomics as one potential pathway linking structural racism and discrimination and breast cancer outcomes.

SOCIAL DETERMINANTS OF HEALTH

Closely related to structural discrimination are social determinants of health. In 1906, W.E.B. DuBois noted that social conditions, not biology, affected the health of Black Americans, causing racial inequities in mortality rates (DuBois, 2003; see also White, 2011). Almost 100 years later, the Institute of Medicine issued the landmark report *Unequal Treatment: Confronting Racial and Ethnic Disparities in Healthcare* which highlighted the impact of racial discrimination on social conditions, such as mortgage lending, access to housing, employment, and criminal justice, which were associated with racial health disparities (IOM, 2003; NASEM, 2024; Yearby, 2020b). This report along with a 2008 report from the World Health Organization were instrumental for the development of the social determinants of health framework in the United States (WHO, 2008; Yearby, 2020b). In 2024, the National Academies revisited *Unequal Treatment* by publishing a new report, *Ending Unequal Treatment: Strategies to Achieve Equitable Health Care and Optimal Health for All*. The new report found that while some progress has been made between 2003 and 2024 to raise awareness, conduct research, and form policies to address inequities, health care inequities had only slightly narrowed, a trend that has been inconsistent (NASEM, 2024).

The social determinants of health (SDOHs) are part of the U.S. HHS Healthy People 2030 Initiative to improve the health and well-being of individuals in the United Sates (HHS, 2021). The SDOHs includes five key social factors: economic stability, education, social and community context, health and health care, and neighborhood and built environment (HHS & OASH, 2024). The SDOHs were added to the Healthy People Initiative as a means to identify and eliminate the causes of health disparities (HHS & OASH, 2024).

In 2011, Paula Braveman et al. argued that health disparities "are a specific subset of health differences of particular relevance to social justice because they may arise from intentional or unintentional discrimination or marginalization and, in any case, are likely to reinforce social disadvantage and vulnerability" (Braveman et al., 2011, p. S150). The 2030 Healthy People Initiative seemingly adopted this approach, when it noted that the SDOHs were central to achieving health equity, in which "everyone has the opportunity to attain full health potential and no one is disadvantaged from achieving this potential because of social position or any other socially defined circumstance" (CDC, 2024; see also Braveman, 2023; HHS and OASH, 2024). The Healthy People Initiative sets national goals, while the SDOHs provide measurable objectives that the federal and state governments use in their work with communities to achieve health equity (HHS & OASH, 2024).

Identifying social and community context as a component of the SDOH indicates that discrimination—such as institutional, interpersonal, and intrapersonal racism—causes challenges and harm to individuals that negatively affect their health. For example, American Indians and Alaska Natives experience profound disparities in social determinants of health, with the highest poverty rates of all racial and ethnic groups in the United States (26.2 percent in 2016) and high rates of homelessness (Solomon et al., 2022). Data also show that 21 percent of Black individuals work in jobs with high risk for injury or illness compared with only 13 percent of White people (Yearby, 2020b). In biomedical research, the SDOH framework could be useful for identifying social factors relevant to a given line of inquiry. Compared with how race has often been collected as a single variable in research, SDOHs are multiplex, and studying them can be challenging because scientists will need to consider a variety of potentially relevant factors. More exploration is needed to further develop the evidence base for biomedical researchers to rely on in this domain.

ETHNICITY

The social determinants of health that correlate with health disparities affect populations in the United States based to a great degree on their perceived race, ethnicity, and indigeneity. There has been far more research on the connections between race, SDOH, and health disparities than there has been with groups identified ethnically (Ford and Harawa, 2010).

In the United States, the concepts of race and ethnicity are difficult to disentangle. They are often treated as synonyms, as is evidenced by the increasing use of the term *ethnicity* to replace the term *race* in Medline-indexed studies (Afshari and Bhopal, 2010) and by the tendency of some Hispanic or Latinx people to use these terms to describe their race (Noe-Bustamante, 2021). By combining the race and ethnicity questions into one, recent changes to the OMB Directive 15 standards now enable respondents to choose solely Hispanic/Latino, without requiring selection of a separate race category. Despite the emphasis on Hispanic/Latino ethnicity in the United States system, there are other ethnic populations in the United States (e.g., Hmong, Armenian). Of course, one limitation is that data about other ethnic groups and communities in the U.S. have not been as consistently or systematically collected.

For purposes of this report, the committee has defined ethnicity as a socially and politically constructed term used to describe people from a similar national or regional background who share common national, cultural, historical, and social experiences. An ethnic group is often defined based on shared values, behaviors, heritage, and language. Ethnicity also varies across historical, political, and geographic contexts. Ford and

Harawa (2010) define ethnicity as "a context-specific, multilevel (i.e., group-level, individual-level), multifactorial social construct that is tied to race and used both to distinguish diverse populations and to establish personal or group identity." It is apparent in both definitions that ethnicity encompasses multiple factors that vary over time and place. Its use in the United States often involves the social or political grouping of individuals, either self-identified or assigned by society, based on shared culture, language, religion, ancestry, and diet.

Based on these definitions, it is evident that using ethnicity in biomedical research is challenging. Compounding the challenge, a person's ethnic identity evolves over the life course. A person's ethnic identity also varies depending on the context. For example, Ford and Hawara noted (2002), "One may identify as Hispanic at work, Latino within his civic organizations, Mexican at home, and American when visiting Mexico" (p. 6; see also Harris and Sim, 2002). The fluidity and nuance of someone's ethnicity belies the OMB's long-running binary classification system consisting of Hispanic/Latino or Not Hispanic/Latino.[2] Self-identification among ethnic groups, moreover, may exhibit generational changes over time. Remarks shared with the committee illustrate this evolution of identity and how this information can be collected for research: "Because myself, as Dominican, . . . I've learned about the generational differences between my mom, calls herself Hispana, because that's what she was when she first came to the United States as she checked off a box. Then I learned to say I'm Latina, I'm not really Hispanic. And then my kids are Latinx, but you would not know that unless you first asked open- ended questions" (Danurys "Didi" Sanchez in remarks to the committee on March 14, 2024).

One of the main reasons for incorporating ethnic identification in biomedical research is the substantial public health, policy, and population health research indicating that certain ethnic groups in the United States exhibit disparate health outcomes. These disparities stem from various factors, including discrimination in health care, unequal access to resources, and the stress-related impacts of discrimination. These stressors often arise from unequal access to the protective social determinants of health in the United States For example, data show that 33 percent of Hispanic children in the United States reside in households below the poverty line (Wight et al., 2011). Moreover, if a child's parent is an immigrant, the likelihood of living in poverty is even higher, with 27 percent of children living in poverty among immigrant parents compared with 19 percent when their parents were not immigrants to the United States (Wight et al., 2011). In addition, ethnicity can be linked to behavioral markers (e.g., diet, tobacco use, physical activity) that influence health in minority populations (Halbert and Allen, 2021).

Previous research, however, has seldom delved into the dimensional (e.g., sociocultural) or relational social constructs that underlie ethnic disparities. There is an

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[2] As of 2024, OMB has broadened what can be considered an ethnicity by enabling people to choose their race(s), ethnicity(ies), or both, and to provide greater specificity about the sub- categories that reflect their identity. Note that virtually all of the sub-categories refer to nations or country of origin.

emergence, though, of attempts to address this gap (Nandi and Platt, 2009; Umaña-Taylor and Shin, 2007). Some measurable elements that can aid in identifying constructs that might contribute to health disparities in biomedical sciences include ethnic self-identification, surname (due to discrimination based on one's name), religion, and language (Ford and Harawa, 2010).

Ethnicity is also intertwined with immigration, citizenship, and nationality. Attributes such as immigration status can warrant distinct measurement (Asad and Clair, 2018; Van Natta et al., 2018). Accounting for individual-level experiences of acculturation should be balanced by recognition of the importance of historical traumas and political policies (Samari et al., 2021; Viruell-Fuentes et al., 2012). Measuring the impacts of political policies is crucial because immigrant status alone may not capture the effects of discriminatory policies on non-immigrant groups. For example, when immigration or security-related policies or laws are enacted that affect an ethnicized group, it can affect their sense of belonging as a group, social support, experiences of discrimination, and familial connections (Johnson et al., 2024; Perreira and Pedroza, 2019). This impact extends to naturalized citizens as well as individuals born in the United States, including limitations on travel to and from the United States for both the affected groups and their family members residing outside the country.

INDIGENEITY

Another concept related to, yet distinct from, race is indigeneity, which emphasizes a connection to geographic location over time. There were tens of thousands of people indigenous to northern North America before European colonization. Many nations and their descendants are found in what is now known as the United States. This unique history is unlike that of any other racial or ethnic group in the United States. Only the Indigenous people of northern North America have lineages of families who lived for millennia on these specific lands, shaping cultural, medicinal, physical, spiritual, governmental, and societal structures. Only these Indigenous people have a history of sovereignty before contact with Europeans and, due to that sovereignty, had treaties drawn between sovereigns in Europe and including the U.S. Congress until 1871. And only Indigenous nations have retained that inherent sovereignty. Inherent sovereignty is the most basic principle of federal Indian law. It means that "the powers lawfully vested in an Indian Tribe are those powers that predate New World discovery and have never been extinguished" (Green and Work, 1976, p. 311).

This concept is critical because "it confirms the extra-constitutional status of [I]ndigenous nations as the original sovereigns of the Americas and does not treat [T]ribal nations as merely one of several ethnic groups" (Wilkins, 2006, p. 908). These 574 Nations[3] have a federal government-to-government relationship stemming from Chief Justice Marshall's Indian Law Trilogy of the early 1800s (Fletcher, 2024). This so-called federal trust responsibility (Department of the Interior, 2014) "is a well-established legal obligation that originates from the unique, historical

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[3] https://www.bia.gov/service/tribal-leaders-directory (accessed August 20, 2024).

relationship between the United States and Indian Tribes. The Constitution recognized Indian Tribes as entities distinct from states and foreign nations." Therefore, only an enrolled AIAN individual can access Indian Health Service care or Bureau of Indian Affairs/Bureau of Indian Education services.[4] One must prove one's enrolled status. No other ethnic or racial group has such a relationship. As such, there are many laws pertaining only to AIANs or their lands. It is important to note that there are many more individuals who may have heritage or lineage in one of these Tribes but are not enrolled members. As such, they are not AIANs by the legal definition. It is the Tribes themselves who determine who is or can become a member. Congress determines who is a Tribe. The legal status of federally recognized Tribes leads to unique considerations for conducting biomedical research with AIAN Tribes (see Chapter 4 for more information on documented best practices).

AIAN ancestry is also measured by a concept known as blood quantum, which was integrated into federal law in 1887, for the purpose of dividing communal Indian lands into parcels and thereby pushing the concept of private land ownership onto Indians. Blood quantum cannot be measured directly but is typically inferred based on family lineage and has been used for sociopolitical purposes, underscoring the social construction of race in the U.S. (Rodriguez-Lonebear, 2021). As discussed in Chapter 2, race and ethnicity are social constructs, without a basis in biology. Despite its colonial and racist roots, blood quantum is used by many Indian Tribes to determine individual Tribal membership (Rodriguez-Lonebear, 2021), and the Bureau of Indian Affairs still requires that each American Indian or Alaska Native submit paperwork proving that they are entitled to a Certificate of Degree of Indian or Alaska Native Blood, known as a CDIB. Some Tribes rely on provable lineage such as having an ancestor who appears on the Dawes rolls and can be directly traced back (National Archives and Records Administration, 2016).

These formal processes for determining AIAN ancestry and legal status can be at odds with other forms of measurement such as racial or ethnic self-identification (Garroutte, 2003). Self-identification can be fraught, given the distinct legal status of federally recognized Tribes. Indeed, once the U.S. Census switched to enumeration using self-identification after 1960, the size of the American Indian population began to grow rapidly. Some welcomed the growth as a revival (Nagel, 1995), while others noted that the new identifiers seemed to be better off in terms of socioeconomic status, which could hide long-standing disparities between American Indians and other Americans (Snipp, 1986). Indigenous self-identification is also among the most fluid racial or ethnic identities, not only in the United States but around the world (Liebler et al., 2016; Shalley et al., 2023), with people who live in urban areas and have mixed ancestry being particularly likely to identify differently at different points in time; however, identity fluidity both within and across generations is much lower for people who live on or near Tribal lands, highlighting the importance of accounting for place in understanding differing outcomes and experiences within the AIAN population (Liebler, 2010).

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[4] See https://www.bia.gov/service/tribal-leaders-directory and https://www.ihs.gov/forpatients/faq/ (both accessed August 20, 2024).

Adding to the complexity around self-identification as AIAN is that the OMB definition differs from the legal definition of American Indian. The OMB has taken a more expansive approach since 1997 (OMB, 1997; Snipp, 2003). The 2024 revision defines the American Indian or Alaska Native (AIAN) category to "[include] all individuals who identify with any of the original peoples of North, Central, and South America" (OMB, 2024, p. 22187). This definition describes people who are Indigenous to the Americas and who have a shared experience of colonization. However, the legal definition of American Indian refers to membership with a Tribe as defined by Congress. The fact that these two definitions use the same term "American Indian" can lead to contradictions or misinterpretation in research. As an example, the OMB would include Aztec and Maya under AIAN. However, these populations are not domestic dependent nations[5] within the boundaries of what is now known as the United States, so they do not meet the legal definition of American Indian. It is important to be cognizant of these different definitions in research contexts to ensure clear, accurate interpretations of research findings.

There is also a well-known bias in many health and vital statistics calculations for American Indians and Alaska Natives in the United States because they typically combine self-identification data from the census (in the denominator) and data from death certificates or cancer registries (in the numerator), which often rely on racial classification by others. Self-identified American Indian and Alaska Natives report being regularly misidentified in everyday interactions (Davis-Delano et al., 2021) and are frequently recorded as White in these data systems, which means their mortality rates and other health disparities estimates are misleading (Gartner et al., 2023; Jim et al., 2014; Rhoades, 2005). This underscores the importance of both understanding data provenance and ensuring consistency in data collection methods for race and ethnicity whenever possible. More generally, as Kimberely Huyser and Sofia Locklear argue, "because there are multiple modes of affiliation to Tribal communities, a multiple-lens approach is useful to understand the full scope of the lives and life chances of AIAN peoples" (Huyser and Locklear, 2023, p. 250; see also Liebler, 2018).

SKIN COLOR AND PIGMENTATION

Skin color is often seen as synonymous with race or, at minimum, treated as the key criterion influencing categorical racial attribution. Recent research across the social and biomedical sciences complicates this view, however, conceptualizing skin color as one among many measures or dimensions that are related to perceptions of race and racism. In particular, there is a growing multidisciplinary literature on *colorism* that examines skin color variation to better understand both within- and between-group inequality across a range of socioeconomic and health outcomes (Branigan and Hall, 2023; Dixon and Telles, 2017; Laidley et al., 2019; Monk Jr., 2021; Stewart et al., 2020; Sweet et al., 2007). Collectively, this research indicates that skin color can be used either alongside other dimensions of race to identify more complex patterns of inequity or on its own

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[5] https://www.justice.gov/otj/about-native-americans (accessed August 20, 2024).

to capture a broader range of variation in human skin color, tone, reflectance, or some combination of the three.

Longstanding debates about the historical origins of race and racism, including its particular manifestation in the United States (Frost, 1990), hinge in part on how researchers interpret color distinctions made all the way back to antiquity (Jablonski, 2012), and whether (or when) they should be understood as expressions of prejudice (e.g., Derbew, 2022; Snowden, 1983). Is race just a rough categorical representation of continuous human variation in skin color, one that indexes privileging of lighter skin over darker skin, or should racial and color prejudices be seen as related but analytically distinct mechanisms for maintaining hierarchical relations? Some aspects of skin color are influenced by genetics and are thus inherited, but the same skin color phenotype (e.g., light skin) can be traced back to multiple lines of evolution in different populations, which may have different genetic bases for the trait; there is not a simple one-to-one relationship between skin color and genetic architecture (Jablonski, 2021; Norton et al., 2006). Skin tones are also shaped by environment, including proximity to the equator, as well as differing cultural valuations that may privilege lightness, darkness, or tanned skin (Dixon and Telles, 2017; Jablonski, 2004; Jablonski and Chaplin, 2000, 2010). The latter are often linked to variation in socioeconomic status between people who work indoors versus outdoors and between those who can or cannot afford skin care products that either change or maintain their skin tone (Glenn, 2008; Hunter, 2007). Research in social psychology also identifies contextual variation in how people weigh skin color, with differences in the magnitude of implicit skin color biases around the world (J. M. Chen and Francis-Tan, 2022) and people in some countries relying more on skin color to make categorical racial attributions than in others (J. M. Chen et al., 2018). The range of skin color variation observed within self-identified racial categories also differs by country, with some countries exhibiting more expansive notions of whiteness, blackness or 'mixedness' than others (McNamee, 2020). Thus, despite noted historical connections between skin color and racial ideology (Jablonski, 2021), treating skin color as the straightforward physical or biological component that underpins both racial classification and contemporary animus is unsupported by existing research across disciplines.

Theoretical and conceptual debates about the connections between skin color and categorical race aside, accurately representing human skin color is relevant to a range of biomedical research. This is perhaps most evident in dermatology, but with expanded importance across specialties given the proliferation of wearable medical devices. The Fitzpatrick skin typing system is the most common approach to assess and categorize skin color. The system was originally developed to measure photosensitivity and is still used in dermatology (Ware et al., 2020), partially because it is convenient and requires no special equipment. However, the Fitzpatrick scale has long had its critics. Even with the addition of two categories to account for darker skin in 1988 (Fitzpatrick, 1988), the scale is relatively insensitive to variation in darker skin tone and can result in underestimating dermatological conditions or misdiagnosis in people with more highly pigmented skin (Fenton et al., 2020). Furthermore, the Fitzpatrick scale and its common use in clinical practice can contribute to conflating race and ethnicity with skin pigmentation (Ware et al., 2020). The von Luschan skin color chart has similar limitations as well as a troubling history, as it was used in unethical research in Nazi Germany.[6] Even so, it is still in use today.

Given these problems, there have been attempts to develop more inclusive scales, such as the Monk skin tone scale (Monk, 2023). Others advocate more quantitative methods (Verkruysse et al., 2024), such as the Melanin index or CIELab system more commonly used in industry, which do not map to racial and ethnic categories. These methods are more objective and sensitive to variation; however, they are less convenient than color scales and do require more specialized equipment. Moreover, different methods can diverge in their measurement of the same skin tone. In research where skin pigmentation is relevant, such as pulse oximetry and optical sensors, methods attempting to precisely measure skin tone and pigmentation are more suitable than using social labels, such as race or ethnicity, as a proxy. Measurements should also align with the mechanism used by the device—for instance, measurements of reflectance (how light bounces off the skin) or transmittance (how light shines through the skin and tissues).

Considerable effort has also gone into testing and developing skin color measures for use in social surveys to understand complex patterns of inequality. These measures have evolved from simple nominal scales (“light,” “medium,” “dark”), initially used to understand colorism among Black Americans (Keith and Herring, 1991), to incorporating a broader range of variation that can be used to understand the role of skin color in both within- and between- group inequality. In the early 2000s, the Massey–Martin scale introduced a color card that interviewers would use to help standardize their observations of respondents’ skin color for face-to-face surveys. This 10-point scale, represented by a series of hands ranging in color from a very light white to very dark black, was initially developed for the New Immigrant Survey (Massey and Martin, 2003) and has since been adopted by the General Social Survey and the 1997 National Longitudinal Survey of Youth, among other data sources. These data have yielded important evidence regarding the nature and extent of colorism in the contemporary United States (Adames, 2023; Bailey et al., 2014; Han, 2020; Katz et al., 2020). The Massey–Martin scale has been critiqued, however, both for its lack of inclusivity (e.g., representing shades between white and black rather than variation in color, per se) and inability to fully eliminate interviewer variation (Abrajano et al., 2023; Cernat et al., 2019; Hannon and Defina, 2020). As a result, some researchers incorporate technical measures obtained through either a handheld colorimeter or spectrophotometer (Gordon et al., 2022; Ostfeld and Yadon, 2022). Others have developed more inclusive color palettes, such as the Monk Scale developed in collaboration with and currently being used by Google (Monk, 2023); see also the PERLA and PRODER palettes developed for use in Latin America (Solís et al., 2023; Telles, 2014).

As with other measures or dimensions of race, there is no one correct way to measure skin color that spans research questions or applications. Recent research highlights the challenges of skin color measurement while pointing to the strengths and weaknesses of different approaches (Campbell et al., 2020; Dixon and Telles, 2017; Gordon et al.,

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[6] https://collections.ushmm.org/search/catalog/irn564926 (accessed October 15, 2024).

2022; Heldreth et al., 2024; Khan et al., 2023; Piña et al., 2023). For example, measures obtained using devices likely will be most useful for technical applications—from wearable medical devices to self-driving cars—where variations in color and skin reflectance that are not visible to the naked eye are still relevant to achieving equity and reproducibility of rigorous scientific results. Measures of skin color as recorded by an interviewer or other observer could be most relevant for understanding explicit discrimination, while measures of skin color reported by the individual in question can represent that individual's own perceived social position (Gravlee and Dressler, 2005; Monk Jr, 2015). Researchers also must carefully consider the relationship between skin color and socioeconomic status and whether they aim to assess their combined effects or establish their separate contributions to a particular outcome (Abascal and Garcia, 2022; Solís et al., 2023). Although best practices for measurement in this area are still in development, it is indisputable that skin color has an important role to play in biomedical research. Incorporating skin color measures can make technical applications more precise as well as highlight the limits of categorical approaches to understanding human variation.

RELATIONAL ASPECTS OF RACE

In addition to codifying the categories of race and ethnicity that are recommended for federal data collection, OMB Statistical Directive 15 also represented a shift from relying on racial classification by others to a focus on self-identification (Snipp, 2003). Thus, another legacy of Directive 15 has been the perception that self-identification, using the OMB categories, is the "gold standard" measure of race and ethnicity (Jarrín et al., 2020; Wallman et al., 2000). This assumption has led some researchers to focus on the level and consequences of "misclassification"—that is, when a measure of self-identification is not concordant with another way of gathering racial or ethnic data (Hahn et al., 1992; Kressin et al., 2003). However, a growing body of research in the social sciences emphasizes the multidimensionality of race and ways of examining both how the multiple measures (or dimensions) differ and how they can interact.

Scholars have demonstrated the benefit of thinking about race multidimensionally and have outlined a typology for disaggregating an individual's "race" into separate components, from their known ancestry to their skin tone to how they are perceived by others (Roth, 2016). Making these distinctions is, in part, about conceptual precision: being clear about which aspect of a person's racialized experience is being considered and why. Importantly, a multidimensional approach also recognizes that how people describe themselves using standard racial or ethnic categories may not be the most relevant measure across all contexts and research studies. Two measures that aim to capture the relational or interaction-based aspects of race and racialization are *perceived race* and *reflected race*. Using measures such as these helps direct research attention away from treating race as a static characteristic of an individual, or what someone *is*, to treating race as a dynamic aspect of social interactions and a consequence of *racism*, which makes how people are perceived and treated by others especially salient.

Perceived race is measured by how someone else would describe the person of interest and, until Directive 15, was typically the default way of assigning research participants to racial categories. In the U.S. Census, race was recorded by an enumerator up until 1960, when the Census Bureau began mailing forms to Americans for self-completion. Many large national surveys still relied on the interviewer's assessment of the respondent's race as recently as the 2000s (Saperstein, 2006). Some have argued that *perceived race* is a more relevant measure than self-identification if the aim is to capture the effects of racial discrimination (e.g., Telles and Lim, 1998). Others have noted the irony of the U.S. Census switching from perceived race to self-identification around the same time (following the Civil Rights Movement) that it began using federal racial data for anti-discrimination efforts (Morning and Sabbagh, 2005; Snipp, 2003). Recent research does show that studies using perceived race versus self-identification can come to different conclusions about the nature and extent of racial inequality (Saperstein, 2006, 2012). Studies that consider the intersection of perceived race and self-identification also find that racial disparities in outcomes such as arrests and home ownership—for which police officers and lenders, respectively, are key gatekeepers—are better attributed to perceived race than self-identification (Penner and Saperstein, 2015; Saperstein et al., 2016). For example, among U.S. young adults who had never been arrested, those who were perceived as Black by the survey interviewer but did not self-identify as Black were three times more likely to subsequently be arrested than those who self-identified as Black but were not perceived as Black (Penner and Saperstein, 2015). These findings underscore the importance of not only disaggregating measures of race but using them in tandem to help isolate potential mechanisms perpetuating racial inequality. In a similar way, using multiple measures of race could augment precision in investigating mechanisms that perpetuate and exacerbate health disparities. Measures of *perceived race* are available in several large national surveys that conducted face-to-face interviews, including the 1979 National Longitudinal Survey of Youth, the 1997 National Longitudinal Survey of Youth, the 1996 and 2000 waves of the General Social Survey, and the National Longitudinal Study of Adolescent to Adult Health.

Reflected race is a more recently proposed measure that aims to understand how a person thinks they are racially categorized by others. The term comes from the social psychological concept of *reflected appraisals* or how people feel they are seen by others more generally (Felson, 1985; Gallagher et al., 2022). It can be treated as a proxy for *perceived race* in studies, such as online surveys, where obtaining an interviewer or other external classification is not practical. *Reflected race* is also a unique measure that can differ from both the actual perceptions of others and how the person self-identifies, with important implications for mental health as well as the likelihood of perceiving racial discrimination (Sosina and Saperstein, 2022; Stepanikova and Oates, 2016). An early measure of reflected race, dubbed "socially assigned race" (Jones et al., 2008), was collected as part of an optional Reactions to Race module for Behavioral Risk Factor Surveillance (BRFSS). Recognizing that people may be perceived differently in different contexts, more recent studies rely on more focused measures that specify how someone would be categorized by "a stranger passing by on the street."[7] Some research highlights that experiencing "racial identity contestation" (Vargas and Kingsbury, 2016),

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[7] Also called *street race*, see Lopez et al., 2018.

or feeling like your identity is not validated by others, can have negative effects on mental health (Albuja et al., 2019). Overall, the growing body of work on *reflected race* shows that how people think they are perceived racially is associated with a host of outcomes, including mental and physical health, with people who think they are seen as White reporting better outcomes (Abuelezam et al., 2022; Stepanikova, 2010). In addition to the BRFSS measure, reflected race questions have previously appeared in the Pew Survey of Multiracial Adults, the New York Longitudinal Survey of Wellbeing, and the Portrait of American Life Study, among other surveys.

GENETIC MARKERS AND ANCESTRY

The relationship between genetics and race or ethnicity is used to different ends depending on the research question of interest and the data at hand. Despite repeated calls for their disambiguation, this conflation of distinct constructs persists in biomedical research. The social constructs of race and ethnicity continue to be used incorrectly as proxies for genetic ancestry, which in turn is sometimes used as a surrogate for specific genetic markers that are thought to be more common in particular groups than in others. Fortunately, this practice is declining in more recent research given increasing awareness of the weak relationship between social constructs and biological markers, although it persists in published literature (Swilley-Martinez et al., 2023). In genetics research, the use of "race" to both describe and define groups has declined with the simultaneous increase of "ancestry" and "ethnicity," indicating a movement towards precision in describing the salient aspects of group differences (Byeon et al., 2021).

To avoid the inappropriate use of race and ethnicity as proxies of genetic variation, several concepts must be disambiguated. First is the concept of *genetic ancestry*, which is defined as "the paths through an individual's family tree by which they have inherited DNA from specific ancestors" (NASEM, 2023, p. 4; see also Mathieson and Scally, 2020). This concept refers to a longitudinal view of shared genetics through a family tree. Genetic ancestry is distinguished from *genealogical ancestry* by the inheritance of DNA along a specific lineage. Individuals can have genealogical ancestors in their family tree from whom they have not inherited any DNA due to a biological process known as recombination down the generations. In practice, most genetics research does not directly measure multiple generations on a family tree and therefore cannot directly measure genetic ancestry. Instead, *genetic similarity* is quantified by estimating "the genetic resemblance between individuals that reflects the extent of shared genetic ancestry" (NASEM, 2023, p. 4; see also Coop, 2022). In practice, these estimates are then used to cluster individuals into "genetic ancestry groups," which are assumed to model a level of homogeneity which meets statistical assumptions with respect to allele frequencies and linkage disequilibrium, or correlation, patterns between variants. Genetic ancestry groups are then used as analytical units in stratified analyses that are meant to seek to control for these differences in genetic architecture as well as unmeasured potential environmental (non-genetic) confounders. Readers interested in a deeper exploration of genetic ancestry and genetic similarity should refer to NASEM (2023).

The standard practice of using “genetic ancestry groups,” which often are delineated at a continental-level (e.g., “European,” “Asian,” and “African”), problematically conflates the concepts of genetic ancestry and race (Byeon et al., 2021; Cerdeña et al., 2022a; Lewis et al., 2023), which propagates the use of these concepts in race-based medicine (Bentz et al., 2024; Cerdeña et al., 2022b). Additionally, this practice has been misappropriated by extremists as proof of biological races to further their supremacist agenda (Carlson et al., 2022). These beliefs have been reinforced through the messaging of direct-to-consumer (DTC) genetic ancestry testing, such as the companies 23andMe and AncestryDNA, which reify race as a biological reality (Phelan et al., 2014). These tests do not directly estimate “genetic ancestry” as defined above, but rather what proportion of the customer’s genome is similar to the company’s reference data (Royal et al., 2010). It is important to dispel these beliefs, as is recommended in a recent NASEM report which said, “When grouping people in studies of human genetic variation, researchers should avoid typological thinking” (NASEM, 2023, p. 103). This recommendation applies to biomedical research broadly.

There are several scenarios in which the use of racial or ethnic identity as a proxy for genetic similarity fails to capture either genetic or environmental factors. The first example of this is the group “Asian,” which typically denotes individuals with ancestry from the continent of Asia, comprising East Asia, Southeast Asia, and South Asia (Lee and Ramakrishnan, 2020), although the predominant group to which it refers depends on socio-cultural context with respect to historical immigration patterns (Aspinall, 2003). This is reflected in genetic data of large-scale studies, such as the UK Biobank (UKB)[8] and NIH’s All of Us Research Program[9] (AoURP). In the UKB, individuals coded as “Asian or Asian British” corresponded to countries of origin in South Asia (India, Pakistan, Bangladesh) while “Chinese” is a category outside of the Asian/Asian British category. In contrast, the analogous category of “Asian” in the AoURP consisted of mostly East Asian individuals, although combined with substantial numbers of South Asian participants as well. The genetic backgrounds from these individuals, even at a subcontinental-level (such as China versus Japan within East Asia) have been found to demonstrate substantial population substructures (GenomeAsia100K Consortium, 2019; IGSR, 2024; Tian et al., 2008) which are not appropriate to combine if statistical methods require relative homogeneity or for the estimation of population-specific allele frequency for clinical genetics (Chan et al., 2022). For example, researchers estimated the genetic risk for familial hypercholesterolemia (FH) across autosomal dominant genetic variants among patients in Singapore and found that Chinese participants had significantly higher genetic risk (1.05 percent) compared with Indian (0.15 percent) and Malay (0.25 percent) participants, driven primarily by a higher prevalence of *LDLR* carriers among Chinese participants (0.76 percent) (Chan et al., 2022). Therefore, researchers using the broad racial category of “Asian” as a proxy for genetic similarity may fail to account for complex substructure with misleading or erroneous results or may obfuscate the genetic architecture of interest. Concurrently, “Asian” as a grouping

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[8] https://biobank.ctsu.ox.ac.uk/crystal/field.cgi?id=21000 (accessed October 15, 2024).

[9] https://www.nature.com/articles/s41586-023-06957-x (accessed October 15, 2024).

to control for environmental factors is also not appropriate, given the extensive heterogeneity between populations (Budiman and Ruiz, 2021), such as rising income disparities (Kochhar and Cilluffo, 2018).

These dynamics are compounded in recently admixed populations, particularly within the ethnic categorization of “Hispanic and/or Latino.” Across the Americas, these groups have recent ancestry in multiple continental and subcontinental regions, primarily Africa, Europe, and the Americas (Bryc et al., 2010; Conomos et al., 2016; Homburger et al., 2015; Moreno-Estrada et al., 2013, 2014). Numerous studies of their genetics have demonstrated the varied composition of populations both between and within current national borders. For example, work conducted in a single study, the Hispanic Community Health Study (HCHS)/Study of Latinos (SoL), estimated participants’ admixture proportions, or proportion of their genome that was estimated to be similar to inferred genetic ancestries (Conomos et al., 2016). They found substantial heterogeneity between groups, such as higher levels of what they estimated to be African ancestry in Dominican and Puerto Rican participants and higher Amerindigenous ancestry in Central American participants. It is important to note that these studies of genetic ancestries are further complicated by complex immigration patterns that vary by time and geography. Within HCHS/SoL, Cuban participants were estimated to have over 80 percent European ancestry. However, this is reflective of both who immigrated to the United States and selection bias for which households would have participated in this study, as demonstrated by comparing these participants to genetic studies done within Cuba, which estimates the average European ancestry proportion to be 71 percent (Fortes-Lima et al., 2018). This demonstrates that the use of Hispanic and/or Latino as a salient genetic category is inappropriate and ineffectual to capture assumed levels of similarity that would be considered appropriate for genetic studies. In addition, the incorporation of environmental (e.g., non-genetic) variables into genetic risk estimation models contribute additional layers of heterogeneity with intersectional differences between groups. For example, a study within HCHS/SoL found that a genetic score for body mass index demonstrated significant heterogeneity between Hispanic/Latino groups which was modified differentially by age at immigration (McArdle et al., 2021). Taken together, these caution against the use of racial or ethnic categories as signifiers of genetic similarity, or homogeneity, especially when considered across environmental contexts in genomic and non-genomic studies.

Another complication within genomic studies is the consideration of multiracial individuals. These participants differ from admixed populations as defined above. While most present-day human populations are to some extent admixed, meaning having ancestry from two or more previously isolated populations, recently admixed populations in the United States are conceptualized as those with mixture between groups previously separated at a continental-level. In the United States, the two largest groups are populations of African Americans and Hispanic/Latino groups. These groups are the result of continuous mixture over the past several hundred years due to forces of colonization, forced enslavement, and complex immigration patterns across the Americas (Bryc et al., 2015; Gouveia et al., 2020; Mathias et al., 2016; Schroeder et al., 2015). As a result, their genomes form a mosaic of previously isolated ancestries, or haplotypes, which can be studied using statistical genetics methods. In contrast, multiracial individuals are defined by having more recently mixed ancestry, within only a few generations, which requires different considerations from both the standpoint of their identification with monoracial (e.g., purportedly single-race) groups as well as appropriate modeling of their genomes, which would have much larger haplotypes, including entire chromosomes from a single ancestry in some biracial individuals. Due to these complications, multiracial individuals are often excluded from analyses, both genetic and non-genetic, and have limited access to medical innovations which rely on discrete groupings (Martschenko et al., 2023; Phillips et al., 2007).

APPROACHES TO ANALYZING DATA FROM MULTIRACIAL INDIVIDUALS

This section contains material is adapted from a piece commissioned for the committee.

In 2000, the U.S. Census allowed Americans to officially self-identify with more than one racial group for the first time (U.S. Census Bureau, 2001). Two decades later, the self-identified multiracial population is measured at 33.8 million—nearly a 500 percent increase—and represents over 10 percent of the U.S. population (U.S. Census Bureau, 2001, 2021, 2023). The dramatic growth in multiracial reporting can be attributed to a number of factors, from an increase in interracial marriage to increasing acceptance of multiracial identities (Lo Wang, 2021; Tavernise et al., 2021). However, the biggest change over the past decade was in how the U.S. Census Bureau captured and coded race and ethnicity responses, producing a sudden jump from 9 million people, or a 276 percent increase, since 2010 alone (Reynolds, 2021). This sensitivity to changes in data collection and coding underscores a point that demographers have long stressed: that census counts based on self-identification reflect "a" multiracial population not "the" multiracial population (Harris and Sim, 2002; see also Goldstein and Morning, 2000). As previous research has shown, the size of the multiracial population depends on both how it is defined and how the data are collected. The largest estimates of multiracial Americans (about 18 percent of the U.S. adult population) come from asking people about the race(s) of their parents, grandparents, great-grandparents, and earlier ancestors, while the smallest estimates come from asking people if they identify explicitly as "mixed or multiracial," with the number of people who select two or more responses from a list of single race or ethnicity categories for self-identification falling somewhere in between (Morning and Saperstein, 2018; Patten, 2015). Although these measurement issues appear most stark when considering people who self-identify as multiracial, they highlight broader conceptual and operational challenges for researchers who are intending to use race and ethnicity in biomedical studies.

Just as it is important conceptually to disentangle genetic measures of ancestry from genealogical ones, it is also necessary to disentangle both genetic and social understandings of ancestry from self-identification using racial or ethnic categories. Although often conflated, each of these measures captures something different about a person's socialization and life experience that is relevant to their health. As discussed above, genetic measures of ancestry reflect similarities and differences in how alleles and haplotypes are distributed across human populations. Genealogical measures of ancestry include pedigrees or family trees that trace kinship across generations using vital records, such as birth, marriage, and death certificates kept by religious institutions and local and national governments. These official genealogical documents may differ from more informal notions of ancestry that are passed down in families. Finally, individuals' known ancestry can differ from what they self-report on surveys. Historically, in the United States both laws and customs shaped how people's ancestral backgrounds affected their treatment in society, the most infamous of these being the "one-drop rule" that defined Americans with any known African ancestry solely as Black (Davis, 2010). Views of racial "mixing" and multiraciality have changed significantly over time from something illegal that needed to be hidden to an aspect of one's identity to celebrate. This history, and the changing stakes of racial classification, is reflected in differences across generations in both awareness of multiracial ancestry and the willingness to report multiracial identification in surveys (Johfre and Saperstein, 2019). Patterns of multiracial self-identification also vary by gender, the specific racial backgrounds involved, and how far back in a person's family tree the first racial "mixing" occurred (Xu et al., 2021). The use of direct-to-consumer genetic ancestry testing is increasingly shaping people's understanding of their ancestry and their likelihood of translating that ancestry awareness into racial or ethnic self-identification in surveys as well (Johfre et al., 2021). This complexity shapes the identities of both monoracial and multiracial people and underscores the importance of carefully considering which concepts and measures of race, ethnicity, and ancestry are most relevant for a given research question.

To date, however, not only does most biomedical research continue to conflate various measures of ancestry and racial or ethnic self-identity, but also multiracial participants are routinely excluded in studies seeking to identify racial disparities in health. This exclusion leaves significant gaps in our understanding of health risks, including those that might differentially affect multiracial people, and consequentially underinvestment in addressing them (Lam-Hine et al., 2024). The few studies that do include a multiracial category in analysis operationalize it differently, creating challenges for interpreting results (Lam-Hine et al., 2024). A variety of different approaches are in use in the literature (Table 5-1), and uncertainty around how to define and categorize multiracial identity likely prevents greater inclusion of multiracial and multiethnic populations in biomedical research.

Relevant to the biomedical context, health care systems are collecting more granular race and ethnicity data, including from people who self-identify as multiracial or multiethnic, and have begun using these data to stratify measures of quality with the goal of ensuring equitable care.[10] Yet, there are few standards in place for how best to categorize people who identify as multiracial or multiethnic. The same dataset can yield different results depending on the methodology for analyzing multiracial individuals. For example, EHR data from a Connecticut hospital of approximately 666,000 people

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[10] Wang presentation to committee, January 31, 2024.

TABLE 5-1 Multiracial Categorization Schemes Currently in Use in the Literature.[1] These are existing approaches, and care should be taken before selecting and using one.

Categorization Schemes and Descriptions	Considerations for Use
Use a single category called "multiracial" for everyone who chooses multiple categories	
a. **Non-Hispanic Multiracial:** Grouping all who identify with more than one race, but not Hispanic or Latino ethnicity, into one multiracial category. b. **Hispanic-Inclusive Multiracial:** Grouping all who identify with more than one race, regardless of their Hispanic origin response, in the multiracial category. c. **Hispanic-as Race Multiracial:** Considering Hispanic or Latino ethnicity as a race option when determining who to include in the multiracial category.	**Pros**: Straightforward; can examine attributes common to multiracial experience. **Con:** Nuanced information about multiracial identity and experiences could be lost. **Example:** Studying racial identity affirmation and belonging because individuals identifying with more than one race tend to report relatively low levels of racial identity affirmation and belonging and systematic exclusion from racial identity-affirming communities.
Sort into all categories selected	
a. **Additive:** Categorizing multiracial respondents into all of their component monoracial groups. b. **Additive + Multiracial:** Categorizing multiracial respondents into all of their component monoracial groups, plus a multiracial group.	**Pro:** Could be useful when examining a circumstance or mechanism where component racial backgrounds could influence outcomes **Con:** Can complicate some analyses because group percentages will not add to 100%. **Example:** Additive + Multiracial could be well suited to studying racial discrimination because multiracial individuals can experience discrimination directed at their multiracial or component racial backgrounds.
Select the single least advantaged category	
Hypodescent: Recategorizing multiracial respondents into their most socially disadvantaged racial group. Note: Hypodescent reflects the historical "one-drop rule" that continues to shape some multiracial identification today.	**Pro:** Could be useful when examining risk factors and stressors that are more likely to be experienced by less socially advantaged groups. **Cons:** Recategorization may not reflect participants' identity; may be more challenging to define compared with other approaches because social advantage and disadvantage are relative. **Example:** Studying racial and ethnic differences in exposure to traumatic events and development of depression

Select the single most advantaged category	
Hyperdescent: Recategorizing multiracial respondents into their most socially advantaged racial group.	**Pro:** Could be helpful when examining circumstances where multiracial individuals' experiences are similar to those of their most socially advantaged component group. **Cons:** Recategorization may not reflect participants' identity; may be more challenging to define compared with other approaches because social advantage and disadvantage are relative. **Example**: Studying unmet psychiatric treatment needs because multiracial Americans access psychiatric treatment at rates similar to White Americans.
Select the single rarest (least common) category	
Rarest: Recategorizing multiracial respondents into their least populous racial group.	**Pro**: Can improve power in estimates for smaller groups that include many multiracial members, such as Native Hawaiian or Pacific Islander and American Indian or Alaska Native. **Con:** Could aggregate people who do not share exposures into one category
Participants select a single category that they most identify with	
Best Race: Recategorizing multiracial respondents into the single race that they identify best with.	**Pros**: Could be useful when examining racial discrimination; can reflect socially assigned race, which may be relevant to the line of inquiry. **Cons:** Could lose information about multiracial identity; this scheme should be used with caution as many multiracial people do not identify with a single race and may refuse to do so.
Analyze subcategories of multiracial identity	
a. **Disaggregated Multiracial:** Grouping multiracial participants into subcategories defined by specific racial identities (e.g., Asian-White; American Indian or Alaska Native-Black). b. **Disaggregated White/non-White Multiracial:** Grouping multiracial participants into subcategories defined by having or not having White identity (e.g., White-Nonwhite; Nonwhite-Nonwhite).	**Pro**: Can help uncover nuances of multiracial identity and experience. **Con:** Low statistical power due to many small categories (using disaggregated White/non-White multiracial could help with low power but risks reinforcing White as the norm). **Example:** Examining racial discrimination, particularly if using a measure that includes multiracial-specific forms of discrimination alongside more traditionally measured ones.

[1] This review focused on schemes that can be coded using the 1997 U.S. Office of Management and Budget's Statistical Policy Directive No. 15 self-reported racial and ethnic categories: *American Indian or Alaska Native*, *Asian*, *Black or African American*, *Native Hawaiian or Other Pacific Islander*, and *White* for race; *Hispanic or Latino* or *Not Hispanic or Latino* for ethnicity.

SOURCE: Adapted from Forthal, Sarah (2024). A mechanism-driven approach to categorizing multiracial participants in biomedical research (Appendix C). Work commissioned by the Committee on the Use of Race and Ethnicity in Biomedical Research at the National Academies of Sciences, Engineering, and Medicine.

include about 38,000 people (5.7 percent) who self-identify as multi-racial/ethnic, but there are various ways to organize the information.[11] Using the methodology based on a paper from the Centers for Disease Control and Prevention (CDC), any person who identifies as Hispanic, regardless of how they identify themselves racially, are categorized as Hispanic, and any who identify as multiracial and not Hispanic would be excluded (Yoon, 2021). Applying a different methodology to the same Connecticut hospital dataset, someone who identifies as multiracial is categorized into the race with the lowest prevalence in the measured population (Mays et al., 2003). For example, in this Connecticut hospital dataset, a person who identifies as Asian and Black would be categorized as Asian.[12]

The use of racial categories assumes a shared within-group social identity (Jackson, 2023). However, this is particularly challenging to assume for multiracial individuals, who share identities with multiple groups and may primarily identify with one, all, or none of their component monoracial groups (Vinluan and Remedios, 2020). Further, different racial identities may be more or less salient for multiracial people in different contexts (Pauker et al., 2018). For example, some multiracial people primarily identify as members of their most minoritized monoracial group due to historical or political reasons (Davenport et al., 2022; Iverson et al., 2022). Ultimately, researchers cannot simply assume that all multiracial people identify with a separate "multiracial" identity, nor that they identify with any monoracial identity. Multiracial people are also exposed to systemic racism, both on the basis of their multiracial and specific racial backgrounds, which increases their risk of several health conditions (CDC, 2018a, b; J. C. Harris, 2016; Lam-Hine et al., 2024; Merrick et al., 2018; SAMHSA, 2021). Though relevant to all racial groups (Iwamoto and Liu, 2010; Neblett Jr. et al., 2012), racial identity affirmation and belonging is particularly prevalent in the multiracial health literature, given common experiences of identity denial and questioning in this population (Albuja et al., 2019, 2020; Fisher et al., 2019; Franco et al., 2021; Jackson, 2023; Nalven et al., 2021; Sanchez, 2010). Thus, the many ways that multiracial backgrounds shape environmental or social exposures are not easily captured by traditional research methods, which rely on drawing fixed and discrete lines between groups for comparisons that are often essentialist in nature (Kaufman, 1999; Mays et al., 2003). For these reasons, there is likely no single best multiracial categorization scheme for all biomedical research purposes. Instead, as with other racial and ethnic categorization decisions (Guluma and Saperstein, 2022; Howell and Emerson, 2017; Shiao, 2019), the most appropriate multiracial categorization scheme will depend on the outcome of interest and the hypothesized mechanism linking race and racism to health.

BIOMARKERS OF STRESS AND OTHER PHYSIOLOGICAL PROCESSES

Rather than using race and ethnicity categories as proxies for studying physiological mechanisms of health and disease, it is far preferable to investigate the phenomenon of interest directly, when possible. Biomarkers are physiological indicators used to assess and monitor biological processes related to health and well-being. These mark-

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[11] *Ibid.*

[12] *Ibid.*

ers can signify various processes, including: (1) as a surrogate endpoint for a disease, (2) a biological mechanism, or (3) an indicator of future disease risk. As it relates to biological mechanisms, biomarkers not only offer insights into future disease risk but can also indicate exposure to various factors. For instance, hormonal biomarkers such as cortisol, norepinephrine, and epinephrine have been used to signal exposure to stressors.

Related to the neuroendocrine, immune, and cardiovascular systems, stress biomarkers are associated with health and disease risk (Dowd and Goldman, 2006). The cumulative physiological effects due to chronic stress or life events, known as allostatic load, can affect immune system functioning, which can result in increased oxidative stress levels and damage to DNA (Djuric et al., 2008). Chronic environmental stress and the consequent oxidative stress on cells and tissues is also linked to aging (Liguori et al., 2018). Allostatic load can be measured via biomarkers, such as levels of cortisol, epinephrine, cholesterol, and interleukin 6, along with blood pressure, among many others (Dowd and Goldman, 2006; Guidi et al., 2021).

In the context of race and ethnicity within biomedical sciences, biomarkers have been instrumental in exploring the effects of adverse exposures on populations, particularly in relation to stressors linked to racialization. For example, researchers have found that exposure to discrimination correlates with immune and inflammatory biomarkers, such as C-reactive protein and IL-6, among other immune markers (Chen et al., 2023; Lawrence et al., 2022; McClendon et al., 2021). The relationship between stress biomarkers and health disparities has led to the hypothesis of "weathering"—that is, that members of racial and ethnic minority groups experience accelerated aging and physical deterioration due to chronic stress (Geronimus et al., 2006; Noren Hooten et al., 2022). Further, there is a significant amount of research indicating that a wide range of stressors, including socioeconomic disadvantage, influence immune-related biomarkers (Kautz et al., 2023; Lam et al., 2021; Muscatell et al., 2020). Moreover, emerging studies suggest that stressful exposures at the neighborhood level, such as living in previously redlined and segregated neighborhoods, also affect these biomarkers (Broyles et al., 2012; Iyer et al., 2022; Simons et al., 2018). Consequently, differences in these biomarkers across racial and ethnic groups can often be traced back to varying levels of stressor exposure at both individual and neighborhood levels. Since these stress-related mechanisms operate similarly across all populations, differences in biomarkers across racial and ethnic groups do not indicate inherent biological differences between groups. Like genetics research, the field of biomarker research, especially when examining issues related to race and ethnicity, is susceptible to biological essentialism. Therefore, it is important to clearly articulate the question of interest and, whenever possible, to measure the factors of interest that may result in variation in biomarker values across groups rather than a measuring proxy such as race or ethnicity.

Aside from stress-related measures, biomarkers vary across every clinical domain. BRCA1 and BRCA2 genes are well-known examples that are associated with increased risk of breast cancer. Hemoglobin A1c is a biomarker for diabetes and is used to both diagnosis and monitor the condition. In some cases, differences that seem correlated with race are accounted for once the biological mechanism is known and a corresponding biomarker can be measured. In ophthalmology, for example, glaucoma is more prevalent among Black than among White populations. Much of this difference was explained, however, by variation in the thickness of the central cornea (Brandt et al., 2001). Identified as a risk factor for glaucoma, thinner corneas are associated with a higher propensity to develop glaucoma (Brandt et al., 2001; Hyman and Mehta, 2004; Wang et al., 2014). This measurable biological construct may account for at least some of the increased risk of glaucoma noted among Black populations (Brandt et al., 2001).

In an example from cardiology, researchers examined health disparities in major adverse cardiovascular events and major hemorrhage after percutaneous coronary intervention (Cai et al., 2019). Disparities in outcomes were often attributed to race; however, after adjusting for other nonclinical and clinical factors, the results indicated that race was not a significant risk factor. Differences were instead attributable to other risk factors, including socioeconomic status, comorbidities, and coronary heart disease severity (Cai et al., 2019).

Biomedical research has demonstrated variability in stress-related biomarkers across racial and ethnic groups. These stress-related mechanisms are phenomena that can be found in all human physiology, and differences are attributable to unequal exposures to stressors, disadvantage, racism, and discrimination. Stress-related exposures can be differentially distributed within and between racial and ethnic groups, so race and ethnicity are poor proxies for these biomarkers. Similarly, it is important to be wary of attributions to race in biomedical contexts and studies of other biomarkers; the existence of a health disparity does not mean that there is a difference in health due to race or ethnicity. More work is needed to continue investigating biomarkers that can more directly interrogate biological processes that may underly health disparities, uncover mechanisms of disease, and avoid the risk of biological essentialism.

CHAPTER SUMMARY AND CONCLUSIONS

This chapter opened by examining the use of the OMB categories in biomedical research. Based on the information presented in this and earlier chapters, the committee provides the following conclusions:

> *Conclusion 5-1: The OMB categories are a minimum set of categories unique to the United States. The OMB categories are often required for inclusion reporting purposes in research. However,*
>
> 1. *the OMB categories are a sociopolitical construct with no biological basis.*
> 2. *the OMB categories are a minimum set of categories, but federal agencies and the scientific community can collect more detailed information.*
> 3. *the OMB categories do not need to be used for scientific analysis, even if they are required for reporting recruitment statistics.*
>
> *Conclusion 5-2: Reporting requirements from NIH and other funders of biomedical research often rely on the OMB categories for ensuring a racially and ethnically diverse sample population. This reliance on the OMB race and ethnicity categories*

for reporting has contributed to the categories becoming enmeshed in science and medicine.

Conclusion 5-3: The 2024 revisions to OMB's Directive 15 on collection of data on race and ethnicity include adding the category Middle Eastern or North African (MENA) and requiring the collection of more detailed subcategories by default. These changes to the standards will improve the quality of demographic data for some research purposes but do not completely resolve limitations to the use of the OMB categories for biomedical research.

- *The OMB relies on a set of racial and ethnic categories that are increasingly defined by regional or national origin in the 2024 policy. However, these measures alone may be insufficient for measuring diversity in biomedical research or addressing research questions of interest.*
- *The OMB categories, including the revised 2024 standards, were not designed for health research, and interpretation of the policy by the NIH and others will influence how the updated standards apply in biomedical research.*
- *Achieving diversity in biomedical research participation should not be limited to representation across the OMB categories.*

Implementing the new OMB standards will reveal new challenges, particularly when it comes to operationalizing the collection of subcategories and coding write-in responses. As Directive 15 notes, regular reviews of the policy will be necessary.

The chapter continued with the committee's articulation of *racism-conscious research*, an answer to the need for an approach that directly acknowledges and addresses how racism has affected biomedical research practices and contributed to health disparities. Based on evidence presented in this and previous chapters, the committee concluded:

Conclusion 5-4: Although race is not biological, it continues to be relied upon as a blunt tool, heuristic, or variable in medicine to assess patients' disease risk. Much of the existing evidence base in biomedical research that involves humans and uses White or European populations as the standard grew out of race-based approaches that perpetuate discriminatory presumptions.

Conclusion 5-5: Genetic differences among groups of people are not racial differences. Genetic differences may have meaning in biology and a role in medicine and research. Race, though, is not a substitute for unseen or unmeasured biological predictors of interest.

Conclusion 5-6: Racism-conscious research invokes an awareness of how unfounded racial assumptions and racism have affected biomedical research, resulting in harms and inequitable treatment and care.

The chapter then explored other concepts and variables which are often conflated with race. These other concepts or measures can be more precise or better suited to the scientific line of inquiry. An overemphasis on race, specifically the OMB categories, has collapsed rich heterogeneity into simple labels that can make doing rigorous research that teases apart nuanced mechanisms of interest challenging or impossible. Some of the concepts explored in this chapter, such as ethnicity, are closely related to race. Common use of *race* and *ethnicity* interchangeably has exacerbated confusion among researchers and the public, but these concepts are nuanced and need to be disentangled to elucidate the specific characteristics or processes of interest. Other concepts like structural racism and social determinants have been linked to health outcomes. Race has multiple dimensions, including not only self-identification but also relational or interaction-based aspects of race and racialization, that contribute to experience. Limitations to self-identified race, such as for the AIAN population, have been largely overlooked. In other cases, race has sometimes been relied on to capture unspecified variation, and further investigation into biomarkers, physiological mechanisms of action, and environmental factors may serve to better explain differences and phenomena in biomedical research. Due to the prolonged emphasis on race, there is less evidence on the use of related concepts in biomedical research, and more exploration and examination is warranted. Along with the committee's recommendations, Chapter 6 introduces best practices for measuring these concepts in the context of biomedical research (see "Approaches and Metrics to Strengthen Inquiry about Race, Ethnicity, and Related Concepts").

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6

Recommendations to Guide the Use of Race and Ethnicity in Biomedical Research

This chapter provides the committee's recommendations for improving the use of race and ethnicity in biomedical research. The chapter begins by outlining conceptual foundations that delineate harmful from appropriate use of race and ethnicity. The committee then presents recommendations for the intentional use of race, ethnicity, and related concepts throughout the research process and discusses their implementation. The chapter concludes with steps that other entities in the research ecosystem can take to support biomedical scientists in operationalizing and adopting these recommendations.

CONCEPTUAL FOUNDATIONS FOR ASSESSING APPROPRIATE USE OF RACE AND ETHNICITY IN RESEARCH SETTINGS

The recognition that race is a social construct raises questions about whether race and ethnicity data should be captured at all in biomedical settings and, if so, for what purposes. The position of this committee is yes—collecting information on race and ethnicity can serve the goals of fairness, inclusion, and equity in biomedical research. In addition, recording race and ethnicity data will continue to be necessary to examine health inequities and for legal reasons. However, despite continued use and measurement, race and ethnicity should never be construed as biological constructs or relied upon as a causal explanation for individual health outcomes. Indeed, questions about human diversity are always multidimensional, and race and ethnicity alone are insufficient to capture the complexity of information that contributes to health outcomes. This is a recurring theme also identified in another recent National Academies report that grappled with the use of race and ethnicity in genomics research (NASEM, 2023).

Describing race and ethnicity as social constructs gives rise to a fundamental tension—race and ethnicity are not suitable proxies for biological mechanisms, yet diverse representation in biomedical research is essential. It is also important to acknowledge how these constructs give rise to differing social realities and to respect the ways that people identify themselves. Although the underlying biology is the same, race and ethnicity, if used thoughtfully, can serve a number of purposes in research, such as to ensure scientific rigor with sample populations that represent a range of life experience and social contexts, to track health disparities, and to account for how individuals self-identify.

Harmful Uses of Race and Ethnicity in Biomedical Research

Here the committee describes three research practices that are harmful yet continue to appear in biomedical research. Avoiding these problems does not inherently mean that the use of race and ethnicity is appropriate. Assessing appropriate use requires careful decision-making, and the remainder of this report is dedicated to this subject and provides recommendations and resources to assist researchers in making these decisions.

Incorrect Assumptions

Harmful uses of race and ethnicity in research can be subtle and hard to detect due to unrecognized, deep-seated assumptions or stereotypes about individuals and groups. An invalid presumption of innate difference between groups of people is at the root of many problematic uses of race and ethnicity in health and biomedical research. It is wrong to make assumptions about a patient or research participant based on their race or ethnicity. Although social determinants of health are often differentially distributed by race and ethnicity, presumptions based on such associations can pathologize people and groups and is misguided.

Causal Inferences from Observational Studies versus Experimental Research

There are key distinctions between experimental and observational research that make a difference when considering whether to use race or ethnicity as a variable in research. Experiments are designed to control variables and evaluate causal hypotheses—an independent variable is manipulated, and the effects on dependent variables are measured. Observational studies, in contrast, examine correlations between variables. Because observational studies do not manipulate isolated variables, they cannot discern causality. Neither race nor ethnicity can be isolated as independent variables in an experimental setting,[1] but these constructs often serve as a proxy for the true variable of interest. Thus, biomedical studies that use race and ethnicity as variables can only point to correlations and do not enable causal inference. Nevertheless, race- or ethnicity-related

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[1] With the exception of controlled social science experiments intended to uncover evidence of racial and ethnic discrimination. For instance, racial and ethnic cues/classifications can be manipulated or otherwise varied in vignettes or audit studies designed to test for bias.

inferences sometimes go beyond claims of association or correlation in research. Besides investigators themselves making inferences, journal reviewers and editors ask researchers to speculate on the pathway between race or ethnicity and outcomes on the way to publication, highlighting the shift needed throughout the research ecosystem to eliminate biological essentialism of race and ethnicity.

In addition, epidemiological differences (e.g., observed differences in disease prevalence across racial and ethnic groups) can be taken out of context or wrongly interpreted to mean that an individual's race or ethnicity is a causal explanation for disease. In clinical medicine, race and ethnicity are often characterized as risk factors for a disease or health outcome. Risk factors are attributes *associated with* an increased likelihood of developing a disease or a health outcome. The presence of a risk factor does not make a particular health outcome inevitable. In a classic example, in the early to mid-nineteenth century, it was observed that people living at low altitude were at increased risk of contracting cholera, leading many to believe that cholera was caused by bad air (miasma theory). John Snow, in a series of pioneering investigations, demonstrated that contaminated water was the source of cholera and that low altitude was associated with cholera only because people living at low altitude consumed more contaminated water than people living at high altitude (Bingham et al., 2004). As with bad air in this cholera example, without sufficient context, variables such as race and ethnicity can be incorrectly invoked in disease etiology as the cause of a health condition.

It is thus important to recognize that race or ethnicity may be correlated or associated with differences in disease prevalence, but differences in disease burden between populations do not unveil the specific factors underlying the disease. In fact, the biological or environmental mechanism may be unknown, and research may be needed to examine other explanatory variables or to better understand the fundamental biology.

Quantifying Racial and Ethnic Differences in Physiological Traits

It is also worth considering the supposed purpose of quantifying racial and ethnic differences in physiological traits in study design. The medical literature is replete with reports of differences in physiological or anatomical traits across racial and ethnic groups. When performed without a scientific rationale or hypothesis, such a search for racial and ethnic differences may appear to be a "fishing expedition" and does not make for sound science. If enough comparisons are made, between-group differences in traits are likely to be found, but within-group differences are also likely to be found. Occasionally, a noted difference in a given trait between racial or ethnic categories offers a potential lead for further hypothesis-driven investigations, which may prove to be illuminating and uncover information about the true drivers of disease. However, careful consideration should be exercised when reporting diseases, outcomes, or traits found to be associated with race or ethnicity by avoiding assumptions and discussing what the study limitations may be, given that it is not a causal relationship.

Racial categories are heterogeneous and have high within-group variation. Because a trait's distribution can vary widely in a population, even if a small difference exists in the means between two groups of people, the difference is not necessarily meaningful for individuals. A poor proxy for other factors that are at play, race is ill suited to tease apart effects due to various confounders, and other measures may be more fitting for the scientific question at hand (see Chapter 5). The same is true for ethnicity. Hence, it is inappropriate to use either race or ethnicity as an explanation for health or research outcomes, and it is necessary to consider the full context, including salient social, behavioral, or environmental factors.

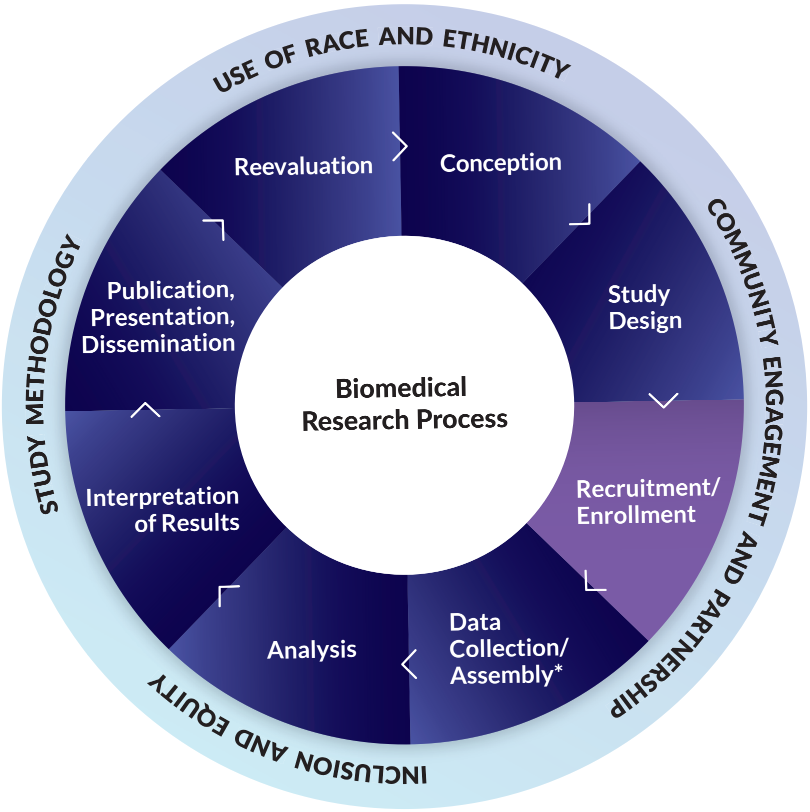
Appropriate Use of Race and Ethnicity Is Context-Dependent

Decisions about the use of race and ethnicity in biomedical research require careful deliberation. Although some situations may be clear-cut, most are nuanced, involving balanced consideration of ethical, contextual, and scientific factors. Important ethical considerations include respect for individuals and communities, beneficence for all parties involved in the research and for the public at large, and justice throughout the biomedical research process (NASEM, 2023; U.S. Department of Health, 1979). Collecting race and ethnicity information for purposes such as recruitment, fairness, and equity may be largely appropriate from an ethical standpoint but still requires careful consideration of context. For example, collecting race and ethnicity data during recruitment can help ensure a diverse population of participants. This information can be used to engage the right population, increase accessibility of research studies, and disseminate research results to those who may benefit. However, even for well intentioned purposes, the correct approach to using race and ethnicity depends on the research question of interest and the specific context (Quinones et al., 2024). *Context* can encompass a variety of biological, social, cultural, behavioral, and environmental factors, including social and historical background that may have contributed to the existing evidence base. Lastly, decisions to use race and ethnicity should uphold scientific validity given the research question of interest. It is important to consider whether race or ethnicity is best suited to the scientific purpose or whether another measure might better address the question.

The remainder of this chapter explores these considerations in more depth and offers recommendations and tools for scientists and others in the biomedical research ecosystem to use in assessing particular use cases and determining appropriate use of race and ethnicity in a context-dependent manner.

CONSIDERATIONS FOR THE USE OF RACE AND ETHNICITY THROUGHOUT THE RESEARCH PROCESS

As discussed in Chapter 2, biomedical research is governed by not only scientific principles, but also ethical principles. Given the breadth of types of biomedical research, the committee organized their analysis around the stages of the research process cycle (Figure 6-1). With some variation, this framework is useful for biomedical research broadly, across the translational spectrum from the bench to the bedside and out into the community. Although societal views and the definition of race and ethnicity will continue to change over time, as will biomedical study designs, this research process framework can be adapted to many scenarios.



Use of Race and Ethnicity

- Disaggregate race and ethnicity
- Define concepts and measurements
- Disclose limitations

Community Engagement and Partnership

- Build trust
- Sustain community partnerships
- Ensure transparency
- Respect data sovereignty
- Form interdisciplinary study teams, including community members

Inclusion and Equity

- Account for time for outreach
- Ensure equitable benefit sharing with the community
- Incorporate multi-racial and multi-ethnic individuals

Study Methodology

- Collect more granular data
- Use appropriate categories and measurements for analysis
- Disclose limitations of legacy datasets

● Applies to all studies ● May not apply to studies not recruiting participants

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*Researchers conducting observational studies with existing data may enter the cycle here but should consider data provenance and prior stages.

FIGURE 6-1 Key considerations for the use of race and ethnicity throughout the biomedical research process. Considerations around the use of race and ethnicity, community engagement and partnership, inclusion and equity, and study methodology (outer ring) should occur at every stage of the research process (inner ring).

The conceptual considerations described in the previous section may be most readily apparent in the early stages of the research process—during its conception and design, as well as during outreach and recruitment of study participants in studies where those phases are relevant. But in truth, issues of race and ethnicity recur throughout all stages of the research process. Because appropriate use is context-dependent and the context will change throughout stages of a study, it is important to evaluate and make decisions about the use of race and ethnicity multiple times during the research process. Based on this reasoning and evidence presented in prior chapters,[2] the committee provides the following conclusions and recommendation:

Conclusion 6-1: Both deciding to use race and ethnicity and deciding to omit race and ethnicity can have advantages and disadvantages in biomedical research. It is important to evaluate potential implications, benefits, and risks not only of using race and ethnicity but also of forgoing collection of these data entirely.

Conclusion 6-2: Addressing the use of race and ethnicity at only one stage of a study fails to capture the unique factors and consequences that can emerge at subsequent steps of the process.

Recommendation 1: At every stage throughout the biomedical research process, researchers should scrutinize, evaluate, and decide whether the use of race and ethnicity is appropriate or inappropriate. Researchers should:

- **Identify how the historical or social context, including prior uses of race and ethnicity in research, affects the underlying evidence base for the question of interest;**
- **Use race and ethnicity in ethical ways based on the context and research question, with a principled scientific rationale documented throughout the study;**
- **Understand distinct contexts and requirements for partnering with specific populations and communities, which could include American Indian or Alaska Native Tribes and their distinct political status as sovereign nations;**
- **Consider the benefits of collecting race and ethnicity information for research purposes, including promoting diverse representation and equity, when these constructs are not central to the research question;**
- **Refrain from making unsupported inferences from the analysis, such as relying on race and ethnicity as causal attributes that drive biomedical research outcomes in individuals; and**
- **Weigh the potential implications, limitations, benefits, or harms of using or not using race and ethnicity.**

In publications, researchers should articulate their decisions about whether and how to use race and ethnicity in their research studies and reflect on the outcomes.

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[2] See discussion in Chapters 3 and 4 about pulse oximetry, race correction, and clinical decision-making tools.

With the goal of eliminating racial and ethnic bias from both biomedical research and its applications in health care, there are four key considerations that researchers will need to address throughout the research process:

1. Assessing whether to include race and ethnicity and, if so, how to use them.
2. Forming enduring partnerships with communities.
3. Ensuring inclusion and equity for everyone involved in the study and those most affected by the study results.
4. Recognizing and characterizing the biases and limitations of datasets and study methodology.

Each consideration is explained briefly in the subsections below, followed by a list of questions to help researchers operationalize these recommendations at each stage of the research process (see "Questions to Assess the Key Considerations"). Subsequent sections of the report provide recommendations and tools for effectively addressing each consideration.

Assessing the Use of Race and Ethnicity

The role of race and ethnicity in a given study should be considered as early as the conceptualization of the research question. From the outset, it is important to consider whether the use of race or ethnicity would be appropriate or inappropriate in this context and for what reasons. For purposes extrinsic to the research question, such as inclusive recruitment, the use of race and ethnicity is generally appropriate. (See "Conceptual Foundations for Assessing Appropriate Use of Race and Ethnicity in Research Settings" above.) When using these constructs, they should be contextualized. It is equally important to consider the benefits and potential limitations or consequences of using race or ethnicity. Working with racial and ethnic communities can help researchers identify some of these potential limitations or unintended consequences.

Forming Partnerships with Communities

If considered at all, community outreach is often addressed only once in a study—typically in conjunction with recruitment. However, considerations for building effective community partnerships should be embedded at each stage of the research process to assist with determining whether the use of race and ethnicity is appropriate. In developing a research program, investigators can start by assessing whether community engagement is suited to the specific aims of the study and, if so, determining what type of community partnerships will be most effective for accomplishing the research goals and understanding community views on how race and ethnicity may be used (see "Building Community Partnerships" below). If the decision is made to use race and ethnicity, it is necessary to consider how the data are most appropriately collected. Another important consideration is the time frame for engagement, including appropriate planning of the steps and time required for successful community outreach. In addition, early in the process the study team should ensure that it incorporates the expertise needed to accomplish the four considerations under discussion here. The study team may benefit from including experts in community engagement or community leaders and liaisons.

As a study is completed, it is important to keep its potential impact on the community in mind by considering how the study results may be used to improve health and not reinforce racial or ethnic stereotypes. Thus, efforts to involve communities in the dissemination of the results should be considered. After a given study, reflecting on the process during an evaluation stage is helpful. Researchers can reflect on how community expertise influenced or altered the research process details or the trajectory of the research. Because sustained investment builds trust among researchers and communities, investigators might also consider ways to maintain a relationship with the community after the specific research study has concluded. Building trust is a continuous process that serves to increase the quality of the data collected and thus support stronger scientific conclusions.

Ensuring Equity and Inclusion in the Research Process

To promote equity and the inclusion of historically underserved racial and ethnic populations at multiple points throughout the research process, study teams should start by considering how diversity is defined in the study and what methods will be used to recruit and include a diverse sample of participants. However, these considerations do not stop with recruitment. It is equally important to consider rigorous ways to design scientific analyses and interpret results to foster inclusion throughout the process. Researchers should also keep in mind how the research could benefit or negatively affect the participants and the communities who contributed to the work. Where relevant, those seeking to evaluate potential effects of their work on health equity might consider the Health Equity Impact Assessment Tool[3] and adapt the questions to their study context. In addition, equity and inclusion are key aspects to examine during the re-evaluation phase of the research process when study teams can assess how to address any challenges encountered in future studies as well as reflect on potential social impact of their work.

Evaluating Datasets and Study Methodology

In the process of designing and executing a research study, it is important for researchers to explicitly define how race and ethnicity data will be collected and used. For this reason, researchers should contemplate two points. First, what is the source of the data: primary/original data collection, secondary data—e.g., legacy study data, data derived from electronic health records (EHRs), or financial claims data—or a

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[3] https://www.camh.ca/en/professionals/professionals—projects/heia/heia-tool (accessed August 20, 2024).

combination of the two? (See the Chapter 3 section "Race and Ethnicity in Secondary Data Analysis" for more detailed descriptions.) Second, how could the source of the data affect the study? Although investigators have less control over the information within secondary datasets, it is still important to recognize how the data were assembled, state what is known about data provenance, assess potential bias, and acknowledge limitations of the datasets used. Of note, recruiting requirements necessarily differ across small and large trials. The committee recognizes that many studies, including Phase I trials, are conducted with small sample sizes. The committee also maintains that the principles of transparency, openness, and reproducibility apply wherever race and ethnicity data are collected—regardless of study size. The committee provides the following conclusion and recommendations:

> *Conclusion 6-3: Continued use of some legacy datasets may be more harmful than beneficial, and some legacy race and ethnicity data should no longer be used in future biomedical research. Because knowledge and reporting has changed over time, combining legacy with current datasets is problematic. Particularly common and problematic in legacy data are issues of missing data and aggregating data into an "Other" category.*

> **Recommendation 2: Whether conducting primary research or secondary data analysis, biomedical researchers should provide an operational definition of race and ethnicity, if used, in all grant applications, manuscripts, and related products. Within these products, researchers should explain their rationale and the limitations of their approach as well as describe attributes of data provenance, such as:**
> - **Which race and ethnicity categories were used for enrollment and/or scientific analyses and why (e.g., which version of the Office of Management and Budget categories was used);**
> - **How race and ethnicity data were reported (e.g., self-identified or socially assigned);**
> - **When data were collected;**
> - **Whether any subcategories were aggregated, including whether samples were relabeled, combined, or harmonized across various sources;**
> - **Whether any race and ethnicity data were derived (e.g., imputation, estimation), and how; and**
> - **Whether bias may exist due to the way categories were defined and handled (e.g., sampling, classification, method of data collection, completeness of data).**

Data-related considerations are critical for biomedical studies that rely on secondary datasets. For instance, the development of biomedical and health technologies usually relies on secondary datasets rather than original data collection, underscoring the importance of characterizing the existing data to understand bias and limitations. Tools such as the Bias Elimination for Fair and Responsible AI in Healthcare (BE FAIR) framework (Cary et al., 2024) and the Racial Bias in Data Assessment Tool (Burkhardt et al., 2021) can be useful resources for evaluating datasets for bias. Moreover, limitations identified need to be disclosed. In addition to accounting for potential bias when designing the technology, model or device performance should be evaluated for bias by conducting comprehensive subgroup analysis (e.g., assessing performance metrics across racial and ethnic groups). Even tools that do not explicitly include race or ethnicity as an input can have differential effects for different subgroups. Technology such as algorithms is often applied in the clinic and then monitored. The performance can shift over time and contexts—known as "model drift"—and requires ongoing monitoring and evaluation.

> **Recommendation 3: Researchers should operate with transparency at every stage in the development, application, and evaluation of biomedical technology that may influence health (e.g., clinical algorithms, artificial intelligence [AI] models and tools, medical devices). Researchers should assess and report the performance of biomedical technology across a range of racial and ethnic groups.**

Questions to Assess the Key Considerations

At each stage of the research process, these four considerations (assessing the use of race and ethnicity, forming partnerships with communities, ensuring equity and inclusion throughout the research process, and considering data limitations and study methodology) raise questions for investigators and study teams to consider. For a compiled checklist of questions that researchers can ask themselves throughout the research process, see Box 6-1. As they move through different phases, study teams are encouraged to revisit these questions as the context changes.

BOX 6-1
Questions for Researchers to Consider while Engaging in the Research Process

Assessing the Use of Race and Ethnicity

- Is the use of race and ethnicity appropriate or inappropriate in this study and for what reasons?
- If race and ethnicity are to be included, what is the purpose for using them? How do these constructs relate to other factors that influence health?
- What are potential limitations or consequences of using, or not using, race and ethnicity in this study?

continued

BOX 6-1 Continued

Forming Partnerships with Communities

- Would community partnerships be effective for both accomplishing the research goals and understanding community views on how race and ethnicity may be used? If so, what type of engagement would meet these needs?
- What efforts have been made to understand the steps and account for the time required for successful community outreach?
- Prior to forming the study team, consider:
  - How should the study team be developed?
  - What expertise is needed, including community and interdisciplinary expertise, to carry out the study and assess whether and how the use of race and ethnicity is appropriate for the study?
- During the evaluation phase:
  - What are ways that community expertise did or did not influence and alter the research process details or the trajectory of the research?
  - How can relationships with the community be maintained after this study has concluded?

Ensuring Equity and Inclusion throughout the Research Process

- How are diversity and inclusion in the study sample defined? Are racial and ethnic categories sufficiently detailed, inclusive, and culturally sensitive to address the research questions of interest?
- What methods will be used to recruit and include a diverse sample of participants? Is a broadly representative sample most appropriate, or are oversamples needed to ensure that smaller populations will be adequately included?
- How can the study ensure that participants and communities will equitably benefit from the research findings and from engaging with the research process?

Evaluating Datasets and Study Methodology

- What will be the source of the data: primary/original data collection, secondary data (e.g., legacy study data, EHR-derived, or financial claims), or a combination of the two?
- Do the race and ethnicity data have the necessary level of granularity to address the research question?
- When working with secondary data, is the provenance of the data known? What efforts have been made to acknowledge or reconcile the limitations of the data?
- What associated concepts (e.g., social determinants of health) could be measured to better inform or complement the analysis? Can multiple measures be included, analyzed, and compared?
- How will race and ethnicity be used in data analysis, if at all? How could context (e.g., social, historical, environmental) influence the analysis and interpretation of results?

APPROACHES AND METRICS TO STRENGTHEN INQUIRY ABOUT RACE, ETHNICITY, AND RELATED CONCEPTS

In biomedical research and clinical care, race and ethnicity are often relied upon for purposes that could be better served by using more specific approaches, concepts, or measures. One of the factors perpetuating this problem is the use of the Office of Management and Budget (OMB) race and ethnicity categories beyond their initially intended uses, which are to track the inclusion of U.S. population groups in federally funded activities and provide fairer access to and allocation of federally funded goods and services. Though the OMB categories are frequently required by funders and sponsors for reporting recruitment statistics, the same categories are often used in the design of the study, to structure data for analysis, and to draw inferences. These latter uses are not required, can be scientifically unsupported, and are often less informative than approaches conceptualized based on the research questions. Parsing racial and ethnic categories in more granular ways or in ways that focus on more meaningful variables of health and disease, such as social determinants of health or underlying biological mechanisms, will enhance the discovery process.

Race is often used in place of a variety of distinct, albeit related, concepts—ethnicity, indigeneity, ancestry, and more—which conflates these concepts and collapses multidimensional information about identity and experience. Using a single self-identified measure of race can also contribute to conflating dimensions of race by overlooking interactive or relational aspects that are a part of the social experience of race. Recognition of the multidimensional aspects of race and multilevel aspects of racism can facilitate disaggregating these ideas in ways that are more useful and precise for research. In addition, race and ethnicity are sometimes used as a proxy for unexplained variance, which can lead to misattributing differences—which may be due to a variety of biological, social, or environmental factors. As demonstrated in Chapter 5, there are myriad ways to measure and interrogate the mechanisms at work. Using targeted approaches to tease apart the underlying mechanisms and phenomena will improve understanding and make for better science. Given these considerations, the committee offers the following conclusions and recommendation:

Conclusion 6-4: The concepts of race and ethnicity, among others, are defined, used, and misused differently across various domains of biomedical research, which has contributed to confusion and misunderstandings. However, there is no single unifying measure for the concepts of race and ethnicity across contexts and use cases.

Conclusion 6-5: Race and ethnicity conflate many concepts and collapse multidimensional information about people's experience and identity. There is a need for disaggregation of related concepts and for increased granularity in the data collected to better capture the information for which race has been a proxy. Greater methodological specificity will be required to disentangle the various concepts that are often collapsed into a single "race or ethnicity" descriptor or variable.

Recommendation 4: Researchers should strive to identify which concepts often conflated with race or ethnicity (e.g., environmental, economic, behavioral, and social factors, including those related to racism) are relevant to their study. Based on those concepts, researchers should select applicable measures and do the following:

- **Researchers should not rely solely on self-identification with OMB race and ethnicity categories.**
- **To the greatest extent possible, researchers should incorporate multiple measures in study design, data collection, and analysis to allow for comparison or combination.**
- **If using a single measure, researchers should articulate a clear scientific justification for why it was chosen and discuss its limitations.**

To assist researchers in operationalizing Recommendation 4, Table 6-1 lists key social and biological concepts for which race frequently serves as a proxy. Instead of categorizing groups of people based solely on broad race categories and using race as the framework and basis for data analysis and drawing conclusions, researchers can refer to this table periodically throughout the research study process to assess what other concepts may be salient to incorporate in the study context. If researchers engage communities during the earliest stages of the research cycle and continue to partner with them throughout the process (see section below, “Building Community Partnerships”), community members can aid in identifying what concepts may be most apt in the specific study. Some of these measures may involve disaggregation or categorization that requires larger sample sizes to statistically power some of these analyses. This may increase the cost of some studies to recruit appropriate sample sizes for the targeted measures.

Incorporating People Who Are Members of Small Populations and Who Identify as Multiracial or Multiethnic

Fostering inclusion in the research process goes beyond the early stages of recruitment. The promise of inclusion may not be fulfilled if participants are recruited and then their data are summarily excluded from analysis due to issues such as small sample size. For instance, the multiracial population represents an increasing percentage of the U.S. population, but people who are multiracial are often left out of analyses. Sometimes their data are not used; other times the data are aggregated into a group labeled “Other.” As demonstrated in Chapter 5, there are many approaches taken to analyzing data from people who identify as multiracial or multiethnic. There are advantages and disadvantages to the various methods, but more work is needed to determine best practices for different applications or types of research. Currently, there is no definitive best practice, and the optimal methodology will depend on the context and research question of interest.

Many considerations for including multiracial and multiethnic people highlight concerns with how smaller racial and ethnic populations are treated in biomedical

TABLE 6-1 Race, Ethnicity, and Associated Concepts†

Concept	Recommended Measures or Approaches	Explanatory Notes (See Text for Further Detail)
Self-identified Race[1,2]	- Updated OMB categories - Other detailed, culturally sensitive race categories	It is important to respect an individual's self-identification and measuring self-identification is especially relevant in assessing representation (e.g., for study recruitment). However, other concepts may be a better fit for understanding and explaining health outcomes.
Relational Aspects of Race[2,3]	- Reflected race or street race - Perceived or socially assigned race	Although self-identified race is often considered the gold standard, relying solely on self-identification can miss important variation in how people are perceived.
Structural Racism[4-7]	- Contemporary contextual factors such as segregation indices, measures of income inequality - Historical context, such as presence of slavery, Black codes, racial covenant laws, or federal policies of removal, reservation, termination - Time or life-course exposure	People are racially classified in everyday life in ways that are reinforced by social structures that maintain hierarchies and stereotypes. It is important to identify and account for the legal, institutional, and other factors that perpetuate racism at a structural level.
Social Determinants of Health (SDOHs)[8,9]	- Environmental factors (e.g., pollution) - Social vulnerability indexes - Educational attainment - Access to services - Health behaviors (e.g., nutrition, tobacco use, use of health remedies and supplements)	SDOHs are closely intertwined with structural mediators of racism; structural-level factors may be root causes of the differences seen in the SDOHs. Using zip code or census tract is not a precise or direct measure of race or SDOHs.
Ethnicity[10-13]	- Language - Religion - National or geographic origin - Cultural practices	When factors such as culture, lifestyle, or ethnic heritage(s) are relevant, they should be measured directly.
Immigration Status[14]	- Citizenship status - Immigrant generation - Degree of acculturation	Often intertwined with ethnicity in the U.S.; immigrants' legal status is an overlooked dimension shaping disparities within and between racial and ethnic groups.
Indigeneity[15-17]	- American Indian/Alaska Natives (AIANs) - Enrollment status as members of one of the 574 federally recognized Tribes (sovereign nations) - Community acceptance - Survivors of removal, reservation, assimilation, and termination federal policies	Tribal Nations were original sovereigns on the land and Tribes are sovereign political bodies in the United States. Researchers should be especially cautious about relying only on self-identification as AIAN given the unique political relationships involved. AIAN suffered Genocide as defined by the United Nations Convention Legal Definition (1948) at the hands of the United States government. Resulting in historical and contemporaneous traumas, problematic health status, lower life expectancies, and health access issues.

TABLE 6-1 Continued

Concept	Recommended Measures or Approaches	Explanatory Notes (See Text for Further Detail)
Skin Color or Pigmentation[18-20]	- Monk scale - Melanin Index - CIELAB color space	The Fitzpatrick scale is still commonly used but poorly suited to the purpose of measuring skin color. The von Luschan scale should be phased out due to its troubling history and inaccuracies. The most suitable tool may differ between contexts such as dermatology/clinical and optical medical device.
Known Ancestry[21]	- Racial or ethnic categorization of a person's parents, grandparents, great-grandparents, and earlier ancestors	People often have more diverse ancestry than is reflected in their self-identification using the OMB categories. Asking about known family ancestry can provide more detail and may reflect (dis)advantage in prior generations.
Genetic Markers; Genetic Variation[22]	- Specific genetic markers - Genetic similarity	Race should not be used as a proxy for genetics; race is commonly conflated with genetic ancestry and continental group labels. Directly estimating genetic similarity, or genetic markers of interest, is recommended instead.
Social and Stress-Related Biomarkers of Health[23,24]	- Markers of chronic stress	Highly context-dependent; many different biomarkers may be relevant to the disease or biological pathway of interest.
Other Health Biomarkers and Biological Indicators[25]	- Context-dependent clinical or biological indicators	Race is often used as a proxy for unknown variability; rather, more research may be needed to understand the underlying biological mechanism.

[†] In the United States, the OMB categories are often used interchangeably with race. The 2024 update to the OMB standards combines race and ethnicity categories under a single question. Ethnic categories are often conflated with race categories and sometimes also used as a proxy for concepts described in the table.

NOTES: Race and ethnicity are often used as proxies for other concepts or measurements. Targeted approaches, such as those described in this table, measure or interrogate race and ethnicity more directly. The concepts and measures above can be exposures, mediators, or moderators depending on the context. Additional detail and references can be found in the corresponding subsections of Chapter 5.

[1]OMB (2024). [2]Roth (2016). [3]López et al. (2018). [4]Adkins-Jackson et al. (2022). [5]Brown and Homan (2024). [6]Dean and Thorpe (2022). [7]Gee and Ford (2011). [8]Blankenship et al. (2023). [9]Yearby (2020). [10]Ford and Harawa (2010). [11]Afshari and Bhopal (2010). [12]Massey and Denton (1993). [13]Wight et al. (2011). [14]Asad and Clair (2018). [15]Gartner (2023). [16]Huyser and Locklear (2023). [17]Liebler (2018). [18]Dixon and Telles (2017). [19]Gordon et al. (2022). [20]Monk (2023). [21]Morning and Saperstein (2018). [22]NASEM (2023). [23]Djuric et al. (2008). [24]Lawrence et al. (2022). [25]Aronson and Ferner (2017).

research more generally. In samples designed to be nationally representative, there can be too few individuals who identify as American Indian or Alaska Native, Native Hawaiian or Pacific Islander, Middle Eastern or North African, or Asian to make valid statistical comparisons. Data from these individuals are often excluded or lumped together into a single residual category from which no meaningful inferences can be drawn. Ensuring diverse samples requires revisiting these past practices and making positive efforts towards respectful and equitable inclusion in biomedical research. Therefore, the committee provides the following conclusions and recommendations:

> *Conclusion 6-6: Many people are left out of research analyses either due to missing data or because none of the available categories reflects their background. More granular categories may be aggregated, potentially obfuscating missing data or a misalignment of participants' identities with the available categories. "Other" is a category label sometimes used to aggregate data—combining race and ethnicity categories that are too small for separate analysis, individuals with missing data, and individuals who do not identify with the available race and ethnicity categories.*
>
> *Conclusion 6-7: There is an increase in multiracial identification in the United States, but there is no standard way to account for multiracial or multiethnic people in biomedical research. Even if they are recruited, many people who are multiracial or multiethnic are left out of analysis, often because of small sample sizes or uncertainty about how to conduct the analysis. There is a need to include people with mixed ancestry or multiple identities in biomedical research and to appropriately incorporate them in analyses to the greatest extent possible to ensure a diverse sample population.*
>
> **Recommendation 5: At each stage of the research process, all racial or ethnic category inclusions and exclusions should be based on a clear scientific rationale motivated by the research question.**
>
> **Researchers should:**
> - **Consider oversampling for smaller populations to ensure adequate power for analysis.**
> - **Describe and characterize all recruited populations, even if some cases cannot be included in an analysis due to limits of small sample size.**
> - **Articulate the purpose of aggregating categories, deriving missing data, or omitting cases.**
> - **Use aggregate category labels that are motivated by the research question (e.g., "Members of minoritized racial and ethnic groups") or reflect the analytical approach (e.g., "Remaining participants").**
> - **Justify the choice of reference population.**
>
> **Researchers should not:**
> - **Combine categories solely to improve statistical power.**
> - **Make inferences about residual categories.**
> - **Aggregate participants into the nonspecific category labels "Other" or "non-White" because they can be isolating and reinforce one category as the norm.**
>
> **Recommendation 6: Researchers should consider the inclusion and analysis of multiracial and multiethnic participants at each stage of the research process, especially when developing research questions and designing the study.**

Throughout the course of a study, researchers should:

- **Identify relevant concepts (e.g., ancestry, self-identification);**
- **Ensure that respondents can select multiple races, ethnicities, or ancestries during data collection;**
- **Report granular data for multiracial or multiethnic respondents to the greatest extent possible, while respecting confidentiality concerns; and**
- **Identify a plausible classification scheme for including multiracial and multiethnic people in analysis, based on the research question or context; or provide a comparison of results using alternate approaches.**

Researchers should design their studies in advance with small racial and ethnic populations in mind, including incorporating oversamples as needed to ensure statistical power for relevant comparisons. When this is not possible, including when using legacy data, all data aggregation should be scientifically justified based on hypothesized mechanisms of interest. For instance, two small populations may experience the same exposure or environment, which could warrant combining the categories. Increasing statistical power is not inherently sufficient justification to aggregate categories, and researchers should consider whether pursuing statistical significance or power will actually improve the quality of the results. Researchers should also avoid using terminology such as "Other" or "non-White" when labeling population groups. To "other" individuals or groups is dehumanizing and is particularly inappropriate when the data were not collected using that term. Using "non-White" implies that White people are the reference group against which everyone else should be compared. Labeling terminology should be respectful of people's identities and relevant to the research question. To be sure, even when offered more granular options, some participants may still prefer to have the opportunity to write-in another racial or ethnic identity because their identify is not captured among the finite number of racial and ethnic categories. Recommendation 5 specifically recommends not assigning participants to the category "Other" as a means of dealing with small group sizes when the participants themselves did not select it.

Some racial and ethnic groups may have shared history or experiences of discrimination, and the term "non-White" has sometimes been used in historical and social research to emphasize solidarity among some minoritized populations. Even so, the term is not well suited to biomedical research because it homogenizes experiences across diverse racial and ethnic groups. Recommendation 5 does not preclude the possibility that there could be a valid reason to compare racial and ethnic groups to White populations; however, researchers should question assumptions that emphasize a division between White/non-White and avoid defaulting to approaches that reinforce White as the norm. For example, if studying consequences of White supremacy, there may be a need to distinguish White populations; however, from a scientific standpoint, researchers should consider whether comparing White and non-White is in fact the most effective methodology because there could be heterogeneous effects across groups, which challenges the practice of modeling all other racial and ethnic groups as one homogeneous population. Regardless, "non-White" is not an appropriate term for aggregating small populations for analysis. A number of other terms could be used instead, and Recommendation 5 offers two alternatives for researchers to consider.

The terms chosen should be specific to the methodology and research context. For example, "Members of underserved racial and ethnic groups" may be relevant in the context of health care access.

As with considering appropriate category labels, inclusion of multiracial and multiethnic respondents is not only relevant at the data collection stage. Accounting for mixed race, ethnicity, or ancestry should also be built into study designs to better understand both within and between population variations. Throughout study design and analysis, researchers should think critically about assumptions related to group "homogeneity" or "admixture"—that is, ideas in which groups of people are categorially described as one or the other (NASEM, 2023; Shim et al., 2014). For data collection, researchers should consider whether self-identification as multiracial is most relevant to their research question or whether measures of ancestry (self-reported, genealogical, or genetic similarity) should also be collected or assessed. At the analysis stage, how multiracial and multiethnic people are accounted for should be scientifically justified and related to the specific research question and potential mechanisms (Yao et al., 2021). For example, a study investigating contemporary racial discrimination as the mechanism of interest for a health disparity might consider using a categorization scheme that best reflects the diversity of experiences faced by multiracial people of different racial backgrounds (Franco et al., 2021; Gay et al., 2022; Harris, 2016). On the other hand, a study to investigate racial identity affirmation and belonging might group all multiracial individuals together, regardless of racial background, because threats to affiliation and belonging are consistently reported among multiracial individuals with a variety of backgrounds (Albuja et al., 2019, 2020; Franco et al., 2021; Nalven et al., 2021; Sanchez, 2010; also see Forthal, 2024 in Appendix C). In the absence of a specific hypothesized mechanism, or when multiple processes may be at play, researchers should consider comparing results using different categorization schemes. How studies define, include, or exclude their multiracial participants can change outcome estimates for other racial categories as well (Facente et al., 2022; Klein et al., 2019; Saperstein, 2009; Yao et al., 2022). For example, in a study of men living with HIV, whether estimates of the Black–White disparity in experiences of stigma were statistically significant depended on how multiracial participants were categorized (Facente et al., 2022; also see Forthal, 2024 in Appendix C).

To implement this approach and determine appropriate categorization schemes for their own work, researchers can consider the following questions:

- What mechanism may be driving the outcome of interest? How is multiracial ancestry or multiracial identity relevant to the research context?
- What is known about this mechanism or context for individuals with multiracial ancestry or identity? What does existing evidence suggest about which aspects of multiracial participants' identity may be most salient?
- Which monoracial category or categories would likely have the most similar outcomes and experiences?

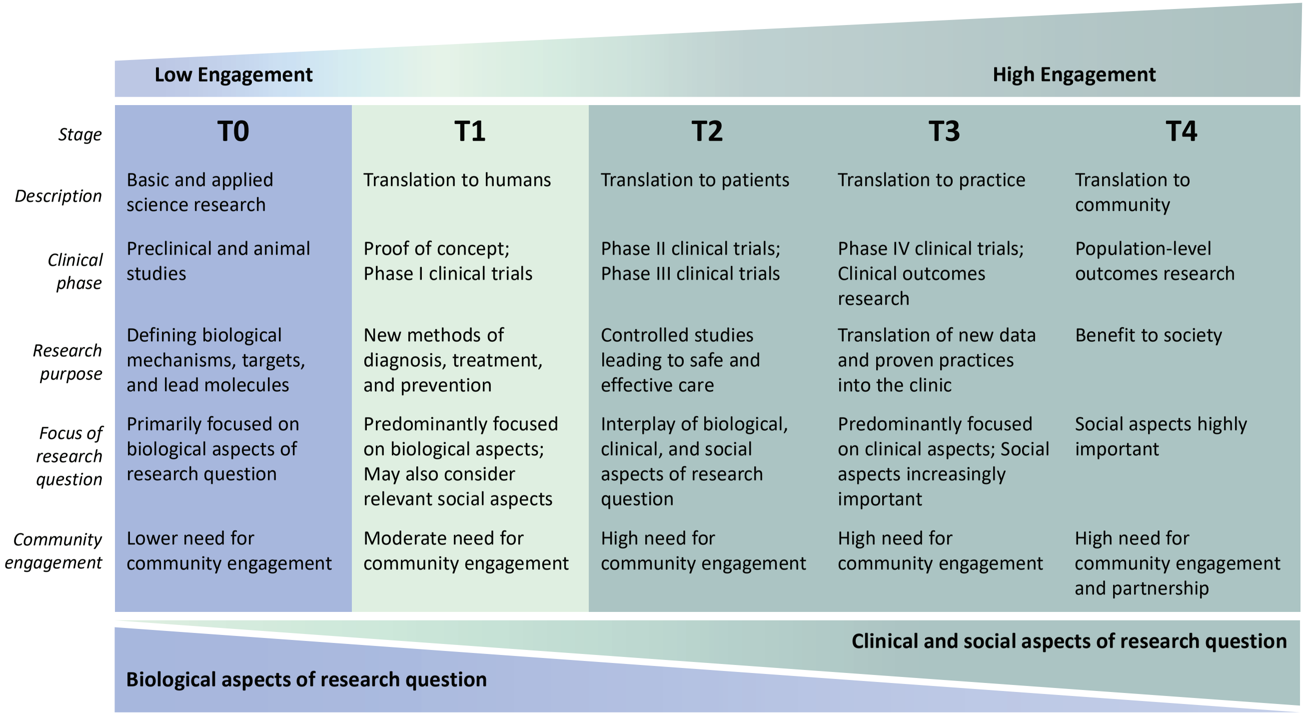
It is also important to weigh the drawbacks of past strategies for including multiracial or multiethnic participants (see Table 5-1). These include asking people who identify as multiracial to select their single "best race" to facilitate analysis and grouping participants into subcategories defined by having or not having a White identity (e.g., White–Nonwhite, Nonwhite–Nonwhite). Treating White people as the norm against which all others should be compared has long been an unquestioned default in research across disciplines, but the selection of a reference category should be done intentionally and responsibly because it affects the interpretability of results (e.g., Johfre and Freese, 2021). Similarly, rather than asking multiracial people to simplify their self-identity down to a "best race"—which may cause discomfort and be less precise for analysis (Giebel, 2023; Jackson, 2023)—researchers should consider collecting additional measures such as perceived or reflected race (see Table 6-1) that may better align with their research question or hypothesized mechanism of interest. Whenever possible, it is preferrable to use or develop methods for including data from multiracial or multiethnic participants that preserve how they chose to identify themselves (see, e.g., the additive categorization scheme, which sorts respondents into every race or ethnicity category they select).

BUILDING COMMUNITY PARTNERSHIPS

Evaluating the Need for Community Engagement

Community partnership is essential to improving the appropriate use of race and ethnicity in biomedical research. However, the type of engagement best suited to a study will depend on the type of study, line of scientific inquiry, and community context. One way to categorize biomedical research is based on where it falls within the operational stages of translational research, as illustrated (Figure 6-2) in a report from the Institute of Medicine and its many antecedents (IOM, 2013). Much of the research at the T0 stage is basic and preclinical work using model organisms and cell and tissue lines, and the focus is on defining fundamental biological mechanisms, molecules, and pathways involved in health and disease. Biological mechanisms are universal among all humans (and often nearly universal among many types of organisms). Therefore, race and ethnicity are less directly relevant to basic science and preclinical research, and T0 studies have relatively low need for community engagement. Consideration should also be given to whether these study teams have the resources or expertise to support meaningful engagement that will ensure benefit sharing with the community participants. Although there are circumstances when early-stage research would benefit from and need community engagement, a lack of standard resources for and expertise in community engagement among basic science study teams could result in short-lived, superficial attempts at engagement that exacerbate rather than resolve problems. Some have characterized the related phenomenon called "health equity tourism" in which researchers pivot into health equity without the requisite depth of knowledge and commitment and, thereby, risk producing misguided or substandard work (Lett et al., 2022). For these reasons, the committee assessed how research contexts differ across the translational spectrum.

For types of biomedical research that fall in stages T1 through T4, community partnership needs to be considered and, in many cases, should be an integral part of the process throughout the research cycle (see Figures 6-1 and 6-2). At the T1 stage, there is a moderate need for community engagement. Careful consideration should be given to whether social questions, including race or ethnicity, may be relevant. Attention should be



Stage	T0	T1	T2	T3	T4
Description	Basic and applied science research	Translation to humans	Translation to patients	Translation to practice	Translation to community
Clinical phase	Preclinical and animal studies	Proof of concept; Phase I clinical trials	Phase II clinical trials; Phase III clinical trials	Phase IV clinical trials; Clinical outcomes research	Population-level outcomes research
Research purpose	Defining biological mechanisms, targets, and lead molecules	New methods of diagnosis, treatment, and prevention	Controlled studies leading to safe and effective care	Translation of new data and proven practices into the clinic	Benefit to society
Focus of research question	Primarily focused on biological aspects of research question	Predominantly focused on biological aspects; May also consider relevant social aspects	Interplay of biological, clinical, and social aspects of research question	Predominantly focused on clinical aspects; Social aspects increasingly important	Social aspects highly important
Community engagement	Lower need for community engagement	Moderate need for community engagement	High need for community engagement	High need for community engagement	High need for community engagement and partnership

FIGURE 6-2. Community engagement and translational stages of biomedical research. The T0–T4 system can be used to categorize research based on where it falls along a translational spectrum. Biomedical investigators can assess where their research sits on the translational research continuum to determine the level of community engagement that should be considered or is needed. At T0, basic science studies focus primarily on biological questions (e.g., analyzing a biological mechanism, identifying drug targets). Moving up the translational spectrum through T1 to T4, clinical and social aspects of the research questions become increasingly important. Clinical aspects might include general or disease-specific clinical indicators. Examples of social aspects are social determinants of health, exposure to racism, and discrimination-related stressors, among others.
SOURCE: Adapted from Blumberg (2012).

given to recruiting diverse groups of participants to the extent possible even when working with small sample sizes. At stages T2–T4, community engagement or partnership is essential, as these types of research deal directly with human populations and questions that are likely to intersect with issues of race and ethnicity. Moving up the translational spectrum from T0 to T4, the type and dimensionality of community engagement will change, and the level of investment needed for meaningful engagement will increase.

> *Conclusion 6-8: Basic, preclinical, and proof-of-concept studies that seek only to interrogate a biological mechanism can, but need not, invoke questions of race and ethnicity. Regardless of this choice, representing human biological diversity, including in early-stage research, is essential to assure generalizability. Biomedical studies that involve human populations and that hold social and clinical implications necessitate a high degree of cooperative community engagement or partnership.*

In addition to the guidance provided in Figure 6-2, researchers can answer the following questions to further evaluate the need for community engagement in their study. Answering “yes” to these questions indicates that community collaboration would benefit the study by integrating community-identified needs and priorities and helping to clarify the social and environmental determinants that provide the context for the study. Considering these questions can also help study teams begin to identify who comprises the community relevant to the research context.

- Is the disease or condition of interest disproportionately represented in some population (defined by exposure, geography, racial or ethnic background, etc.)?
- Do the specific aims of the study involve racial or ethnic communities who could benefit from the research?
- Are there plans to investigate social issues related to the biomedical topic at hand, either now or possibly in the future?
- Could these data be (re)used to address research questions related to health disparities in racial or ethnic populations?

The Value of Community Engagement and Partnerships

The existing guidance for engaging and partnering with communities, which was presented in Chapter 4 and Table 4-1, is a solid foundation for biomedical researchers to work from. Importantly, community engagement is a collaborative process between the research team and the people who will be affected by the study and its outcome. It is rooted in a set of scientific and ethical principles (see Chapter 2, section “Guiding Principles”) that guide the interactions, communication, decision making, and organization of the partnership. Given how race and ethnicity are intertwined with people’s identity and experience, collaborative engagement at every stage of the research process is essential, as it can provide researchers a key perspective and deeper understanding about context that is vital for the use of race and ethnicity in research.

Information gathered by the committee also emphasized the importance of true partnership throughout the entire research cycle. Partnership in research means "we [community members and researchers] make decisions together. Community members have a voice at the table. They are part of the decision-making. It's a collaborative where it's not just me getting an email, and the claim being made that I'm part of the team. It's real work. We're academics, folk in practice, and community. And when I say community, I'm talking grassroots folk" (Ella Greene-Moton in remarks to the committee on March 14, 2024). Members of the community can play a role in identifying and prioritizing research questions that are important to them. A speaker emphasized, "I think that at the beginning of research, even the questions, let's formulate them together" (Gladys Vega in remarks to the committee on March 14, 2024). Community members and representatives can also give valuable input on designing protocols that meet their needs and that account for the barriers they face to participation and provide insight and networks to aid in the dissemination of research results.

Forming partnerships with community leaders and members requires patience, time, funding, and expertise. It is important to understand the pros and cons of different approaches to community engagement (see Table 4-1) and to recognize that more extensive community engagement plans may require a longer study timeline. Research teams may need a community engagement expert who can facilitate meetings between community leaders and research team members, identify challenges, develop strategies for building trust and respect, develop an engagement or partnership plan, manage that plan, and handle logistics.

Some communities or populations may have unique needs, preferences, or requirements. Approaching Tribal Nations could involve more formal contact and entrée for research purposes than typically needed in working with other communities (see Chapter 4 section "Collaborating with Indian Tribes on Biomedical Research Studies"). A liaison could help navigate these complexities.

To maintain existing relationships, as well as build new ones, research entities must be involved in ongoing relationship-building activities to cultivate a consistent presence in surrounding communities of interest. Funders are also key partners in creating opportunities and support for in-depth community participation in research. They can structure funding allocations and reporting timelines that provide the money and time needed to build effective and lasting partnerships. However, as discussed in Chapter 4, funding models are frequently not supportive of sustained community engagement. Further, many funders do not allow for community partners to serve as co-PIs on studies, and instead involves them as sub-awardees on grants. This model inherently doesn't allow for an equitable partnership between researchers and community members. Although outside of the scope of this report, this is an area that requires careful consideration and change to advance this important work. The committee makes the following recommendation:

Recommendation 7: Researchers collecting and using race and ethnicity data in biomedical research with human populations should identify and partner with specific communities relevant to the research context. Researchers should collaborate with community engagement experts and organizations and, to the greatest extent possible, partner directly with community members to optimize authentic, continuous, and sustained researcher–community member engagement undergirded by mutual trust.

- **From the earliest stages of the project, these partnerships should be established to inform hypothesis development and study design, including how**

race and ethnicity information should be collected and used, through results interpretation and dissemination.
- **Research teams should communicate potential benefits to community partners from project initiation through results dissemination.**
- **In the case of secondary data use, researchers should consult documentation or original investigators from participating studies to understand how communities were involved in the process.**

IMPLEMENTATION OF THE REPORT'S RECOMMENDATIONS

Aware of the broad scope of biomedical research, the committee developed an approach that can be applied in many biomedical contexts and outlined general considerations for the use of race and ethnicity across the research process. However, implementing the foundational concepts and recommendations will differ across disciplines and studies, as the specific context varies. To help operationalize these recommendations, the committee presents a few hypothetical research scenarios that contextualize the recommendations. Following these examples are some unique considerations applicable to basic science, industry (e.g., pharmaceutical development), artificial intelligence, and the development of medical devices. Closing out the chapter are strategies for operationalizing the recommendations that are directed to everyone in the biomedical research community.

Research Scenarios

The following are hypothetical scenarios that researchers may encounter. They serve as a thought exercise for how the recommendations could apply in different contexts.

Scenario 1

MK is an established principal investigator (PI) at a large research center at an urban R1 university, with a network of many potential collaborators. One of her colleagues has expertise in qualitative research methods and community outreach and is her co-PI on a new National Institutes of Health (NIH) grant about a health condition. Given the specific aims to study this health condition, the team wants to ensure the work will benefit the local community. Before enrolling participants, MK's co-PI holds a series of listening sessions at local churches and other community centers. As a result, they modify their study objectives and decide to also measure social determinants of health and environmental exposures to better understand and contextualize the disease of interest.

MK's prior research has primarily been funded through NIH grants, and in the past her team has primarily used the NIH planned enrollment table (based on the 1997 OMB categories) to determine their data collection strategy. For this new study, the team decides a priori that they intend to make some between-group comparisons among racial and ethnic groups, so instead of collecting a representative sample, the team plans to oversample smaller groups to ensure sufficient statistical power. For data collection, MK's team is planning to use the 2024 OMB categories, including the more detailed subcategories. In addition to collecting self-identified categorical race and ethnicity data for NIH grant reporting, MK's co-PI assesses other dimensions of diversity, including age, sex and gender identity, income, and educational attainment, and will include open-ended prompts for qualitative analysis such as: *What words or terms come to mind when I ask you to identify yourself?* To study interpersonal experiences with racism, they also collect reflected race.

Throughout the study, MK and her team continue to assess how race and ethnicity are being used and to update community members. Afterward, the team shares results with the community and integrates lessons learned for the next study.

See: Recommendations 1, 2, 4, 6, 7; Table 6-1; Table 6-2; Box 6-1

Scenario 2

DW is a new assistant professor in biostatistics at a mid-size research institution. With their team, DW would like to create an algorithm-based risk calculator that uses risk factors to guide decision-making about additional testing in patients with a suspected disease condition. Evidence in the literature suggests that race may be a (non-causal) risk factor for the condition.

DW is using an EHR dataset from a local hospital system, and they have access to clinical indicator data as well as demographic information. Before starting to develop the algorithm, DW conducts some initial analysis to become familiar with the dataset, understand its limitations, and evaluate potential biases. They find a number of limitations, including a high proportion of missing race and ethnicity data, that they note for any later manuscripts. They also identify a group of multiracial individuals and test out different categorization schemes that could be most appropriate for including them in analysis.

To optimize the algorithm, DW tests various parameter sets, both with and without race and ethnicity. In early versions, it appears that including race and ethnicity variables may improve the performance of the algorithm, but they find that another parameter set without race or ethnicity performs equally well. In this case, DW concludes that it is unwarranted to use race and ethnicity as proxies for unknown social factors and decides against using them in the algorithm.

Even so, DW conducts a thorough subgroup analysis for the racial and ethnic groups included in the dataset, including a multiracial group, and finds that the algorithm performs similarly across different groups. When DW publishes the results of their algorithm, they detail the rationale for their decisions regarding race and ethnicity in the manuscript and also makes the information available to other researchers via a repository.

See: Recommendations 1, 2, 3, 6; Box 6-1

Scenario 3

JR is a postdoctoral fellow analyzing factors associated with disease severity. The existing dataset has information about relevant physiological traits as well as demographic data, including sex, age, and self-reported race. JR finds a correlation that suggests race could be a risk factor for disease severity. He knows that causal inferences cannot be made from a correlation with race and that caution should be exercised in reporting race as an association in this context. In discussions with his PI, the two of them decide to include the result in their manuscript and acknowledge the limitations, stating the following:

> *Our results suggest an association between self-reported race and disease severity. Nonetheless, this result should be interpreted with caution. While race may be correlated with increased disease severity, there could be a variety of plausible explanations, including undetermined physiological factors or social influences such as structural racism, and further research is needed to elucidate the underlying mechanism. We hypothesize that XYZ could be contributing to the result. Of note, a limitation of the dataset is a lack of information about social and environmental factors to better contextualize the results.*

When JR goes on to present his findings at a conference a few months later, he makes sure to clearly articulate the limitations of their study design and to emphasize that race and ethnicity are not causative factors for the disease outcome they examined. In his future studies, he learns to collect and use datasets with more nuanced measures and stays away from searching for arbitrary correlations without rationale.
See: Recommendations 1, 2, 4; Box 6-1

Basic Science and Early-Stage Biomedical Research

Driven by curiosity about how biological systems work, basic science expands the foundation of scientific knowledge and sometimes leads to unexpected breakthroughs and applications in medicine. Basic science research seeks to reveal fundamental biological mechanisms and can give rise to hypotheses about health and disease that can inform applied research and may translate into clinical treatments. Basic biomedical research commonly uses a variety of informatic, imaging, biochemical, biophysical, molecular biology, and immunology techniques, along with cell culture for in vitro studies and animal models (e.g., mouse) for in vivo work. Early-stage preclinical studies are designed to show preliminary proof-of-concept to begin to translate discoveries from the bench to humans. These studies are generally small in scale and can look quite different from clinical trials, which must meet specific criteria to test treatments or interventions in humans. Even small Phase I clinical trials prospectively assign participants to different groups to evaluate the effect of an intervention on a health-related outcome (NIH, 2017). In contrast, basic discovery research is not subject to the same criteria. Preclinical studies sometimes involve secondary research with human tissue, such as harvested cells, biopsies, or post-mortem samples, to explore a biological mechanism, characterize a condition, demonstrate feasibility, or validate a hypothesis.

In considering the translational spectrum of biomedical research (Figure 6-2), the committee acknowledges that race and ethnicity may be less directly and immediately relevant to basic science or early-stage research that seeks only to examine biological mechanisms (see Conclusion 6-8). Indeed, fundamental molecular and cellular mechanisms are often shared across species and are the same across racial and ethnic groups. Though there are epidemiological differences in disease prevalence, and in the many potentially salient social or environmental factors that may contribute to them, this does not mean that the underlying biological mechanisms necessarily differ across groups. For example, rates of cardiovascular disease may vary across populations, but the cellular mechanisms and biological sequelae are generally the same for everyone, though genetic variation may exist.

Although it could be easy to rely on the universality of biology to say that race and ethnicity have no role in the context of basic science or preclinical studies, it is worth considering what may be missed by failing to consider race and ethnicity at all in early-stage research. It is nonetheless important for basic science investigators to consider how race and ethnicity may have influenced past evidence that was gathered in this area and whether race and ethnicity could be relevant to applications of this line of research in the future. Even in basic science, decisions about whether to use race and ethnicity should be deliberate, and if a future application of this research could invoke social context, it is important for researchers to start thinking about the potential implications of these social dimensions early in discovery science. Building awareness of potential implications of race and ethnicity in early-stage research could catalyze progress in subsequent translational stages of research.

One approach is employing racism-conscious research (see Chapter 5 section, "Moving Towards Racism-Conscious Research") early in research. At study design, investigators can ask how race and ethnicity may influence or intersect with some attribute(s) of this research study, either now or in the future (Figure 6-1). It may not be apparent how race and ethnicity could be relevant when working with animal models; however, for example, most animal models have low-pigment skin, so using these animals to design optical sensors or study mechanisms that could be influenced by skin pigmentation could lead to bias when the results are translated to humans with highly pigmented skin. As another example, mouse models are often modified with human genes for mechanistic studies. Even though the studies are in mice, differential distributions of alleles in human populations that correlate with ancestry may be relevant when genetically modifying mice. Even if race and ethnicity are not immediately pertinent, it is valuable to understand potential implications early on.

Many basic science study teams are small and have limited grant-based funding, posing additional challenges to adopting some of this report's recommendations. These smaller scale, discovery-based studies may lack the funding or expertise to develop extensive community engagement plans or to address questions about social context, but investigators can reach out to collaborators and other partners for input and guidance. These challenges also highlight the importance of assembling diverse, interdisciplinary study teams from the beginning of a project to help identify potential blind spots in the research question or study design early in the process. Despite the practical limitations of small-scale basic science, investigators can be thoughtful about study design choices and acknowledge the limitations of their approach. To be successful, efforts to root out the effects of biased data and analysis will need to be included in the earliest stages of research, not only at clinical applications. Building awareness of possible connections between basic science and race and ethnicity can train investigators to pause before beginning a study and to be watchful for biased assumptions and evidence.

Considerations for Industry

Recommendations in this report also apply to industry-sponsored research. For industry, engaging with communities and advocacy groups remains an important way to build trust, enhance awareness, and provide education and outreach about the drugs and treatments they are developing. Understanding the populations most likely to be affected with a disease could help identify potential barriers to participating in clinical trials so that the trial design could better serve communities by addressing contextual and socioeconomic factors. For example, patients may be willing to participate in a study, but their work schedule for their livelihood could prevent them from attending follow-up visits. Alternatively, time off work may not be an option for some participants, or they may not have transportation to a distant trial site. In response, industry is increasingly undertaking decentralized trials, which have the potential to increase engagement among underserved communities. Technology may facilitate decentralized clinical trials, making recruitment more efficient and easing the burden of follow-up for participants; however, these strategies are not without drawbacks. Care should be taken to ensure that patients are not excluded due to lack of access to internet or mobile devices, digital illiteracy, rural residence, or socioeconomic status.

A couple of factors make industry-sponsored research unique. First, industry-sponsored research is regulated in the United States by the U.S. Food and Drug Administration (FDA) (see Chapter 4). Historically, private companies, though they may be committed to addressing race and ethnicity in research, have not been able to resolve such issues as a lack of diversity and inclusivity alone. To overcome this challenge, systemic support will be needed across regulatory bodies, industry, and public–private partnerships. The committee concluded:

> *Conclusion 6-9: FDA is a powerful regulator and, via industry guidance, heavily influences the use of race and ethnicity in industry-sponsored research for inclusion purposes.*

Second, industry often undertakes research on a global scale. Although this report focuses on U.S.-based constructions of race and ethnicity, it is important to recognize the complexity of these issues in an international context. Racial and ethnic descriptors vary greatly among countries. In different countries, race and ethnicity labels are frequently conflated with each other and with categories like nationality, citizenship, caste, tribe, or dialect group (Morning, 2008). In addition, similar terms have different meanings to people in different countries. Large-scale clinical trials are typically international, so issues of race and ethnicity cross borders. Data collection practices and privacy laws vary by country, creating variance that may be a barrier to the harmonization of racial and ethnic group categories. The extent to which major international regulatory authorities can work together will facilitate progress.

Although not unique to industry, mistrust is a particular barrier that must be overcome to improve inclusion in private sector biomedical research and development. Among racial and ethnic minority groups, there is often mistrust of the health care system and medical research due to past harms, safety issues, or unclear public health communication (Pahus et al., 2020; Scharff et al., 2010). The biopharmaceutical industry faces further mistrust due to public perceptions of the profit motive inherent in drug development and perceived conflicts of interest. These dynamics create a negative cycle where lack of diversity in clinical trials compounds existing mistrust, increasing reluctance to participate in trials among racial and ethnic minority populations.

It should be noted that some evidence suggests the contrary—that underrepresented populations are just as willing to participate in research as those who identify as White (Wendler et al., 2006), but some racial and ethnic groups may be underrepresented in trials because they are not as frequently invited to participate, have more limited access to certain health care resources and institutions, or face greater obstacles (e.g., childcare and transportation) to taking part (Fisher and Kalbaugh, 2011; Wendler et al., 2006). Supported by sustained investment across the health care landscape, proactive communications about the benefits of and safeguards relating to clinical trial participation could begin to overcome trust deficits. Gaining community trust through partnership could build a foundation for improving representation in industry research and development.

Considerations for Biomedical Applications of AI

Efforts to employ clinical algorithms and other decision-making tools across the health care ecosystem in a way that maximizes benefits and reduces potential harms are hampered by the need for more guidance on the development, assessment, and implementation of these tools. As discussed in earlier chapters,[4] there are some guidelines available from government organizations and professional societies regarding both statistical and AI-based clinical algorithms. However, the existing AI-specific guidance provides little commentary directly on the use of race and ethnicity in algorithms. In addition, much of this available guidance is based on assessments of algorithms that are already in clinical use for the purpose of mitigating deleterious effects on health outcomes, particularly for racial and ethnic minority groups. As a result, the existing guidance is often insufficient to address the numerous pitfalls that can accompany both the design and application of these tools in clinical practice (Cary et al., 2024; Jain et al., 2023).

The application of clinical algorithms, especially AI-based ones, in medicine is rising, and the need to ensure they are safe, fair, and transparent is increasingly recognized. While more is needed in terms of standardized policies, particularly at the federal and state level, to identify and implement best practices for developing, testing, and implementing clinical algorithms to promote equitable care, new guidelines provide some standards for algorithmic developers. FDA issued guidance broadening oversight of clinical-decision support tools, including algorithms (FDA, 2022). In 2023, the agency published a draft guidance on AI and machine learning-enabled device software functions (FDA, 2023); updated guidance is anticipated in 2024 (Morris and Sharma, 2024). In addition, a recent rule issued by the U.S. Department of Health and Human Services underlines the importance of addressing racial bias in clinical algorithms as part

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[4] For an overview of existing guidance for AI in clinical algorithms, see Chapter 4, section "Lessons from Clinical Guidelines and Algorithms."

of broader nondiscrimination protections in healthcare. The rule stipulates that health care entities must actively identify and mitigate discriminatory effects, including race-based bias, when using AI and other decision-support tools (HHS, 2024a; HHS, 2024b).

Analytic strategies targeted at various points of the algorithmic life cycle are emerging to mitigate racial and ethnic bias in AI algorithms (Cary et al., 2024). Strategies include collecting higher-quality data from representative patient groups and carefully characterizing any biases in secondary datasets, which are subject to limitations of missingness, inaccuracy, and bias (see Chapter 3 section, "Race and Ethnicity in Secondary Data Analysis"). When developed from datasets with these limitations, AI algorithms can have cascading negative consequences for racial and ethnic minority groups by increasing the potential for misdiagnosis or late diagnosis and restricting access to lifesaving medical interventions. For this reason, it is important for researchers to carefully consider the provenance of the data they use in their studies and assess any potential sources of bias along with other limitations (see Box 6-1 and Recommendation 2). However, one obstacle to assessing bias when dealing with AI tools is that algorithms are often proprietary, preventing individual researchers from digging into their inner workings without employing creative workarounds (Obermeyer et al., 2019). Lack of access to an algorithm's training data and detailed methodology also limits opportunities to understand the mechanisms behind any disparities in its performance, especially across different racial or ethnic groups (Obermeyer et al., 2019).

Several tools can be used to assess bias in datasets. The METRIC framework is a framework for assessment of the quality of biomedical data comprising 15 dimensions that enable AI algorithmic developers to know about biases that may affect fairness of algorithms (Schwabe et al., 2024). The Racial Bias in Data Assessment Tool provides an evidence-based assessment tool for assessing the risk of racial and ethnic bias in datasets for secondary analysis (Chapin Hall, 2024) . Algorithm design and development strategies focus on the selection of the predictor variables, the outcomes and methods used for deriving the algorithm. If a dataset is assessed to be biased, mitigation techniques may include data weighting or sampling methods to make it more representative of the population in which it would be used. Derivation of the algorithm can be optimized for fairness by adjusting the method to incorporate some aspects of fairness in addition to statistical fit to the data, such as ensuring that error rates across racial groups are similar when minimizing overall error (Ghassemi, 2024). After an algorithm is implemented, monitoring measures include its impact on treatment allocation and health outcomes over time to ensure they do not deteriorate. More generally, development of clinical algorithms should investigate and track anticipated pitfalls of using race and ethnicity throughout algorithmic life cycle from the design phase to implementation and monitoring (see Chapter 4 section, "Guidance for Race and Ethnicity for Clinical AI Algorithms").

Algorithmic biases sometimes stem from a lack of understanding of domain-specific clinical and social aspects, and one solution is to enhance statistical and AI expertise with social science, health disparities, and clinical expertise to bring a multi-disciplinary approach to algorithmic development (Cary et al., 2024). Social scientists typically consider of bias as inclinations in human thinking and reasoning that must be addressed during algorithmic design. Health disparities researchers and clinicians see bias as a contributing cause to health care inequities in access, allocation, and outcomes. For example, an algorithm analyzed by Obermeyer and colleagues (2019) had racial biases because differential access to health care means that health care cost is a poor proxy for health. This is well-known in health disparities research, and algorithmic bias could be mitigated if health disparities researchers were involved in developing this algorithm. Thus, a multidisciplinary approach could help to identify, assess, and mitigate biases more effectively (e.g., Joyce et al., 2021).

The guidance provided in this section is necessarily brief since the application of AI in biomedical research is an emerging and dynamic area. However, the committee acknowledges that AI technologies, especially generative AI that creates new content (e.g., text, images, and audio) that mimics human-generated content, are rapidly evolving and will certainly be used in biomedical research and clinical algorithm development. Some are optimistic that AI can be used to promote equity (Pierson et al., 2023). Yet, the deep learning technology that underlies recent advances in generative AI has significant drawbacks—notably a lack of interpretability, which can be problematic in applications where understanding the reasoning behind decisions is crucial, such as in health care (Clusmann et al., 2023; Tian et al., 2023). Furthermore, the huge volume and variable quality of data utilized in the development of generative AI are likely to conceal racial and ethnic data biases (see Box 4-3), which can be difficult to detect and overcome (Omiye et al. 2023).

Development of Medical Devices

Medical devices are approved through different regulatory pathways than traditional pharmaceuticals. The FDA has long used the 510(k) pathway to bring new medical products to market, and this has been the dominant pathway for medical devices (Aboy et al., 2024). In recent years, most medical devices with an AI or machine learning component have been cleared through the 510(k) pathway (Benjamens et al., 2020; Muehlematter et al., 2023; Reuters, 2023). The 510(k) pathway provides clearance for devices that have proven to be "substantially equivalent" to a device that has already been approved, also known as the predicate (Muehlematter et al., 2023). One challenge with this approval pathway has been the variable interpretation of substantial equivalence, leading to the approval of several generations of devices with claims of equivalence to each other, thereby straying further from the original predicate and creating safety concerns for patients (Muehlematter et al., 2023).

Suggestions to improve this complex pathway for all parties have long been documented. A 2010 workshop hosted by the Institute of Medicine, for example, provided perspectives from industry associations as well as academic and patient organizations on improvements to this clearance process to benefit patient safety (IOM, 2010). Suggestions provided by workshop participants included better educating the American public about the premarket approval process, creating robust guidance for FDA to better exercise its regulatory authority, and mandating the reporting of adverse events when using these new devices (IOM, 2010). With the increased use of AI methods in these products, there is also a need for more scrutiny on these components when determining substantial equivalence with older predicates to improve care and mitigate patient harm (Muehlematter et al., 2023). Furthermore, many of the predicates against which new devices are assessed are often built on legacy data that may now be considered outdated or problematic. Thus, there is a need for more guidance (see Recommendations 2 and 3) on how to reconcile with the use of these inequitable devices that have not yet been recalled.

Another persistent challenge accompanying the development of many new medical devices is the issue of small sample sizes (see Recommendation 5) for safety group testing, which often lacks representativeness and results in insufficient statistical power to do robust subgroup analyses. For example, when evaluated with separate equal-sized subgroups of lightly and highly pigmented skin, many pulse oximeters exhibit inaccuracies detecting hypoxia in people with darker skin (Bickler et al., 2005; Feiner et al., 2007). These discrepancies and inequitable device performance have contributed to disparities in health outcomes, such as during the Covid-19 pandemic (Fawzy et al., 2022). Legal scholars have also argued that continuing to utilize these devices in clinical care settings may open health care institutions up to potential legal liability by potentially violating a recently finalized healthcare antidiscrimination law[5] (Kupke et al., 2023). The equitable design of medical products is compromised when population subgroups within safety test groups are too small to have statistical power, such as those currently used for device testing. Therefore, the committee concluded:

> *Conclusion 6-10: There is a need for more guardrails to ensure that health technologies meet federal safety thresholds for all clinically relevant subgroups, not only a given assessment group overall.*

One potential way to enforce such standards is to have payers reimburse for only the devices and algorithms that meet these requirements. A recent UK report emphasized the importance of transparency around the performance of medical devices across subgroups with different skin tones (UK Department of Health and Social Care, 2024). Moreover, fostering expertise on the collection and use of race and ethnicity data among device engineers, regulators, and industry partners in this space could also be useful when it comes to better integrating this information into the development of these devices (Ferryman et al., 2023). Given that equity issues encoded into medical technologies have many facets, efforts to understand and address them will benefit from sustained and in-depth conversations across disciplines and among industry, academia, and the general public.

Strategies for Operationalizing the Recommendations

Adopting this report's recommendations will require coordinated efforts across the biomedical research ecosystem as well as a willingness to be patient and flexible. This report is only the start, and the conversation must not stop here. Addressing the complex issues inherent in how to use race and ethnicity thoughtfully in biomedical research will require sustained and in-depth conversations across disciplines and sectors. It will also involve increasing awareness of the problem itself and the potential solutions.

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[5] Federal Registrar. 2024. Nondiscrimination in health programs and activities. https://www.federalregister.gov/documents/2024/05/06/2024-08711/nondiscrimination-in-health-programs-and-activities (accessed August 28, 2024).

Those from academia, industry, regulatory bodies, funders and sponsors, and communities will have to work together to implement the recommendations. Unfortunately, few spaces for this collaborative dialogue currently exist, but creating crosstalk across sectors and disciplines can promote adoption of these recommendations.

The National Academies population descriptors report (NASEM, 2023) used similar implementation strategies and serves as a good case study. Since that report was published, journal editors from seven major journals[6] published a joint statement advocating the recommendations in the National Academies report and providing 10 precepts of their own built from the National Academies report's findings, conclusions, and recommendations (Feero et al., 2024). Since its release, the report has generated conversation among key actors in the field of genomics as it has been discussed at conferences, including the annual meeting of the American Society of Human Genetics, and a recent NIH workshop.[7] In late 2023, 11 institutes and two offices at NIH posted an ethical, legal and social implications research funding opportunity, which cited the population descriptors report and called upon "applicants who propose to address or analyze race, ethnicity, genealogical ancestry or genetic ancestry are strongly encouraged to review" the 2023 National Academies report when designing their research strategy (NIH, 2024).

Recommendations 1 through 7 in this report focus on actions that researchers should take. This section speaks to other actors in the biomedical research ecosystem. Notably, many of these actions should be done in collaboration with other actors and in partnership with researchers for sustained implementation of the report recommendations.

Journal Editors

To disseminate and build awareness of this report's recommendations, journal editors could develop special issues with invited articles about topics such as illustrative examples of implementing reporting recommendations, fostering community partnerships in biomedical research, and measuring social and environmental variables that affect health and disease. Journals can also take action by implementing guidelines for what is expected in manuscripts submitted for publication. *The American Journal of Human Genetics*, for example, stated its support for the recommendations in the NASEM population descriptors report on its "Information for Authors" webpage[8] describing its policies and manuscript requirements. As another example, *JAMA* provided guidance on reporting race and ethnicity in medical and biomedical journals a few years ago (Flanagin et al., 2021). Based on this article, professional societies, like the American Society of Nephrology, have adapted the *JAMA* guidance and created checklists for researchers, clinicians, and editors to use when submitting and reviewing manuscripts. Checklists can be a helpful way to operationalize publishing guidelines, but such tools need to

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[6] *Journal of the American Medical Association* (JAMA), Genetics in Medicine, American Journal of Medical Genetics, Nature Genetics, Human Genetics and Genomics Advances, Journal of Genetic Counseling, and American Journal of Human Genetics.

[7] https://obssr.od.nih.gov/news-and-events/events/population-descriptors-legacy-genomic-data-challenges-and-future-directions (accessed July 26, 2024).

[8] https://www.cell.com/ajhg/authors (accessed July 26, 2024).

be disseminated to both authors and reviewers and used consistently to have the most impact. American Heart Association Journals, for example, include a checklist organized by article subsection (e.g., methods, results) for reporting racial and ethnic disparities.[9]

While it is helpful for individual journals to have policies and guidance for prospective authors about race and ethnicity in articles, true change will be effected the more that journals can come together to develop consistent reporting guidelines, including across disciplines. For example, the International Committee on Medical Journal Editors (ICMJE), which is a group of medical journal editors that convenes to improve the quality of medical science and reporting, could provide more information or host a convening for interpreting their guidance on race and ethnicity. ICMJE recommendations currently state that authors should define how they determined race or ethnicity and provide a justification for this use. Their recommendations also state that "race and ethnicity are social and not biological constructs; authors should interpret results associated with race and ethnicity in that context" (ICMJE, 2024). Although this recommendation is in alignment with the messages of this report, more detailed guidance and illustrative examples of how to do this successfully could be helpful for a broader understanding and adoption of this report's recommendations.

Some journals have had guidelines around the use of race and ethnicity for some time, but the guidance and level of detail vary across publishers and disciplines. In addition, having a policy is not sufficient if it is not consistently applied and monitored. As discussed at length in Chapter 4, despite some existing guidelines, race and ethnicity are not reliably defined in publications or used in consistent, rigorous ways (see, for example, Martinez et al., 2023). More accountability and consistent enforcement of guidelines, throughout the publication process, are needed to make additional progress.

Professional Societies

To increase awareness of the problems with many current uses of race and ethnicity and to help biomedical scientists more appropriately use race and ethnicity in their research, professional societies can serve an important role as conveners and educators. Professional societies can hold workshops, provide online training modules, commission surveys and reports, and write articles that highlight the ways in which biomedical research can make lasting changes. For example, the Society of General Internal Medicine (SGIM) published an article on how to integrate anti-racist principles into the research process, which includes recommendations for using race data throughout the research lifecycle (Gonzalez et al., 2024). Moreover, professional societies can also develop example case studies and offer sample questions for researchers asking participants about their racial and ethnic identification, which can serve as educational tools and provide best practices for those engaging in this work. (See section, "Research Scenarios," for examples of case studies).

Professional societies can also revise existing courses and training modules specific to proper study design and conducting reproducible and rigorous science to include

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[9] See https://www.ahajournals.org/disparities-research-guidelines and https://www.ahajournals.org/pb-assets/policies/AHAJournals_DisparitiesGuidelines_Checklist.pdf (accessed August 21, 2024).

information about this report and ways to implement the report's recommendations, such as addition research scenarios like those described in this chapter. For example, the Collaborative Institutional Training Initiative (CITI) Program has a course on research study design which provides an overview of research study design and approaches to optimize the reproducibility of research results.[10] CITI could ensure that this or similar modules and courses provide a framework and tools for researchers to learn about that will help them understand how to use race and ethnicity appropriately in their research.

Professional societies can also act as partners in disseminating the report by hosting panel discussions, webinars, workshops, and podcast episodes about the recommendations and including presentations in upcoming conferences to ensure that the conversation continues. These types of meetings and conferences also provide a venue for bidirectional exchange of ideas among those who are more senior in the field and earlier career individuals, which is key for setting the foundation for sustained change.

Funders of Biomedical Research

Funders of biomedical research can host workshops and conferences to raise awareness about the considerations for using race and ethnicity in the research that they support. For example, the Doris Duke Foundation has co-hosted meetings with the National Academy of Medicine in this regard to foster discussions among their clinical algorithm grantees, and the NIH has hosted workshops with scientists working on population descriptors to share and discuss approaches to using population descriptors for legacy datasets.

Funders could also incorporate material from this report into available or required training opportunities. For example, key messages of this report could be incorporated into responsible conduct of research (RCR) training, which is a required course for all NIH intramural investigators and for all trainees on an NIH institutional research training grant or fellowship. RCR courses include instruction on proper data acquisition and ethical data use, which could include the principles outlined in this report on appropriate collection and use of race and ethnicity data.

Funders can examine the guidance in this report and change or update their policies on how they would like to see grantees think about and use (or not use) race and ethnicity in research. Requesting articulated scientific rationales and approaches could ensure that researchers are held accountable for considering how race and ethnicity are used at the study design phase. This increased transparency may be particularly salient for funders of health technologies, which, as discussed earlier in this chapter, commonly rely on secondary datasets. Funders can also change policies to hold investigators accountable for properly engaging communities in the research lifecycle and ensuring that researchers are building partnerships with relevant communities to inform their research design.

Finally, for researchers to build relationships and do the necessary community engagement outlined in Recommendation 7, funders of biomedical research need to recognize the increased time and resources it takes to engage and build lasting relationships with

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[10] https://about.citiprogram.org/course/research-study-design-rsd/ (accessed July 26, 2024).

racial and ethnic minority populations in biomedical research. As described in a recent National Academies report, “Investment of time and resources are needed to build and restore trust with underrepresented and excluded communities” (NASEM, 2022, p. 7). Federal research awards typically are for a period of 3 to 5 years, which is meant to encompass all aspects of the research life cycle. However, as discussed in Chapter 4, these timelines often do not align with the time and resources it takes to build and sustain relationships with racial and ethnic minority communities. This may be particularly true for research conducted with Tribal nations, which, as discussed in Chapter 4, requires approval and partnerships with sovereign Tribal governments. The committee provides the following conclusion and recommendations for funders and publishers of biomedical research:

> *Conclusion 6-11: Funding timelines and publishing pressure often do not account for, and are thus misaligned with, the time required for outreach to and partnership with racial and ethnic minority populations for participation in research. Reservation-based research, for example, requires longer timelines for approvals to navigate the unique legal and political status of Tribal nations.*
>
> **Recommendation 8: Funders, sponsors, publishers, and editors of biomedical research should provide consistent guidelines to assist researchers in developing and examining their work and to promote the thoughtful use of race, ethnicity, and related concepts to enhance adoption of these recommendations.**
>
> - **Journal publishers and editors, research funders, and sponsors should require researchers to provide a scientific rationale for their use of race and ethnicity, describe data provenance, and acknowledge limitations of their use.**
> - **Journal editors and funding agencies should provide reviewers with specific guidelines for reporting race and ethnicity that should be used to assess publication and funding decisions.**
> - **Funders of research to develop health technologies should require researchers to report results across racial and ethnic groups and encourage researchers to provide datasets, algorithms, and code in an open-source format to the greatest extent possible.**
>
> **Funders, sponsors, publishers, and editors of biomedical research should periodically evaluate their policies on the use of race and ethnicity to assess the extent to which the policies are followed and upheld, monitor progress, consider the need for updates, and ensure the guidelines reflect current best practices.**
>
> **Recommendation 9: To support partnerships between communities and research teams, funders and sponsors should require as appropriate a community engagement plan as part of the application. Funders should provide resources and timelines that encourage researchers to build and sustain collaborations. Research institutions, medical centers, and other biomedical research organizations should develop and support lasting, equitable relationships with community partners.**

This report offers ways to change how race and ethnicity are used, analyzed, and reported in biomedical research. When implemented, these changes have the potential to improve the scientific rigor of biomedical research, mitigate bias that continues to affect research and health care, and build lasting trust among the scientific community and racial and ethnic communities. However, issues of race and ethnicity remain complicated and challenging to address. As this report has emphasized, appropriate or inappropriate use of these constructs is context dependent. Because next steps will differ depending on the context of the research, all participants in the biomedical research ecosystem have a role to play in operationalizing the recommendations. Individual researchers and clinicians can do their part by scrutinizing their decisions to use—or not use—race and ethnicity throughout the research process, assessing whether study results and clinical tools were developed based on robust evidence and making thoughtful inferences and interpretations of the evidence.

While putting these recommendations into practice across the biomedical research ecosystem will take time and effort, the report represents a vision of the future where the biomedical community moves beyond the limits of focusing on race to adopt practices that will facilitate an understanding of the true factors of disease.

> *Conclusion 6–12: The biomedical research enterprise has long emphasized race at the expense of exploring other concepts such as racism and discrimination that are known to have more direct effects on health. Much of the existing evidence base has deep-rooted bias and requires reexamination. Rebuilding the evidence to examine the role of racism and other associated concepts beyond race and ethnicity categories will require investment from funders and sponsors of biomedical research.*

Moving forward starts with recognizing and acknowledging assumptions, biases, and flaws in the existing evidence base. Yet making progress does not have to be daunting. It is an exciting time for the biomedical research community to chart a path forward to improve the use of race and ethnicity for better science and better health.

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Appendix A

Study Approach and Methods

STUDY APPROACH AND METHODS

The committee was tasked with evaluating the current use of race and ethnicity in biomedical research and providing recommendations for the use of these constructs in future research. To accomplish this charge, the committee examined the current literature, engaged in targeted outreach to relevant parties, and hosted a series of public information-gathering sessions to gain diverse perspectives across multiple avenues.

EXPERTISE

The committee was composed of 16 individuals with expertise spanning biomedicine, human genetics, epidemiology, sociology, biostatistics and biomedical informatics, real-world data, clinical algorithms and tools, health disparities research, bioethics, health policy, medical anthropology, implementation science, and community-engaged research practices. Committee biographies can be found in Appendix D.

LITERATURE REVIEW

To inform its work, the committee examined current literature related to the study charge by using staff-led targeted searches along with reviews of available guidance on the use of race and ethnicity in biomedical research. National Academies staff conducted a literature search in Embase, Medline, and Scopus between August 17 and September 15, 2023. These databases index research in biomedicine, health sciences, and other relevant fields. The search terms were composed of MeSH terms in addition to specific vocabulary related to race, ethnicity, biomedical study design and execution, clinical algorithms, race norming/adjustment, health disparities, and other related topics (see Table A-1). Relevant publications in English from 2010 to present day were considered.

TABLE A-1 Preliminary Search Terms - Keyword Matrix

Keyword	MEDLINE/PubMed	Embase
Biomedical research	Biomedical Research/ Biomedical Research/Methods Biomedical Research/ Organization & Administration	Medical research
Race	Racial Groups/	Ancestry group Race Race difference
	Racism/ Racism/Prevention & Control	Racism
Ethnicity	Ethnicity/	Ethnicity Ethnic group “ethnic or racial aspects”
Algorithm	Algorithms/	Algorithm Algorithm bias
Study Design	Clinical Trials as Topic/	Clinical trial
Medical Teaching	Education, Medical/	Medical Education

The initial search results were organized by National Academies staff based on emerging themes that were relevant to the statement of task, some of which included the use of race and ethnicity in clinical algorithms, the development of clinical trials, and specific subfields of biomedicine. Committee members, speakers, and members of the public also submitted articles and comments that informed the committee’s deliberations and drafting of the report.

PUBLIC MEETINGS

The committee convened four public meetings to solicit information from experts and members of the public, which included representatives from community organizations and patient advocacy groups. The committee’s first meeting was held virtually in October 2023, and the public session provided an opportunity for the committee to clarify questions related to the statement of task with the sponsoring organizations. Subsequent public sessions were held on December 14, 2023, January 31, 2024, and March 14–15, 2024. The agendas for these meetings are included in chronological order.

FIRST COMMITTEE MEETING OPEN SESSION

October 24, 2023

Session Objective: To hear from the sponsors of the study regarding their perspectives on the charge to the committee.

1:00 p.m. ET **Welcome and Session Overview**
M. Roy Wilson, Wayne State University, Committee Chair

1:10 p.m. **Sponsor Perspective and Charge to the Committee**
Presenter: *Sindy Escobar Alvarez,* Medical Research Program Director, Doris Duke Foundation

1:30 p.m. **Discussion with Committee**

2:00 p.m. **Adjourn**

OPEN SESSION

December 14, 2023

SESSION I: HISTORICAL CONTEXT AND PERSPECTIVES ON THE USE OF RACE AND ETHNICITY IN BIOMEDICAL RESEARCH

Moderator: M. Roy Wilson, Wayne State University

Session Objectives:

- Explore the historical context of the use of race and ethnicity in biomedical research
- Consider consequences of the past and current use of race and ethnicity in biomedical research

12:30 pm **Welcome and Overview**
M. Roy Wilson, *Committee Chair*
President Emeritus
Wayne State University

12:40 pm **Introduction to the Session**
M. Roy Wilson, *Committee Chair*
President Emeritus
Wayne State University

12:45 pm **Speakers' Opening Remarks**
Dorothy Roberts
George A. Weiss University Professor of Law & Sociology
University of Pennsylvania

Catherine Lee
Associate Professor of Sociology
Rutgers University

David Chae
Associate Professor and Associate Dean for Research
Tulane University

Neil Risch
Director
Institute for Human Genetics
University of California San Francisco

1:45 pm **Panel Discussion**

2:10 pm **Break**

SESSION II: EXAMINATION OF EXISTING GUIDELINES AND LESSONS LEARNED IN RELATED FIELDS

Moderator: Aliya Saperstein, Stanford University

Session Objectives:

- Learn about existing guidelines and their reexamination
- Discuss lessons learned from other fields and sectors grappling with questions of race and ethnicity and related guidance

2:25 pm **Brief introduction to the session by the moderator**

2:30 pm **Speakers' Opening Remarks (15 minutes each)**
Shazia Siddique
Assistant Professor of Medicine
University of Pennsylvania

Rae Anne Martinez
Postdoctoral Fellow
Minnesota Population Center, University of Minnesota

Anne Lewis
Research Scientist
Brigham and Women's Hospital and Harvard Medical School

3:30 pm **Panel Discussion**

3:55 pm **Concluding Remarks**

4:00 pm **Adjourn**

PUBLIC WORKSHOP

January 31, 2024

9:00 AM ET	**Welcome and Overview** M. Roy Wilson, *Committee Chair* President Emeritus Wayne State University

SESSION I: HUMAN PHYSICAL VARIATION AND EFFECTS ON HEALTH RESEARCH

Moderator: Neil Powe, University of California San Francisco

Session Objectives:

- Learn how human phenotypic variation in skin pigmentation, for example, can be characterized
- Discuss how variation in traits like skin color and hair contributes to downstream effects in biomedical research
- Consider new approaches to measure and account for phenotypic variation in research

9:05 AM	**Brief Introduction to the Session** Neil Powe Constance B. Wofsy Distinguished Professor and Vice-Chair of Medicine University of California San Francisco
9:10 AM	**Speakers' Opening Remarks (15 minutes each)** Nina Jablonski Atherton Professor, Evan Pugh Professor Emerita of Anthropology The Pennsylvania State University Heather Norton Associate Professor and Director of Graduate Studies University of Cincinnati Kimani Toussaint Senior Associate Dean for Research and Strategic Initiatives Thomas J. Watson Sr. Professor of Science Brown University
9:55 AM	**Panel Discussion**
10:20 AM	**Break**

SESSION II: ALTERNATIVES TO USING RACE AND ETHNICITY CATERGORIES IN RESEARCH

Moderator: Roland J. Thorpe, Jr., Johns Hopkins Bloomberg School of Public Health

Session Objectives:

- Discuss alternatives to using race and ethnicity categories (e.g., the OMB categories) in research
- Explore qualitative and quantitative methods for examining race and ethnicity in research
- Consider the advantages and disadvantages of collecting race and ethnicity data

10:35 AM **Brief Introduction to the Session**
Roland J. Thorpe, Jr.
Professor and Associate Vice Provost of Faculty Diversity
Johns Hopkins Bloomberg School of Public Health

10:40 AM **Speakers' Opening Remarks (15 minutes each)**
Ellis Monk
Professor of Sociology
Harvard University
Paris "AJ" Adkins-Jackson
Assistant Professor of Epidemiology and Sociomedical Sciences
Columbia Mailman School of Public Health

Chandra L. Ford
Professor of Behavioral, Social and Health Education Sciences
Professor of African American Studies
Emory University

11:25 AM **Panel Discussion**

11:50 AM **Break**

SESSION III: RACE AND ETHNICITY IN CLINICAL DATA COLLECTION, ALGORITHMS, AND TOOLS

Moderator: Shyam Visweswaran, University of Pittsburgh

Session Objective:

- Examine how race and ethnicity are currently used in clinical algorithms and decision-making tools and discuss the effects of this use
- Explore whether and how race and ethnicity could be used in the development of future clinical algorithms

12:30 PM **Introduction to the Session**
Shyam Visweswaran
Professor and Vice Chair of Clinical Informatics
University of Pittsburgh

12:35 PM **Speakers' Opening Remarks (15 minutes each)**
Karen Wang
Assistant Professor of Internal Medicine and Health Informatics
Yale School of Medicine

Judy Wawira Gichoya
Associate Professor in the Department of Radiology and Imaging Sciences
Emory University School of Medicine

Marzyeh Ghassemi
Assistant Professor, Electrical Engineering and Computer Science and Institute for Medical Engineering & Science
Massachusetts Institute of Technology

1:20 PM **Panel Discussion**

SESSION IV: INTERSECTION OF RACE AND ETHNICITY IN BIOMEDICAL RESEARCH AND CLINICAL APPLICATIONS

Moderator: Carmen Guerra, University of Pennsylvania

Session Objective:

- Discuss how incorporating race and ethnicity (or not) in early-stage research influences applications in the clinic
- Explore best practices for collecting patient or research participant information for use in research

1:45 PM **Introduction to the Session**
Carmen Guerra
Ruth C. and Raymond G. Perelman Professor of Medicine
University of Pennslyvania

1:50 PM **Speakers' Opening Remarks (15 minutes each)**
Valerie M. Harvey
Immediate Past President
Skin of Color Society

Ruth Carlos
Professor of Radiology and Assistant Chair for Clinical Research
University of Michigan

Elizabeth Selvin
Professor of Epidemiology
Johns Hopkins Bloomberg School of Public Health

2:35 PM **Panel Discussion**

3:00 PM **Break**

SESSION V: INDUSTRY PERSPECTIVE ON THE USE OF RACE AND ETHNICITY IN RESEARCH

Moderator: Husseini Manji, Oxford University, UK Govt Mental Health Mission

Session Objective:

- Discuss how regulatory considerations influence collection of race and ethnicity data.
- Explore incentives and disincentives for changing how race and ethnicity data are collected for industry research.

3:10 PM **Introduction to the Session**
Husseini Manji
Co-chair, UK Govt Mental Health Mission
Professor, Oxford University

3:15 PM **Speakers' Opening Remarks (15 minutes each)**
Vaibhav Narayan
Chief Industry Officer of UK Mental Health Mission
University of Oxford

Anne Lawrence
Head of US Clinical Operations
GSK

Pierre Theodore
Executive Director of Health Equity
Genentech

4:00 PM **Panel Discussion**

4:25 PM **Concluding Remarks**

4:30 PM **Adjourn**

OPEN SESSION

March 14, 2024

COMMUNITY PERSPECTIVES ON THE USE OF RACE AND ETHNICITY DATA IN HEALTH RESEARCH

Session Objectives:

- Understand experiences from community groups about the collection and use of race and ethnicity data during different phases of community-based participatory research, including:
    - learning about the research goals, building partnerships, designing the study, participating in research, and learning about the results and benefits to the community.
- Learn from community members and research participants about current research practices involving race and ethnicity that should be continued, stopped, or modified.
- Listen to what changes related to the use of race and ethnicity in research community members may want to see and discuss possible ways to implement those changes in biomedical research practices.

2:00 pm **Welcome**
M. Roy Wilson, *Committee Chair*
President Emeritus
Wayne State University

2:05 pm **Introduction to the Session**
Margaret Moss, *Session Moderator*
Professor and Associate Dean for Nursing and Health Policy
Katherine R. & C. Walton Lillehei Chair in Nursing Leadership
University of Minnesota School of Nursing

2:10 pm **Level-setting Opening Talk**
Ella Greene-Moton
Administrator
Community Based Organization Partners, Community Ethics Review Board
President
American Public Health Association

2:25 pm **Q&A with Opening Speaker**

2:40 pm **Introduction to the Panel**
Matthew F. Hudson, *Session Moderator*
Director of Cancer Care Delivery Research
Prisma Health

2:45 pm **Panelists' Opening Remarks**
Jamil Rivers
Founder
The Chrysalis Initiative

Audie Atole
Conservation Officer
Jicarilla Apache Nation

Gladys Vega
Chief Executive Officer
La Colaborativa

Donald Adams, Jr.
Assistant Director of Design Innovation
University of Illinois System, Office of Medicaid Innovation
Patient Engagement Advisory Panelist
Patient Centered Outcomes Research Institute

Danurys "Didi" Sanchez
Senior Research Staff Associate
Taub Institute for Research on Alzheimer's Disease and the Aging Brain
Columbia University Irving Medical Center

Sela Panapasa
Associate Research Scientist, Research Center for Group Dynamics
University of Michigan

3:30 pm **Panel Discussion – Race and Ethnicity Considerations throughout the Research Process**

- Community involvement in study design
- Knowledge that researchers should have prior to data collection
- Questions at the time of recruitment
- Data management and stewardship
- Benefit sharing and post-participation communication
- Recommendations that community members have for the committee

4:15 pm **Reflections on the Panel Discussion**
Eliseo Perez-Stable
Director
National Institute on Minority Health and Health Disparities (NIMHD)
National Institutes of Health (NIH)

	Monica Hooper Deputy Director National Institute on Minority Health and Health Disparities (NIMHD) National Institutes of Health (NIH)
4:25 pm	**Concluding Remarks**
4:30 pm	**Adjourn**

OPEN SESSION

March 15, 2024

RACE AND ETHNICITY IN BIOMEDICAL AI

Session Objectives:

- Hear from experts in artificial intelligence (AI) about the growing impact of this technology on biomedical research and implications for the use of race and ethnicity in research and algorithms
- Learn about potential applications of natural language processing (NLP) and large language models (LLMs) in biomedical research and how race and ethnicity are used in biomedical and clinical AI
- Explore whether and how race and ethnicity could be used in the development of future clinical algorithms

8:30 a.m. ET	**Welcome and Introduction to the Session** M. Roy Wilson, *Committee Chair* President Emeritus Wayne State University
8:35 a.m.	**Speaker Presentations** Tristan Naumann Principal Researcher Microsoft Research Health Futures Monica Agrawal Incoming Assistant Professor Duke University
9:05 a.m.	**Q&A with the Speakers** Genevieve Wojcik Assistant Professor of Epidemiology Johns Hopkins Bloomberg School of Public Health
9:30 a.m.	**Adjourn**

Appendix B

Community Engagement Continuum Table

TABLE B-1 The Community Engagement Continuum: An Extended Comparison of Levels of Engagement. Moving from left to right across the levels of engagement, the investment required by researchers increases. Similarly, sound communication between researchers and community members will also increase.

	Outreach	Consult	Involve	Collaborate	Shared Leadership
Definition	Interaction with the community where information flows from a researcher or research entity to the community.	An information-seeking practice that incorporates community input about research or intervention design, implementation, or dissemination in the decision-making process.	The involvement of stakeholders by researchers towards achieving goals established by the researcher.	The formation of partnerships between researchers and stakeholders to achieve a common goal	Consensus-driven research process based on a strong system of relationships, reciprocity and trust
Goal	To disseminate information by communicating and informing; can be the first step towards additional relationship building	To inform communities about research proposals or results, listen to community members' opinions and needs, and use the feedback to inform decision making.	To create community buy-in, community participation, and community ownership; facilitate trust building and community acceptance; and improve outcomes through interventions tailored to community needs.	To work together on accomplishing a mutually agreed upon research goal.	To work together as equals on accomplishing a mutually agreed upon research goal. Shared leadership leads to collective ownership of a problem and its solution. With shared ownership comes increased responsibility, accountability, power, and diversity of strategies. It acknowledges that the researcher is not the only expert for a given project; engaging different voices is critical to the success of certain projects.

Governance (decision making)	The holder of information	Researcher informs the community about proposals that affect new or existing systems and interventions. Researcher establishes the mechanisms and methods for soliciting feedback from the community. The researcher considers input from community members when making decisions.	The community's input informs decision making made by researchers	Gain consensus between external stakeholders and partners and researchers, ensuring decisions are mutual	Stakeholders represented equally in the partnership Consensus-driven, equally shared decision making. • Shared planning and accountability • Shared responsibility for outcomes • Participatory evaluation
Extent of community involvement in research	The community passively receives information	The information received by the community and community input is limited to the specific research questions asked by the research	Community involved or participates	Community collaborates	Strong bidirectional relationship
Communication flow	Unidirectional to the community	To community and back	Bidirectional	Bidirectional	Bidirectional • Requires the establishment and maintenance of systems for transparency and consistent, rigorous, open dialogue • Ensure communication across all levels of the partnership • Rely on a variety of communication approaches

continued

	Outreach	Consult	Involve	Collaborate	Shared Leadership
Objective	Researcher provides community with information	Get information/ feedback from community	Involve more participation from community on issues	Form partnerships with community on each aspect of project from development to solution	Final decision making is at the community level
Entity relationship	Co-exist	Share information	Cooperation	Collaborative	Equal partnership and shared structures and governance
Outcomes	To establish and use communication and outreach channels	Develop connections	Visibility of partnership established	Partnership and trust building	Strong trust; broader health outcomes affecting the community
Examples for use of race and ethnicity	Researcher provides community participants with information about why race and ethnicity are being collected and how the data will be used	A researcher seeks input from community advisory board on a research proposal to design the protocol for collecting race and ethnicity-related data	A researcher seeks the help of community-led organizations to reach diverse populations for input on a research study of racial or ethnic health disparities	A researcher partners with a community organization to help identify and screen participants for a study about a health issue important to the community	A research team and community work together to identify a health problem important to the population; the community and study team co-design the research aims, protocol, and procedures
Examples of specific research studies or programs	**Recruitment of Three Generations of African American Women into Genetics Research (Taylor et al., 2008):** Participants were recruited using methods such as advertisements, presenting to churches, and outreach to HBCU sororities	**NIH *All of Us*:** Research program that supports and recommends that awardees establish community or participant advisory boards to provide input on such issues as recruitment methods and design of promotional messaging and engagement materials	**NIH Community Engagement Alliance (CEAL):** A research network designed to work with community-based organizations to strengthen partnership through community-engaged research to address racial, ethnic, and socioeconomic health disparities	**Jackson Heart Study:** A 20-year prospective community-based cohort that successfully enrolled 5,306 African American by mobilizing community support and engagement through partnerships	**Wisconsin Alzheimer's Institute:** Organization committed to health equity for people living with dementia; primary goal was to support the community; community members initiated their participation in research

Pros	• Allows for relatively quick, broad dissemination of public health information • Potential for subsequent relationship building and networking • Less costly approach to establishing community engagement • Expedient, limited deliberation, information is controlled	• Gives researchers a platform to solicit community input during Decision making • Communities afforded influence as local experts • Builds trust between researchers and community • Teaches researchers about community norms • Increases cultural sensitivity and humility • Holds researchers accountable to community for suggestions that were incorporated or excluded • Dialogue fosters transparency • Researcher perceived as an expert or leader in the community	Community involvement increases the changes that research can affect better public health outcomes	Increased commitment from community partners—in the form of time or other resources—is needed over time to foster a collaborative relationship	• Builds long-lasting relationships that can extend beyond the initial goals and scope of the project • Can create organizational structures that go beyond the research project and into the community • These structures can then facilitate the sustainability of the initiative
Cons	• Does not offer higher levels of engagement • Limited public/community input or influence	• Potentially extends research timelines • May require additional resources to collect, analyze, and disseminate community input	• Requires time, effort from community members.	• More labor intensive for health department staff • Relinquishing power to community stakeholders and partners can be difficult.	• Takes time, consistency, flexibility, and focus. • Better suited for broader issues that people of varying skill levels and interests can participate in.

continued

	Outreach	Consult	Involve	Collaborate	Shared Leadership
	• Limited by the networks accessible to the researchers and communities perceived as accessible or priority • Could be perceived as impersonal or intrusive	• If feedback is not incorporated in final decisions, it could expose researcher to criticism • Requires increased sensitivity about public messaging and media coverage • Researcher must continually reach out beyond existing partners. If not, consulting is considered a rounding up of the “usual suspects” without reaching a deeper level of engagement		• Authentic community engagement will require this in certain situations. • Less control of the process means researchers must accept unknown outcomes	• Government agency participation often requires extensive review and approval • Community processes can be complex and labor-intensive, and they require dedicated resources such as time, funding, and people with the necessary skills
Methods	Information and public health materials distributed via email lists, mailing lists, phone calls; through direct community visits and presentations; at community events and meetings, public announcements, listening sessions or media interviews	Surveys, questionnaires, facilitated discussions, focus groups, interviews, social media engagement, email blasts, websites, SMS mobile, community input sessions, advisory boards, community driven information dissemination (newsletters, etc.)	Involve stakeholders and partners to obtain feedback or input on research.	Stakeholders and partners share the responsibility with researchers for achieving the goals	• Create a common agenda and research aims • Establish shared framework for performance measurement • Maintain continuous communication • “Backbone” support, such as providing staff to create meeting agendas, take minutes, keep track of key documents

Best practice considerations	• Use existing networks to expand outreach. • Work to understand cultural norms of communities targeted for outreach. • Partner with localized entities familiar with and accessible to target audience	• Appropriate representation of target populations • Community-based participatory approaches • Community input sessions • Neighborhood planning sessions. Scientific caffes	• Acknowledge the effort required by community participants and stakeholders and fair reimbursement of effort and travel expenses such as parking, tolls, mileage	• Consistent communication and transparency and honesty about the research process and goals • Inclusive: involve collaborators as early in the research planning process as possible • Engage a diverse spectrum of community stakeholders and partners (depending on the nature of the research, some examples include government agencies, community-based organizations, faith-based organizations, private sector businesses)	• Researcher remains flexible about how the shared leadership group identifies the problem and develops solutions • Researcher ensures partners have knowledge and resources needed for shared leadership • Research support data needs and other infrastructure needed for shared decision making • Be explicit about who is sharing leadership • Establish clear governance structure • Hold all parties accountable • Build relationships outside your networks • Take advantage of emergent opportunities • Prioritize and build on early wins to create and nurture structures, processes and relationships that will carry forward into future work

NOTE: This table is a general guide, and there may be other considerations for specific populations. For example, engaging with American Indian Tribes may involve different steps.

SOURCE: Adapted from the CDC Principles and NYC Department of Health and Mental Hygiene guides.

Appendix C

Multiracial Analysis Schemes

To assist in their information gathering, the committee commissioned the following piece. Opinions and statements included in the paper are solely those of the individual author and are not necessarily adopted, endorsed, or verified as accurate by the Committee on the Use of Race and Ethnicity in Biomedical Research or the National Academies of Sciences, Engineering, and Medicine.

A MECHANISM-DRIVEN APPROACH TO CATEGORIZING MULTIRACIAL PARTICIPANTS IN BIOMEDICAL RESEARCH

Sarah Forthal, M.Phil., M.P.H.

In 2000, the US Census allowed Americans to officially self-identify with more than one racial group for the first time (1). Two decades later, the self-identified Multiracial population is measured at 33.8 million—nearly a 500% increase – and represents over 10% of the US population (1–3). In parallel, several prominent biomedical research organizations have initiated programs to understand and eliminate long-standing and unjust racial health disparities (e.g., 4–8). Multiracial people are exposed to systemic racism, both on the basis of their Multiracial and specific racial backgrounds, that increases their risk of several health conditions (9–14). Yet, most of these disparities programs have struggled to incorporate the growing Multiracial population into their research and intervention development.

A critical challenge preventing greater inclusion of Multiracial populations in biomedical research is uncertainty around how to define and categorize Multiracial identity. Studies seeking to identify racial disparities in health routinely exclude or erase Multiracial participants, leaving significant gaps in our understanding of Multiracial health risks and consequentially, underinvestment in addressing them (12). The few studies that do include a Multiracial category in analysis operationalize it differently, creating challenges for interpreting results (12).

Compounding the issue, how studies define, include, or exclude their Multiracial participants can significantly change outcome estimates for other racial groups as well (15–18). For example, a study of men living with HIV found that the approach to categorizing Multiracial participants determined whether a Black-White disparity in experiences of stigma was observed (15).

So how *should* studies categorize Multiracial participants? Multiracial people have different experiences with racism based on their phenotypes and racial backgrounds (11,19). In addition, Multiracial identity is characterized by the complex interplay of ancestral background, self-identification, societal norms, and external perceptions (20,21), which do not always converge and can be situationally and developmentally fluid (22). Thus, this experience is not easily captured by traditional research methods for racial categorization, which rely on fixed and discrete lines to be drawn between groups for comparisons and are essentialist in nature (23,24).

In this paper, I describe an approach to categorizing the Multiracial population in biomedical research that honors the diversity of this population and improves methodological rigor by employing theoretically grounded measures of race. Echoing foundational work on operationalizing race in sociology (25–27) and the consensus that racial disparities in health are driven by underlying (28) racially-patterned social mechanisms for which race is a proxy (29,30), I argue that there exists no single "best" Multiracial categorization scheme for all biomedical research purposes. Instead, the most appropriate Multiracial categorization scheme should be determined by the hypothesized mechanism linking race and racism to health.

Assumptions Implicit in Categorization of Race

Categorization of race in research is often determined by standard practice and data availability (31), but each choice in fact encodes certain assumptions. First, racial categories assume a shared within-group social identity (32). However, this is particularly challenging to assume for Multiracial individuals, who share identities with multiple groups and may primarily identify with one, all, or none of their component monoracial (i.e., single-race) groups (28,33,34). Further, different racial identities may be more salient for Multiracial people in different contexts (35). For example, some Multiracial people primarily identify as members of their most minoritized monoracial group due to historical or political reasons (33,34). Ultimately, researchers cannot simply assume that all Multiracial people identify with a separate "Multiracial" identity, nor that they identify with any monoracial identity.

Second, racial categorization makes the statistical assumption that outcome risk is similar for participants categorized into the same group and meaningfully different from participants categorized into the other groups (36). For example, comparing risk of asthma between study participants identifying as monoracial Black and monoracial White assumes that risk of asthma is similar within the Black and White groups and meaningfully different between them. This is a reasonable assumption given that Black Americans are on average more likely than White Americans to experience environmental and social stressor exposures associated with asthma, due to historic and current systemic racism in the US (37). Yet, making this assumption is less straightforward when considering Multiracial populations, who carry with them the experiences of multiple racial groups. Is the risk of a Multiracial Black and White individual more like other Multiracial individuals, other Black, or other White individuals? Or is it a combination of these? A unique experience on its own? Answering these questions necessitates a clear understanding of the underlying mechanisms driving asthma risk and its relationship to the individual's racial identity. Failure to engage critically with these assumptions may result in under-theorized and unjustified categorization of race.

Potential Mechanisms Linking Race to Health

Race, a socially constructed classification system based on essentialist interpretations of physical traits, has no biological basis and is not a cause of differential health risk in itself (38). Instead, racial disparities in health are caused by several mechanisms rooted in contemporary and historic systemic racism (39). These include racial patterning in exposure to discrimination, unmet treatment needs, other chronic illness, adverse childhood experiences, other traumatic events, including criminal justice system involvement and exposure to violence, and life stressors, including economic disadvantage (40–46). Some of these mechanisms are highly prevalent in Multiracial populations (9,14,43), while others are more highly prevalent in Black, Indigenous, and Latine populations, sometimes including their Multiracial members (47–50).

Racial disparities in health may also be driven by patterning of protective factors such as racial identity affirmation and belonging (i.e., self-identifying as, being in community with, having a sense of belonging in, and having positive attitudes towards one's racial group(s)) (51). Though relevant to all racial groups (52,53), racial identity affirmation and belonging is particularly prevalent in the Multiracial health literature given common experiences of identity denial and questioning in this population (32,54–59). Researchers investigating racial disparities should always explicitly name the mechanism they hypothesize links race to the health outcome of interest (29).

Outlining a More Theoretically Motivated Approach

Despite its fraught nature, careful categorization of race is critical to identify and act on racial health disparities (60). At the same time, it is clear that traditional research methods for racial categorization become increasingly problematic when applied to Multiracial populations. An alternative approach suggests that the most informative way to categorize Multiracial participants differs based on the mechanism hypothesized to drive the health disparity of interest.

This approach acknowledges that Multiracial individuals experience racialized exposures both on the basis of their Multiracial and specific racial backgrounds, and that different aspects of their identities may be more salient to different mechanisms linking race to health. For example, a study investigating contemporary racial discrimination as the mechanism of interest for a health disparity might consider the categorization scheme that best reflects the diversity of experiences faced by Multiracial people of different racial backgrounds (11,57,61). On the other hand, a study investigating racial identity affirmation and belonging might group all Multiracial individuals together, regardless of racial background, because threats to this are similarly experienced by Multiracial individuals (32,54–59).

I conducted a review of methodological research on Multiracial categorization approaches and applied research on health disparities in depression (which is my area of expertise and tends to be more inclusive of Multiracial participants) to identify how Multiracial participants have been categorized in the literature to date. Of note, I focus on schemes that can be coded using the 1997 updated Office of Management and Budget's Statistical Policy Directive No. 15 (SPD 15) self-reported racial and ethnic categories: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White for race and Hispanic or Latino for ethnicity (62), as studies using these categories have to date been most commonly used to support national health equity programs. However, the principle of mechanism-driven categorization can be applied to any other survey structure, including the 2024 updated SPD 15 which uses a combined race/ethnicity question and includes a new Middle Eastern or North African category (63). The Multiracial categorization schemes identified from the literature are as follows:

1. Grouping all who identify with more than one race, but not Hispanic or Latino ethnicity, into one Multiracial category (16,64–67) → *This is how the 2020 US Census categorized Multiracial respondents (68) and is very commonly seen in the disparities literature. I refer to this as the* ***"non-Hispanic Multiracial"*** *scheme.*
   ⇨ Variations:
   a. Grouping all who identify with more than one race, regardless of their Hispanic origin response, in the Multiracial category (58) → ***"Hispanic-inclusive Multiracial"*** *scheme.*
   b. Considering Hispanic or Latino ethnicity as a race option when determining who to include in the Multiracial category (15,33,67,69) → ***"Hispanic-as-race Multiracial"*** *scheme.*
2. Grouping Multiracial participants into subcategories defined by specific racial identities (e.g., Asian-White; American Indian or Alaska Native-Black) → ***"disaggregated Multiracial"*** *scheme.*
   ⇨ Variations:
   a. Grouping Multiracial participants into subcategories defined by having or not having White identity (e.g., White-Nonwhite; Nonwhite-Nonwhite) (19) → ***"disaggregated White/non-White Multiracial"*** *scheme.*
3. Recategorizing Multiracial respondents into their most socially disadvantaged racial group (16,21,39,40,72,73) → ***"hypodescent"*** *scheme; note that this reflects the legacy of hypodescent, i.e., the historical 'one-drop rule' that continues to shape some Multiracial identification today (73,74).*
4. Recategorizing Multiracial respondents into their most socially advantaged racial group (33,34) → ***"hyperdescent"*** *scheme.*

5. Recategorizing Multiracial respondents into their least populous racial group (24) → ***"rarest"*** *scheme; note that some researchers recommend this to improve precision in estimates for smaller groups that include many Multiracial members, such as Native Hawaiian or Other Pacific Islander and American Indian or Alaska Native (12,24).*
6. Recategorizing Multiracial respondents into the single race that they identify best with (24,25,75,76) → ***"best race"*** *scheme.*
7. Categorizing Multiracial respondents into all of their component monoracial groups (77) → ***"additive"*** *scheme.*
   ⇨ Variations:
   a. Categorizing Multiracial respondents into all of their component monoracial groups, plus a Multiracial group (16) → ***"additive + Multiracial"*** *scheme.*

Researchers seeking to apply a mechanism-driven approach to categorizing Multiracial participants would first identify the primary mechanism they hypothesize is driving the racial disparity of interest. Then, based on existing evidence and social theory, they would determine which aspect of the Multiracial participants' racial identity may be most salient to this mechanism, and consequentially, which racial (or Multiracial) category their outcome risk is most likely to be similar to. To illustrate this process, some examples matching Multiracial categorization schemes with the potential mechanisms linking race to health are described below. The mechanisms and categorization schemes listed are not exhaustive and should be only used as a starting point for one's own research.

Examples: Potential mechanisms driving racial disparities in health and suggested Multiracial categorization schemes

- Racial identity affirmation and belonging (mechanism) → Hispanic-inclusive Multiracial (categorization). Individuals identifying with more than one race, regardless of their Hispanic origin response, report relatively low levels of racial identity affirmation and belonging and systematic exclusion from racial identity-affirming communities (32,54–59,78,79). However, because the relationship between race and ethnicity among Hispanic and Latino individuals can be complex (80,81), the "non-Hispanic Multiracial" and "Hispanic-as-race Multiracial" schemes should also be considered plausible. Note that the 2024 revision to SPD 15 mirrors the "Hispanic-as-race Multiracial" scheme in its use of a combined race/ethnicity question.
- Racial discrimination (mechanism) → Additive (categorization). Multiracial individuals can experience discrimination directed at their Multiracial or component racial backgrounds (11,57,61). However, because most existing measures of racial discrimination do not include Multiracial-specific forms such as identity denial or questioning, I recommend using "additive" without the Multiracial indicator. If using a measure that includes Multiracial-specific forms of discrimination alongside more traditionally measured ones, consider the "additive + Multiracial" scheme or one of the "disaggregated Multiracial"

schemes. The "best race" scheme may also be useful here, as it can reflect socially assigned race (12). However, use this with caution as many Multiracial people do not identify with a single race and may refuse to do so (82).

- Unmet psychiatric treatment needs (mechanism) → Hyperdescent (categorization). Multiracial Americans access psychiatric treatment at rates similar to White Americans (83,84).
- Chronic illness (mechanism) → Additive + Multiracial (categorization). Multiracial Americans have both distinct and shared chronic illness risk profiles with their component monoracial groups (85,86). However, note that the relationship between Multiracial and monoracial risk profiles may differ for specific illnesses. Choose the categorization scheme that best reflects this relationship in each case.
- Adverse childhood experiences, other traumatic experiences, life stressors (mechanism) → Hypodescent (categorization). Risk factors include poverty, community violence, and caregiver trauma, all which stem from historical, cumulative, and intergenerational traumas that are more likely to be experienced by less socially advantaged groups (43,87–89).

Conclusion

As the Multiracial population continues to grow, it is critical that the biomedical field adapt its research tools to ensure rigorous inclusion in health equity efforts. In service of this goal, this paper outlined a novel approach to categorizing Multiracial study participants based on the hypothesized mechanism linking race and racism to health. It additionally provided examples of existing Multiracial categorization schemes and their applicability to different potential health disparity-driving mechanisms. By addressing the weaknesses of traditional racial categorization approaches, this mechanism-driven approach has the potential to improve measurement of health disparities and inform more effective interventions to improve the health of Multiracial and monoracial populations alike.

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Appendix D

Committee and Staff Biographical Sketches

M. Roy Wilson, M.D., M.S. (*Chair*), is chancellor emeritus of the University of Colorado Denver and Health Sciences Center and president emeritus and Distinguished Professor of Ophthalmology at Wayne State University. He also served as deputy director of strategic scientific planning and program coordination at the National Institute of Minority Health and Health Disparities of the National Institutes of Health (NIH). Dr. Wilson holds elected memberships in both the National Academy of Medicine and the American Academy of Arts and Sciences and is the author of an award-winning memoir, *The Plum Tree Blossoms Even in Winter*. He has served on the advisory council to the NIH director, as well as the advisory councils of the National Institute on Minority Health and Health disparities and the National Center for Research Resources. Dr. Wilson served on the executive committee of the NIH-funded Ocular Hypertension Treatment Study and chaired the data monitoring and oversight committees of both the NIH-funded Los Angeles Latino Eye Study and the African American Eye Disease Study. Dr. Wilson received his undergraduate degree from Allegheny College and M.S. in epidemiology from UCLA; he completed medical school, ophthalmology residency, and glaucoma fellowship at Harvard Medical School.

Allison Aiello, Ph.D., is the James S. Jackson Healthy Longevity Professor of Epidemiology at the Mailman School of Public Health and the Robert N. Butler Columbia Aging Center. Previously, Dr. Aiello was a professor of epidemiology at the Gillings School of Global Public Health. She has served as the deputy director of the National Longitudinal Study of Adolescent to Adult Health (Add Health) since 2021. In 2019, Dr. Aiello was awarded the Carol Rowland Hogue Award for Outstanding Mid-Career Achievement in Epidemiology from the Society for Epidemiological Research for her achievements. Dr. Aiello's research focuses on identifying the processes by which health inequities in aging emerge across the life course, with the goal of uncovering points of intervention. Her research program has focused on some of today's most pressing and complex health exposures and conditions, including socioeconomic inequalities, biological aging, Alzheimer's disease, immunity, and susceptibility to infectious diseases. She received her Ph.D. in epidemiology from Columbia University with distinction and was awarded the Anna C. Gelman Award for outstanding achievement and promise in epidemiology.

Efrén J. Flores, M.D., is an associate professor at Harvard Medical School and serves as faculty in thoracic imaging at Massachusetts General Hospital (MGH), where completed his diagnostic radiology residency and fellowship. Dr. Flores is a nationally recognized health services researcher focused on understanding health disparities and advancing health equity among historically underserved racial and ethnic minority communities. He has served in several leadership roles at MGH, including his current role as vice-chair for radiology diversity, equity, and inclusion and as the founding director of the Radiology Inclusion and Systemic Equity Center. Dr. Flores is recognized as a national thought leader in health disparities research as evidenced by numerous awarded grants, invited presentations nationally, and peer-reviewed publications. His health equity work is guided by the overarching goal of fostering trust and a sense of belonging. In recognition for his work, Dr. Flores was selected as one of the inaugural NAM Scholars in Diagnostic Excellence in 2021, and he currently serves on several institutional and national committees, including as co-chair of the health equity committee for the Radiological Society of North America and as associate editor of health equity for the *Journal of the American College of Radiology*.

Carmen Guerra, M.D., M.S.C.E., is the Ruth C. and Raymond G. Perelman Professor of Medicine at the Perelman School of Medicine at the University of Pennsylvania. She is also the vice chair of diversity and inclusion for the Department of Medicine and the associate director of diversity and outreach for the Abramson Cancer Center where she leads community outreach and engagement, including a Genentech-funded Cancer Clinical Trials Ambassador Program that promotes clinical trial awareness through peer-to-peer education. A general internist trained in epidemiology and a health equity researcher, Dr. Guerra has designed and evaluated interventions to increase access to cancer screening and cancer clinical trials for underserved populations. Dr. Guerra serves on the American Cancer Society's Guideline Development Group and is an author of the American Cancer Society's current colorectal, cervical, and lung cancer screening guidelines as well as the current HPV vaccination guidelines. In recognition of her contributions, Dr. Guerra received the American Cancer Society's St. George Medal in 2017, the Association of Community Cancer Centers Research Award in 2022, and the American Society of Clinical Oncology Excellence in Health Equity Award in 2023. She is also a member of the advisory board of Guardant Health, a company developing blood tests for colorectal cancer, and is the U.S. deputy chair of the health equity workgroup of the Multicancer Early Detection Consortium.

Elizabeth Heitman, Ph.D., is a professor in the Program in Ethics in Science and Medicine and Department of Psychiatry at the University of Texas (UT) Southwestern Medical Center in Dallas, Texas. Her work focuses on cultural aspects of ethics in clinical medicine, biomedical science, and public health, particularly international standards of research ethics and education in the responsible conduct of research (RCR). Dr. Heitman teaches research ethics and RCR across UT Southwestern through the Center for Translational Medicine and Graduate School of Biomedical Sciences, and she leads ethics education for two National Institutes of Health (NIH) training grants on cardiovascular health disparities, Obesity Health Disparities PRIDE and the Jackson Heart Study Graduate Training and Education Center at the University of Mississippi Medical Center. Dr. Heitman co-directs two NIH Fogarty International Center–sponsored international research ethics education programs, one with Universidade Eduardo Mondlane in Maputo, Mozambique, and one with Universidad Peruana Cayetano Heredia in Lima, Peru. She is a national associate of the U.S. National Research Council and has been chair or member of eight U.S. National Academy of Sciences programs in research integrity education in the Middle East, North Africa, Indonesia, and Malaysia. In 2015–2016 she co-chaired the National Academies Committee on Gene Drive Research with Non-Human Organisms.

Matthew F. Hudson, Ph.D., M.P.H., is the director of cancer care delivery research at Prisma Health (Greenville, South Carolina), and professor of medicine at the University of South Carolina School of Medicine Greenville. Dr. Hudson conducts and oversees research on patient-, provider-, and organization-based interventions improving cancer care outcomes and patient well-being. Dr. Hudson served on multiple National Institute of Minority Health and Health Disparities study sections designed to augment workforce diversity. Dr. Hudson's own research examines racial differences in pain reports and management experiences among patients with cancer. Dr. Hudson served the Patient Centered Outcomes Research Institute (PCORI) as a member of their patient engagement advisory panel; he also co-authored the PCORI report *Equity and Inclusion Guiding Engagement Principles*. Dr. Hudson received his Ph.D. from Dartmouth College, M.P.H. from the University of California at Berkeley, and B.A. from the University of San Francisco. Dr. Hudson also received a certificate from the National Cancer Institute's Multilevel Intervention Training Institute (MLTI), and subsequently served MLTI as a small group junior faculty member.

Husseini K. Manji, M.D., is co-chair of the UK Government Mental Health Mission and professor at Oxford University. Previously, Dr. Manji was global head of science for minds at Johnson & Johnson (J&J), where he led a global team to discover and develop new therapeutics for major neurologic, psychiatric, and pain-related diseases with a high unmet need for effective treatments. Dr. Manji's research has helped to conceptualize severe neuropsychiatric disorders as genetically influenced disorders of synaptic and neural plasticity and led to the investigation of key novel therapeutics. The major focus of his research has been the investigation of disease- and treatment-induced changes in gene and protein networks that regulate synaptic and neural plasticity in brain and behavior disorders. Before joining J&J, Dr. Manji was director of the Mood and Anxiety Disorders Program, the largest research program of its kind in the world, at the National Institute of Mental Health. His work led to approval of the first novel antidepressant mechanism in decades, SPRAVATO (esketamine) nasal spray for adults with treatment-resistant major depressive disorder, by the U.S. Food and Drug Administration, Canada, and the European Commission. Dr. Manji is a member of the National Academy of Medicine. He also serves on the scientific advisory boards of the Dana Foundation and of Vanna Health.

Amy Moran-Thomas, Ph.D., is associate professor of anthropology at the Massachusetts Institute of Technology and teaches in the graduate program in history, anthropology, and STS (Science, Technology, and Society). She is interested in how social perspectives on design can contribute to producing more equitable technologies. Her work combines insights from ethnographies of science and medicine; material histories of design; and STS perspectives on health and environment. Her essays helped draw attention to longstanding racial biases encoded in color-sensing medical devices and catalyzed clinical reexaminations of the pulse oximeter, including recent U.S. Food and Drug Administration hearings that led to new safety advisories. Dr. Moran-Thomas' writings have appeared in publications such as *New England Journal of Medicine* and *Wired*. Her first book, *Traveling with Sugar: Chronicles of a Global Epidemic* (2019), offers an anthropological account of diabetes technologies in use and the lives they shape in global perspective. Research and writing were supported by the Mellon-American Council of Learned Societies, the Wenner-Gren Foundation, and the Rachel Carson Center for Environment and Society and received five book awards, including the Wellcome Foundation's Medal for Anthropology as Applied to Medical Problems. Professor Moran-Thomas received her Ph.D. in anthropology from Princeton University in 2012.

Margaret Moss, Ph.D., J.D., R.N., is an enrolled member of the Mandan, Hidatsa, and Arikara Nation in North Dakota. She is currently professor and associate dean for nursing and health policy at the University of Minnesota School of Nursing. She holds both nursing and juris doctorates. She has been a nurse for 34 years and an academic for 23 years across four universities. Previously at the University of British Columbia (UBC), she was a professor in the Faculty of Applied Science, School of Nursing (20%) and director of the UBC First Nations House of Learning (80%). During this time, she served as interim associate vice president of equity and inclusion at UBC (2022). Dr. Moss sat on the American Academy of Nursing board of directors in 2021–2023, is a new member of the National Academy of Medicine (2022), and is a member of the National Academies Board on Population and Public Health. Dr. Moss was a committee member on the recent consensus report *Federal Policy to Advance Racial, Ethnic and Tribal Health Equity* (2023). She wrote an award-winning text, *American Indian Health and Nursing* (2015) followed by *Health Equity and Nursing* (2020). She co-led the development and launch of the *UBC Indigenous Strategic Plan* (2020) and was a consultant on the *In Plain Sight Report: Addressing Anti-Indigenous Racism in Healthcare in BC* for the Minister of Health (2020). Dr. Moss was named an inaugural member of the *Forbes 50 over 50 Impact list 2021*. She was a Robert Wood Johnson Foundation health policy fellow, staffing the U.S. Senate Special Committee on Aging, and was a Fulbright chair at McGill University in Montreal, Canada.

Elizabeth O. Ofili, M.D., M.P.H., is a professor of medicine at Morehouse School of Medicine and a practicing cardiologist with Morehouse Healthcare in Atlanta, Georgia. She serves as chief medical officer for Morehouse Choice Accountable Care Organization, a Centers for Medicare & Medicaid Services shared savings program, which includes federally qualified health centers across the state of Georgia. Dr. Ofili is a nationally and internationally recognized clinician scientist with particular focus on cardiovascular disparities and women's health. In 2002, as president of the Association of Black Cardiologists (ABC), she led the initiative to implement the landmark African American Heart Failure Trial (AHEFT), whose findings changed practice guidelines for the treatment of heart failure in African Americans. Dr. Ofili is the founder and chief executive officer of AccuHealth Technologies Inc./Health 360x™ , a patient-centered platform for population health management and clinical trial diversity. Dr. Ofili is the immediate past chair of the board of the Association of Black Cardiologists. She serves as chair of the board of directors of Alliant Health Group, a nonprofit quality improvement organization. Dr. Ofili is a principal investigator (PI) in the National Research Mentoring Network and contact PI of the Coordination and Evaluation Center for the National Institutes of Health Faculty Institutional Recruitment for Sustainable Transformation (FIRST) Program for Inclusive Excellence. She serves as PI of the Amgen-sponsored African American Heart Study, multi-PI of the Georgia Clinical and Translational Science Alliance, and contact PI of the Research Centers in Minority Institutions Coordinating Center. She serves in advisory roles for Amgen's Rise program and the Bristol-Meyers-Squib-Pfizer alliance initiative. Dr. Ofili has received many awards for her contributions and is an elected member of the National Academy of Medicine. Dr. Ofili graduated with distinction from Ahmadu Bello University School of Medicine in Nigeria and received an M.P.H. from Johns Hopkins University.

Neil R. Powe, M.D., M.P.H., M.B.A., is chief of medicine at the Priscilla Chan and Mark Zuckerberg San Francisco General Hospital and the Constance B. Wofsy Distinguished Professor at the University of California, San Francisco. He also serves as the chief science officer for the Commonwealth Fund. Dr. Powe led the National Kidney Foundation–American Society of Nephrology Task Force on Reassessing the Inclusion of Race in Diagnosing Kidney Diseases which led to elimination of race from estimation of kidney function, for which he was recognized by Time100 Health. As member and now chair of the *Journal of the American Medical Association* oversight committee, he provided important decision making regarding a podcast on structural racism. Dr. Powe is a member of the National Academy of Medicine and has served on previous National Academies consensus study committees. Among his honors are the Diversity Award from the Association of Professors of Medicine, the John M. Eisenberg Award for Career Achievement in Research and the Robert J. Glaser Award from the Society of

General Internal Medicine, the David Hume Memorial Award from the National Kidney Foundation, the 2021 John Phillips Memorial Award for Distinguished Contributions in Clinical Medicine from the American College of Physicians, the Cato Laurencin Lifetime Research Award from the National Medical Association, and election to the American Academy of Arts and Sciences. Dr. Powe holds an M.D. and M.P.H. from Harvard, and at the University of Pennsylvania he completed residency, was a Robert Wood Johnson Clinical Scholar, and earned an M.B.A.

Aliya Saperstein, Ph.D., is the Benjamin Scott Crocker Professor in Human Biology and a professor of sociology at Stanford University. Her research focuses on the conceptualization and measurement of race/ethnicity and the consequences of these methodological decisions for studies of stratification and health disparities, including in the field of precision medicine research. Her work has been published in *Science*, the *Proceedings of the National Academy of Sciences*, *American Journal of Sociology*, *and* the *Annual Review of Sociology,* among others. Dr. Saperstein has been a visiting scholar at Sciences Po and the Russell Sage Foundation. Her scholarship has been honored with multiple article awards as well as the Early Achievement Award from the Population Association of America. Dr. Saperstein has a Ph.D. in sociology and demography from the University of California–Berkeley.

Roland J. Thorpe, Jr., Ph.D., is a professor in the Department of Health, Behavior, and Society, founding director of the Program of Men's Health Research in the Hopkins Center for Health Disparities Solutions, and director of the Johns Hopkins Alzheimer's Disease Resource Center for Minority Aging Research at the Johns Hopkins Bloomberg School of Public Health. Dr. Thorpe is a social epidemiologist and gerontologist whose research focuses on how social determinants of health affect health and functional outcomes among men across the life course. Dr. Thorpe serves as principal investigator (PI) on several National Institutes of Health–funded grants and is a multiple PI of the Artificial Intelligence/Machine Learning consortium to Advance Health Equity and Researcher Diversity (AIM-AHEAD). Dr. Thorpe is the inaugural associate vice provost for faculty diversity at Johns Hopkins University. He is a fellow of the Gerontological Society of America and the Academy of Behavioral Medicine Research. Dr. Thorpe earned a bachelor's in theoretical mathematics from Florida A&M University, a master's in statistics, and a Ph.D. in clinical epidemiology with a graduate minor in gerontology from Purdue University. He received postdoctoral training in health disparities and gerontology from the Division of Geriatric Medicine and Gerontology at the Johns Hopkins School of Medicine. Dr. Thorpe is a member of scientific advisory boards, including the National Center for Health Statistics Board of Scientific Counselors, and is the editor-in-chief of *Ethnicity & Disease*.

Shyam Visweswaran, M.D., Ph.D., is a professor and vice chair of clinical informatics in the Department of Biomedical Informatics at the University of Pittsburgh. His research broadly focuses on computerized clinical decision support driven by machine learning; patient-specific modeling, in which statistical models are tailored to the characteristics of the patient at hand and optimized to perform well for that patient; and the development of statistical machine learning methods for causal discovery using electronic health record data, molecular data, or both. His current research focuses on cataloging clinical algorithms that incorporate a person's race and ethnicity and developing computational methods for understanding the effect of race and ethnicity on model bias. He holds an M.B., B.S. degree (M.D. equivalent) from the Jawaharlal Institute of Post-Graduate Medical Education and Research in Pondicherry, India, an M.S. degree in physiology and biophysics from the University of Illinois at Urbana–Champaign, and a Ph.D. in intelligent systems (artificial intelligence) from the University of Pittsburgh. He completed his neurology residency at Boston University.

Genevieve L. Wojcik, Ph.D., is an associate professor of epidemiology at the Johns Hopkins Bloomberg School of Public Health. As a statistical geneticist and genetic epidemiologist, her research focuses on method development for diverse populations, specifically understanding the role of genetic ancestry and environment in genetic risk in admixed populations. Dr. Wojcik integrates epidemiology with statistical and population genetics to better understand existing health disparities in minority populations, as well as underserved populations globally. In 2021, she was the recipient of one of National Human Genome Research Institute's (NHGRI's) Genomic Innovator Awards (R35). She is a long-standing member of multiple NHGRI consortia focused on diverse populations, such as the Population Architecture using Genomics and Epidemiology (PAGE) Study and the PRIMED consortium. Prior to her faculty appointment, Dr. Wojcik was a postdoctoral research scholar at Stanford University in the departments of genetics and biomedical data science. She received her Ph.D. in epidemiology and M.H.S. in human genetics/genetic epidemiology from the Johns Hopkins Bloomberg School of Public Health and her B.A. in biology from Cornell University. She was recently a member of the National Academies Committee on the Use of Race, Ethnicity, and Ancestry as Population Descriptors in Genomics Research, which published its report in 2023.

Ruqaiijah Yearby, J.D., M.P.H., is the inaugural Kara J. Trott Professor in Health Law at the Moritz College of Law, a professor in the Department of Health Services Management and Policy at the College of Public Health, and a faculty affiliate of the Kirwan Institute for the Study of Race and Ethnicity at The Ohio State University. An expert in health policy and civil rights, Dr. Yearby has received over $5 million from the National Institutes of Health (NIH) to study structural racism and discrimination in vaccine allocation and from the Robert Wood Johnson Foundation to study the equitable enforcement of housing laws and structural racism in health care. She was a keynote speaker for the fifth annual conference of the ELSI Congress and has served as a reviewer for NIH, the Swiss National Science Foundation, and the Wellcome Trust. Dr. Yearby is on the editorial board of the *American Journal of Bioethics* and is a committee member for the U.S. Department of Health and Human Services Secretary's Advisory Committee on Human Research Protections. Her work has been published in the *American Journal of Bioethics*, *American Journal of Public Health*, *Health Affairs*, and the *Oxford Journal of Law and the Biosciences*.

STAFF BIOGRAPHIES

Sarah H. Beachy, Ph.D., PMP (*Study Co-Director*), is a senior program officer with the National Academies of Sciences, Engineering, and Medicine. In this capacity, Dr. Beachy serves as director of the Roundtable on Genomics and Precision Health and the Forum on Regenerative Medicine, in addition to leading other projects. In these roles, she has facilitated impactful activities on topics such as Population Descriptors in Genetics/Genomics Research, Improving Diversity of the Genomics Workforce, Changing the Culture of Data Sharing and Management, and An Examination of Emerging Bioethical Issues in Biomedical Research, among others. In 2022, Dr. Beachy was awarded a National Academy of Medicine Cecil Award for Individual Excellence for her contributions to the National Academies. Prior to her time at the National Academies, Dr. Beachy completed an AAAS Science and Technology Policy Fellowship in diplomacy at the U.S. Department of State, working closely with the Office of the Science and Technology Adviser to the Secretary. She was selected as a Mirzayan Science and Technology Policy Fellow at the National Academies in 2011. Prior to moving into science policy, Dr. Beachy was a postdoctoral fellow in the Genetics Branch at the National Cancer Institute, where she generated and characterized transgenic mouse models of leukemia and lymphoma. She earned her Ph.D. in biophysics from the Roswell Park Cancer Institute Graduate Division at the University at Buffalo.

Samantha N. Schumm, Ph.D. (*Study Co-Director*), is a program officer with the Board on Health Sciences Policy at the National Academies of Sciences, Engineering, and Medicine. During her time at the National Academies, she contributed to a consensus study on the Use of Race, Ethnicity, and Ancestry as Population Descriptors in Genomics Research as well as planned public workshops and led working groups on topics including workforce development and emerging manufacturing technologies in regenerative medicine. Prior to joining the National Academies in 2021, she studied mild traumatic brain injury at the University of Pennsylvania, using a variety of neuroscience techniques. Dr. Schumm developed a novel computational network model of the hippocampus brain region and analyzed emergent complex behaviors of neuronal networks. Her other interests include writing and promoting effective, inclusive mentorship in the sciences. Dr. Schumm has a Ph.D. in bioengineering from the University of Pennsylvania and a B.S. in biomedical engineering from Yale University.

Lydia Teferra is a research associate with the Board on Health Sciences at the National Academies of Sciences, Engineering, and Medicine, staffing the Roundtable on Genomics and Precision Health and the Forum on Regenerative Medicine. She graduated from Northwestern University in 2020 with a B.A. in psychology and global health and has been working at the National Academies for 3 years. During her time at the Academies, she has staffed a number of projects, including consensus studies on the use of respiratory protection for workers and the public along and the use of nonhuman primate models in biomedical research. Prior to her time at the National Academies, Ms. Teferra interned and volunteered for local nonprofit organizations addressing a number of public health issues. She hopes to pursue a master's degree in public health in the near future.

Ashley Pitt is a senior program assistant for the Board of Health Sciences Policy. Ms. Pitt graduated from the University of South Carolina in 2022 with honors, earning a bachelor of arts in public health. Prior to joining the National Academies, she worked as an assistant office manager for an oral surgeon where she demonstrated expertise in optimizing operations and enhancing communication between the front office and clinical staff.

Joseph Tumfour, M.H.S. (*until July 2024*), is an associate program officer with the Board of Health Sciences Policy at the National Academies of Sciences, Engineering, and Medicine, where he supports the consensus study on the Use of Race and Ethnicity in Biomedical Research. He earned his M.H.S. in environmental health and engineering from the Johns Hopkins Bloomberg School of Public Health, his B.S. degree in environmental biology from Kean University, and his A.S. degree in biology from Union County College. Mr. Tumfour's primary interest is in environmental health and justice, including a key role for community involvement in research and in formulating policies, legislation, and regulations. He aims to understand how environmental challenges adversely affect disadvantaged communities. During his time at Hopkins, he worked on impactful projects such as analyzing radon levels in Pennsylvania homes that reside in environmental justice communities. Prior to joining the National Academies, Mr. Tumfour worked as an environmental health and safety engineer at Genscript Biotech Corporation.

Alex Helman, Ph.D. (*from March 2024*), is a senior program officer with the Board on Health Sciences Policy at the National Academies of Sciences, Engineering, and Medicine. During her time at the Academies, Dr. Helman has led impactful activities on topics such as Mitigating Liability for Clinical Research Involving Pregnant and Lactating Populations, Building Research Equity for Women and Underrepresented Populations, and Strategies to Recruit, Retain, and Advance Women in STEMM Disciplines. She also led the Prevention Working Group and the Evaluation Working Group for the National Academies' Action Collaborative on Preventing Sexual Harassment in Higher Education. Before joining the National Academies full time, Dr. Helman was as a 2018 Mirzayan Science and Technology Policy Fellow at the National Academies. Prior to her science policy work, Dr. Helman studied vascular contributions to cognitive impairment in individuals with Down Syndrome. Dr. Helman received her Ph.D. in molecular and cellular biochemistry from the University of Kentucky, and her B.S. in biochemistry from Elon University.

Francis K. Amankwah, M.P.H., is a senior program officer in the Health and Medicine Division of the National Academies of Sciences, Engineering, and Medicine. He is currently the responsible staff officer on the National Academies' consensus study on *Unequal Treatment Revisited: The Current State of Racial and Ethnic Disparities in Healthcare*. Among his recent work are the workshops on Innovation in Electronic Health Records for Oncology Care, Research, and Surveillance; Promoting Health Equity in Cancer Care; Innovation in Cancer Care and Cancer Research in the Context of the COVID-19 Pandemic Care; and Suicide Prevention in Indigenous Communities. He served as the responsible staff officer on the National Academies' congressionally mandated consensus study which produced the consensus report *Medications in Single Dose Vials: Implications of Discarded Drugs*. He also played an integral role in the development of the National Academies' consensus reports *Guiding Cancer Control: A Path to Transformation* and *Making Medicines Affordable: A National Imperative*. He is a recipient of the Health and Medicine Veteran, Mount Everest, and Fineberg staff achievement awards. He earned his M.P.H. and a graduate certificate in global planning and international development from Virginia Tech. He was raised in Ghana, West Africa, and earned his B.S. degree in agricultural science from Kwame Nkrumah University of Science and Technology.

Ronique Taffe, M.P.H., joined the Board on Population Health and Public Health Practice in 2023 as the program officer for the Roundtable on the Promotion of Health Equity. Previously she worked for the National Association of County and City Health Officials (NACCHO) where she supported health equity work within the context of overdose, injury, and violence prevention. She worked at the National Committee for Quality Assurance (NCQA) for a number of years where she supported the product development team in developing and maintaining evidence-based and equitable health plan accreditation standards. Ms. Taffe obtained her M.P.H. from the University of Maryland, College Park, in public health practice and policy, and her bachelor's degree from the University of Maryland, Baltimore County, in health administration and policy with a minor in sociology. She was selected to participate in the 2020 inaugural class of the National Academy of State Health Policy Emerging Leader of Color Fellowship.

Clare Stroud, Ph.D., is senior board director for the Board on Health Sciences Policy at the National Academies of Sciences, Engineering, and Medicine. In this capacity, she oversees a program of activities addressing the basic biomedical and clinical research enterprises needed to improve the health and resilience of the public, including examining social and ethical issues that accompany science and technological advances. Previously, she served as director of the Forum on Neuroscience and Nervous System Disorders, bringing together leaders from government, industry, academia, and patient advocacy organizations to discuss key challenges and emerging issues in neuroscience research, development of therapies for nervous system disorders, and related societal issues. She also served as director for consensus studies and other projects on topics such as dementia caregiving, preventing cognitive decline and dementia, clinical research data sharing, young adult health and well-being, and disaster preparedness in health systems. Dr. Stroud first joined the National Academies as a science and technology policy graduate fellow. She has also been an associate at AmericaSpeaks, a nonprofit organization that engaged citizens in decision making on important public policy issues. Dr. Stroud received her Ph.D. from the University of Maryland, College Park, with research focused on the cognitive neuroscience of language and face perception. She received her bachelor's degree from Queen's University in Canada and spent a year at the University of Salamanca in Spain.

Michael Zierler, Ph.D., is the founder and co-owner of RedOx Scientific Editing, a small shop that provides developmental editing and related editorial and writing services. He has an undergraduate degree in biology from Brown University and a Ph.D. in biology from Johns Hopkins University, where he worked on the regulation of gene expression in eukaryotes, stockpiling of DNA polymerases during embryogenesis, and intramolecular movements in hemoglobin studied using hydrogen exchange. Prior to graduate school, he spent a summer studying the behavior of lemon sharks off the Florida Keys and worked for a cardiothoracic surgeon at the West Roxbury Veterans Affairs Medical Center, doing research in the laboratory and the operating room on monitoring and improving the physiology of the heart during open heart surgery using mass spectrometry and a miniaturized pH electrode. After graduate school, he completed a postdoctoral position at the State University of New York, Stony Brook, helping to identify the molecular components of the Salmonella injectisome, a bacterial invasion system. He has taught biological sciences at the high school and college levels. He has also served as the deputy mayor and the chair of the planning board in his hometown of New Paltz, New York.

Benjamin Weston, M.D., M.P.H., is the 2022–2024 National Academy of Medicine Fellow to Advance State Health Policy. Dr. Weston is an associate professor in the Department of Emergency Medicine at the Medical College of Wisconsin. He serves as chief health policy advisor for Milwaukee County working to enhance the health of 1 million citizens. In addition, Dr. Weston is the director of medical services for the Milwaukee County Office of Emergency Management, overseeing medical services for the 15 fire departments throughout the county. He practices clinically in the emergency department at Froedtert Hospital, a Level 1 Trauma Center. His research interests include prehospital care, resuscitation, health equity, and public health surveillance. Dr. Weston served as the medical director for the Milwaukee County/City/Municipality COVID-19 Emergency Operations Center. He has been featured on MSNBC, CNN, BBC, Good Morning America, NBC Nightly News, and in *Politico* and *The New York Times*. He has provided medical direction and oversight for events including NFL, NBA, MLB, Indycar, and USA Triathlon. He has been selected as *Milwaukee Business Journal*'s 40 under 40, named the Public Health Leader of the Year, and listed as "Best of Milwaukee" in *Milwaukee Magazine*. Dr. Weston received his M.D. and M.P.H. from the University of Wisconsin School of Medicine and Public Health and completed his emergency medicine residency at Hennepin County Medical Center. Dr. Weston is dual board-certified in emergency medicine as well as emergency medical services by the American Board of Emergency Medicine after completing his emergency medical services fellowship at the Medical College of Wisconsin.