NAAC Accredited Grade A+

RESEARCH POLICIES

Comprehensive documents covering Research Management & Promotion Polices of the University

Datta Meghe Institute of Medical Sciences
(Deemed to be University)
Sawangi (Meghe), Wardha

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RESEARCH POLICY

PREAMBLE:

The DMIMS (DU) is committed to enhancing the contribution of research to health and social care. Research is essential to the successful promotion and protection of health and wellbeing, and also to modern, effective health and social care services. At the same time, research can involve an element of risk, both in terms of return on investment and sometimes for the safety and wellbeing of the research participants.

Proper governance of research is essential to ensure that the public can have confidence in, and benefit from, quality research in health and social care. The public has a right to expect high scientific, ethical and financial standards, transparent decision making processes, clear allocation of responsibilities and robust monitoring arrangements.

The broad aim of research policy of the University is to ensure smooth governance and promotion of research, but also safeguarding the wellbeing of research participants/subjects. The Policy set out principles, requirements and standard. It defines mechanism to deliver them and describe the monitoring and assessment arrangements. To improve the research and safeguard of the public, policy clearly recommend for enhancing ethical awareness and scientific quality, promoting good practices.

Research policy is for all those who design research studies, participate in the research, host research in their organization / institutions, fund research proposal or infrastructure, manage research and undertake research.

1. PURPOSE

This policy sets the framework for the development and implementation of research activities at Datta Meghe Institute of Medical Sciences (Deemed to be University) within which academic staff carry out their required research obligations, and all courses / programme undergraduate, postgraduate, Fellowship, M.Phil, Doctoral, Staff & Faculty and, & other can engage and be supported in their research.

2. OBJECTIVES

The Policy shall foster conducive milieu for interdisciplinary research practices generating consequential and meaningful outcomes for the nation in general and the region in particular.

The Policy shall promote creation of favorable environment to create centers of excellence for research and development, and for dissemination of knowledge and its relevant application regionally, nationally and globally.

3. ORGANIZATIONAL SCOPE

This shall be the University wide policy

4. POLICY CONTENT AND GUIDELINES

4.1 Requirement to undertake research

a) All academic staffs have the right and are required to conduct research and engage in scholarship and to publish their findings.

b) All academic staffs have the right to and should, where appropriate, seek research funds in support of their research.

c) The requirement to undertake research is a career expectation and over time will be balanced as appropriate with the other obligations of academic staff including significant administrative responsibilities.

d) All doctoral and postgraduate students have the right and are required to conduct research and engage in scholarship and to publish their findings as a mandatory requirement for their course.

e) All doctoral and postgraduate students have the right to and should, where appropriate, seek research funds in support of their research.

f) Nothing in this policy is to be construed to prevent Heads of institutions from allocating teaching and other responsibilities in the light of the research record of academic staff.

4.2 Research Management

a) Advice and policy in research matters shall be coordinated through a following mechanism and number of committees / bodies (see Appendices):

b) The University Research Committee (URC), chaired by the Director Research and Development shall be the University's senior research management body.

c) URC shall advise the Academic Board on research strategies to be pursued, develops policy (including issues in postgraduate student research and scholarships) and reviews progress in these areas.

d) All constituent units of University shall have research coordinator / Convener, at institutional level, to coordinate and to advise the URC and their own Faculties on matter related to research.

e) Constituent Units of University shall nominate a Research Officer (RO) / Convener to coordinate the research activities with URC.

f) Research Coordinator / Convener shall also assist the URC in monitoring research and development activities.

g) The Research and Development Department, URC shall provide information related to research opportunities to staff and postgraduate students

h) The URC shall mange the Intramural Research & Extramural research the internal administration of research, monitoring and evaluation of research in coordination with various subcommittees.

i) The Department, Institutes shall apply for funding agencies for research, however all a copy of proposal and application shall be provided to URC for documentation and monitoring.

4.3 Resources in support of research

a) University research funds - The University shall have an annual research budget. The budget shall be utilized for creating necessary infrastructure for research, capacity building activities for research, providing seed money for researchers, providing incentives for the researchers.

b) Seed money for researcher: URC shall recommend Registrar of the University for seed money for research that is aligned with Universities strategic priority and to research which are of significant consequences. URC shall constitute a committee for

selecting research/researcher for seed money. The committee shall have at-least one subject expert in the specific area (topic) research to be assessed for seed money.

c) **Incentives & processing fees for publication:** The University shall provide the financial incentives as per criteria policy who published their research in scientific, peer reviewed journals.

d) **Special leave for faculty and students:** All faculties as / staffs and students of the University shall be granted leave as per sabbatical leave policy to avail the special leave for research activities as per the service rules. For leave extending more than permissible days as per the service rules shall be availed on recommendation of the Director, Research and Development. The special leave shall be utilized for attending workshop, meetings, conferences, seminars. Symposiums or any other activities exclusively for the purpose of research.

e) **Central research laboratory:** The University shall have the facility of central research laboratory with all necessary equipment and instrumentation for the purpose of research. The in-charge of the central research laboratory shall periodically keep informed faculties and students about the facilities available at laboratory.

f) **Research Guidance Centre:** The University shall have a research guidance centre with various research stations like epidemiology, clinical epidemiology, biostatistics, research methodology etc. Research guidance centre shall provide technical assistance to researcher on solicitation. The centre shall also organized capacity bundling activities for researchers of the university.

g) **Journal of Datta Meghe Institute of Medical Sciences:** The University shall publish the quarterly multi-disciplinary scientific, peer reviewed journal. This shall provide opportunity to researchers from University to publish their research.

h) **Staff Research Society (SRS) and Clinic Pathological Meet (CPC):** SRS and CPC shall be two separate activities to be organized monthly by the University. The Univeristy shall nominate the convener / secretary for these activities. These activities will be the forums for researchers from university to present their research work.

i) **Hospital and peripheral health centers:** The University shall provide researchers the clinical material and laboratories of hospital and health centers for undertaking research. All research shall follow the ethical principles strictly, as per the Helsinki Declaration, University guidelines of ethical conduct of research and SOP Institutional Ethics Committee (See Appendix)

j) **Library facility:** The University shall provide the library facility – scientific Journals and books in hard bound as well as electronic from for all researchers.

k) **Capacity building in research through various indication programs of the University:** The University is conducting Induction programs for freshers at various levels. These induction programs provide opportunity to sensitize students regarding research. The URC shall ensure that all induction programs shall make a mandatory

session on research methodology for capacity building of students in research at various levels.

4.4 Research Planning

a) Each Institute/Centre/Department shall develop and implement its own research plan. These plans are to be drawn up by Heads of Institutes / Deans /Directors in consultation with URC.

4.5 Evaluation and monitoring of performances

a) The Deans/principal of the respective institute shall monitor performance against their research plans on the basis of agreed criteria and will advise the academic board through URC on the outcome of this process.

b) The research performance of individual staff shall be monitored and evaluated as part of the staff development planning process.

c) All Staff shall supply full and accurate details of their research outputs on an quarterly as well as annual basis to their Head of Institutes and to URC.

d) The URC shall provide Registrar quarterly research report to be presented in the academic meetings of University.

e) The Registrar of the University shall publish an annual report with list of staff and student publications, funded projects, funding received etc.

4.6 Doctoral and Postgraduate research

a) Doctoral and Postgraduate, Undergraduate, Fellow research students make a vital contribution to the research environment and output of the University.

b) Heads of Institutes /Deans shall be responsible for ensuring that the management of postgraduate research degrees complies with University policy.

c) The timing and frequency of the report shall be set out according to the PhD and postgraduate policy of the University

d) Head of the Institutes/Deans, Head of Departments are responsible for ensuring all necessary support of postgraduate student research.

e) Any request for fudging for doctoral and postgraduate students shall be forwarded through Director, Research and Development.

4.7 Statutory and Ethics obligations

a) Academic staffs are required to carry out their research in compliance with all statutory, ethical and contractual obligations. (See Appendix 1 for Ethical Conduct of research)

b) All research projects conducted by staff and students that involve human subjects or animal subjects, including those undertaken as part of a teaching programme, must secure the prior approval of the relevant ethics committee (see the Institutional Ethics Committee – Appendix 2 and the Animal Ethics Committee Appendix 3).

4.8 Publication and intellectual property rights

a) The standard expectation is that all research outputs will be published in a publicly available form.

b) This expectation is subject to any considerations that justify either restricted publication or delayed publication.

c) Such considerations include the need to observe any contractual, confidentiality or privacy obligations entered into in respect of the research or the need to ensure the protection of any intellectual property arising out of the research.

d) All Staffs and students of the University are required to comply with the University's Intellectual Property Right Policy (See Appendix 5).

5. LEGISLATIVE COMPLIANCE

a) Though the University is required to manage its policy documentation within a legislative framework; there is no specific legislation directing this policy

6. APPENDICES

Appendix 1: University guidelines for ethical conduct of research
Appendix 2: Helsinki Declaration
Appendix 3: SOP of Institutional Ethics Committee
Appendix 4: SOP of Animal Ethics Committee
Appendix 5: Intellectual Property Right Document
Appendix 6: SOP of Central Research Laboratory

7. POLICY SPONSOR

Vice Chancellor of the University

8. CONTACT PERSON

Registrar and the Director Research and Development shall be contacted for any matter related to this policy

DATTA MEGHE INSTITUTE OF MEDICAL SCIENCES

[DEEMED UNIVERSITY]

Intramural Grant Program

Guidelines

Research & Development

THE INTRAMURAL GRANTS PROGRAM

The Intramural Grants Program (IGP) is all-inclusive and harmonized highly competitive grant program that supports Undergraduate, Interns, Post-Graduate, Doctoral Scholars, Young Research Scholars, Fellows, Faculty research and bursary, proficient development, programmatic projects and innovative works in all disciplines of Medical Sciences. It is designed to support Undergraduate, Post-Graduate, Doctoral Scholars, Young Research Scholars, Fellows, Faculty in becoming competitive in securing external funding and sponsorship. Supported projects are expected to result in appropriate scholarly products that will increase the national and international recognition of the awardees, their programs, constituent colleges and the University.

Datta Meghe Institute of Medical Sciences-Deemed to be University [DMIMS (DU)] - Intramural Grant Program (IGP) conduct basic, translational, and clinical research. Intramural grant Program are open to any faculty or staff member, student group, or unit within the Datta Meghe Institute of Medical Sciences (Deemed University) community.

Seed Grant - Provides funding for all disciplines to assist students and faculty with initiating research projects or producing data for extramural grant applications, or creative scholarship and research projects with a demonstrated likelihood of significantly enhancing the reputation of DMIMS (DU).

Innovative Research Grant - Provides funding for faculty to generate preliminary data for extramural grant applications or research materials for original or innovative creative research, scholarship and works. Provides support to enhance faculty competitiveness for extramural grant applications and to complete highly significant creative scholarship, work or research projects. When a research proposal is favorably reviewed by an extramural grant review panel but not yet funded, the PI is encouraged to bring these research efforts to fruition.

Intramural Grant Program Information Update

In keeping with efforts to advance both diversity and sustainability at DMIMS (DU), we would like to clarify that early translation, interdisciplinary research, or technology innovation is encouraged within the Intramural Grants Program (IGP), in addition to other areas of basic bioscience, clinical and public health research. We encourage you to apply for an IGP award and welcome proposals in all disciplines.

Applicants are encouraged to contact the following coordinators of R&D, DMIMS (DU) to discuss your proposal prior to submitting it for committee review.

Undergraduate and Post-Graduate Applicants are encouraged to contact Prof Samarth Shukla (samarth21174@gmail.com) / Prof Sourya Acharya (souryaacharya@yahoo.co.in) to discuss your proposal prior to submitting it for committee review. Doctoral, Young Research Scholars, Fellows and Faculty Applicants are encouraged to contact Prof Abhay Gaidhane (abhaygaidhane@gmail.com)/ Prof Quazi Syed Zahiruddin (zahirquazi@gmail.com)

Applicants can meet personally the above research officials with prior appointments at Research House, R&D, DMIMS(DU) for more information (rddmimsu@gmail.com).

Acknowledgements

Any publication of the research work resulting from this Grant must include an appropriate acknowledgment of the Intramural Grants Program. Although no one form is required, we recommend the following:

This [research, et al.] is made possible in part by support from the Intramural Grants Program of the Datta Meghe Institute of Medical Sciences.

Human Subjects Research

Any project that involves the use of human subjects must be approved by the Human Subjects Institutional Ethical Committee. For details of the procedures, please contact Institutional Ethical Committee Office at The Research House, R&D, DMIMS (DU) (iec.dmims@gmail.com).

Committee approval must be completed and submitted to the R&D DMIMS (DU) so that regular funding can be received.

Applicants are strongly encouraged to attend Orientation Programs and Research Workshops provided to strengthen their proposals.

Timeline- Intramural Grant **(Please review each funding opportunity for specific eligibility criteria and check back frequently for the release of special funding announcements.**						
	Faculty / Young Research Scholars	**Fellows**	**Intern**	**Undergraduate**	**Postgraduate**	**Doctoral Scholars (PhD)**
Advertisement	July-August	June/July	September to December	1st Week January	September to December	July-August
Submission date for Request for Proposal (RFP)	Submission is allowed throughout the year.	August	January	Last week of January	January	September
Presentation and decision of Review Committee	Evaluation/scrutiny would be done in **March, June, September and December.**	September	February	February	February	October
Orientation	November	March	March	March	March	November
Monitoring & Evaluation	Biyearly Progress Report	Biyearly Progress Report	Biyearly Progress Report	1 Project progress report during the project. (June)	Biyearly Progress Report	Biyearly Progress Report
Report submission *(Special approval is required in case of extension)*	Two years after approval	April	By 31st December	By 31st December	Two years after approval	Three years after approval

Maximum Grant Amount per Beneficiary (INR)	Upto 100,000 (One Lakh Rupees)	Upto 25000 (Twenty five thousand)	Upto 10000 (Ten Thousand Rupees) (At the time of the submission of the Report).	10000 fixed (Ten Thousand Rupees) (At the time of the submission of the report).	Upto 25000 (Twenty five thousand)	Upto 40000 (Forty thousand)
Duration of Project *(Special approval is required in case of extension)*	Maximum 1 year	1 Year	1 Year	2 months (Any 2 months from April to September)	Maximum 2 years	Maximum 3 years
Maximum Beneficiaries	As per application Merits (upto Budget Limit)	As per application Merits (upto Budget Limit)	As per application Merits (upto Budget Limit)	JNMC: 50 SPDC: 20 MGAC: 14 SRMMCON:10 RNPC : 10 Total: 104	As per application Merits (upto Budget Limit)	As per application Merits (upto Budget Limit)
Criteria & Eligibility	Staff of Constituent colleges: • JNMC • SPDC • MGAC • SRMMCON • RNPC	Fellows enrolled under school of advance studies	UGs of constituent colleges: • JNMC* • SPDC • MGAC • SRMMCON • RNPC ** Can avail the Intramural grant only after submitting the proof of submission for*	UGs of constituent colleges: • JNMC* • SPDC • MGAC • SRMMCON • RNPC **JNMC student must apply to ICMR_STS to avail the Intramural grant.*	PGs of constituent colleges: • JNMC • SPDC • MGAC • SRMMCON • RNPC **JNMC and SPDC Postgraduate student must apply to ICMR_PG Thesis grant to avail the*	Scholars of constituent colleges: • JNMC • SPDC • MGAC • SRMMCON • RNPC

			publication		*Intramural grant.*	
Total Maximum Budget*	5000000 (Fifty Lacs Rupees) Maximum ceiling is not more than 50 Lacs. JNMC: 22 Lacs SPDC: 09 lacs MGAC: 14 lacs SRMMCON: 05 Lacs RNPC:05 Lacs			1040000 (Ten Lakh Forty Thousand Rupees)	1400000 (Fourteen Lac Rupees) JNMC: 6 Lacs SPDC: 3 lacs MGAC: 2 lacs SRMMCON: 2 lacs RNPC : 1 lac	500000 (Five Lacs)

*** Interns and Fellowship Intramural grant will be adjusted from the existing sanctioned budget of the faculty Intramural Grant Scheme.**

Annexure – 1

Note:-

i. Maximum number of beneficiary of all the constituent colleges will be provided grant amount. If grant for particular college is unutilized due to less number of candidates or any other reason, then the committee is authorized to allocate to other deserving applicant of other constituent college.

ii. Release of sanctioned Grant amount will be 70% at during the project & 30% upon submission of manuscript for publication.

iii. The amount of sanctioned grant will be flexible within the constituent colleges of DMIMS depending upon the quantity as well as quality of research work.

iv. Funds will not be utilized for typing, printing, Xeroxing, binding, stationary, attending conferences/seminar/workshops, publications, etc (If required special approval may be sought from competent authority)

v. There shall be **Review committee**, comprising of

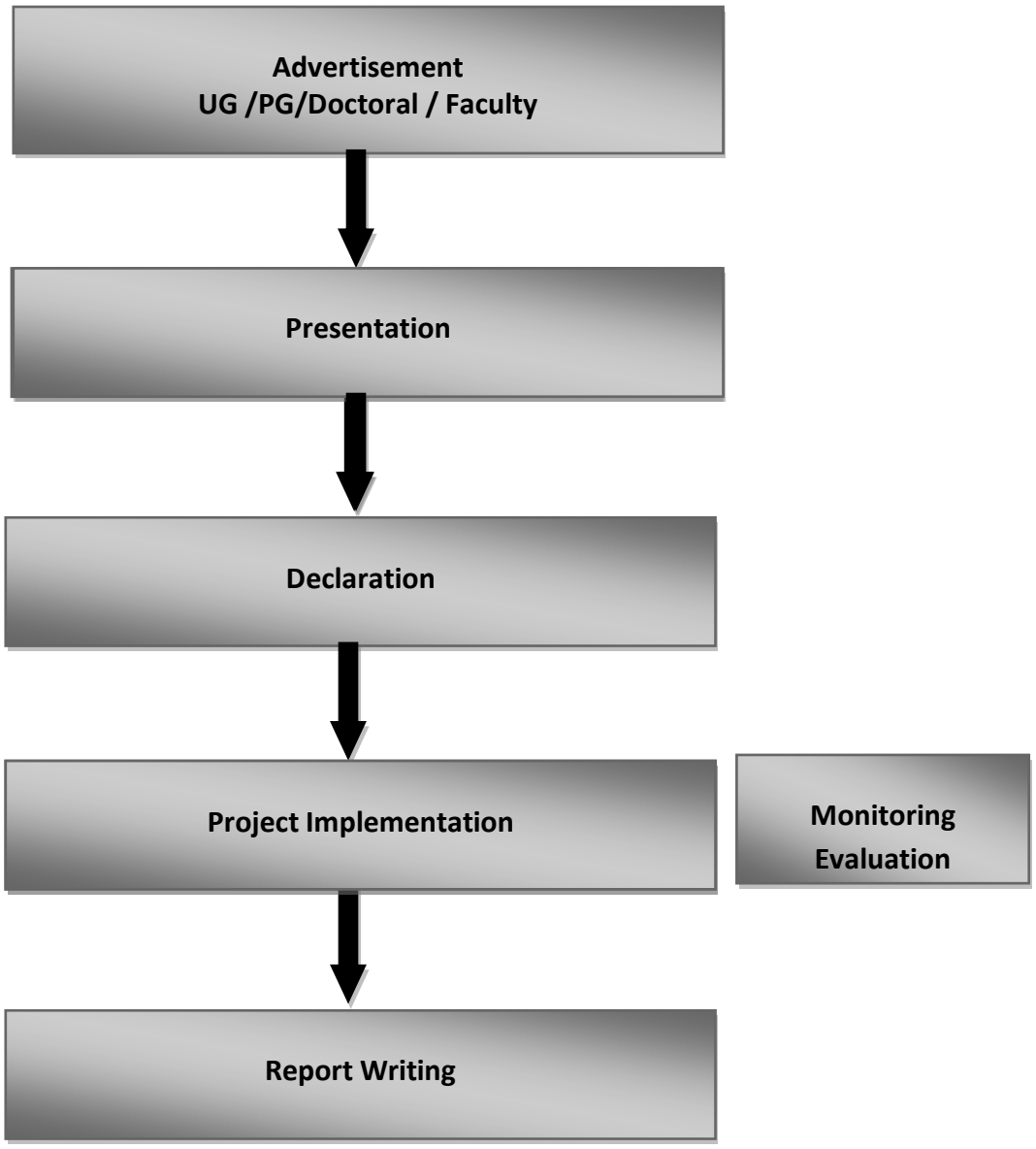
   a) Director, R & D (Chairman)
   b) Head of institutions/Dean academics
   c) Core R & D members
   d) In-charge- Central Research lab (Member Secretary)
   e) Minimum One nominee (special invitee) by Director R & D

vi. The Review committee shall have right to seek the advice of the research guidance clinic pertaining to any research proposal/project report.

vii. Faculty Research

Preference will be given to

i. Early Career Research Scholars
ii. Fellowship Scholars (INR 25000/- per scholar)
iii. Post-Doctoral Researchers
iv. Multidisciplinary / Interdisciplinary research
v. Collaborative/ Inter-institutional research
vi. Start-up entrepreneurs
vii. Collaborative Alumni Researchers


Advertisement
UG /PG/Doctoral / Faculty
Presentation
Declaration
Project Implementation
Monitoring
Evaluation
Report Writing

Annexure – 2

BUDGET DISPENSING PROTOCOL

UNDER GRADUATE

Upon Approval of the scrutiny committee and submission of manuscript for publication, R&D UG In-charge shall submit the certified list via HOI to the Finance Officer. The Finance Officer shall release the due amount of INR 10,000/- within 15 days of submission of the approved work.

POST GRADUATE, DOCTORAL, FACULTY

Approval Committee shall approve the budget depending upon the nature of work under 3 headings:

1. Stores: Material Procurement
2. Hospital: Patient related expenses
3. Cash (with justification)

STORES: MATERIAL PROCUREMENT PROCEDURE:

- The researcher upon approval will submit the list of material along with the quantity for procurement by the stores through the department adhering to the ongoing protocols.
- The researcher shall coordinate with the stores for procuring the rates and total amount required for the whole project, which will be approved by the R&D. The amount shall not exceed the sanctioned budget. If it does than researcher will have to bear the cost. For additional budget requirement special approval is required from competent authority.
- R&D shall submit the approved budget to designated accountant under finance officer for the said purpose, who shall maintain a separated ledger of individual research project.
- Finance officer shall accord approval to the store for the purchase of the material

and the store shall indent the same to the researcher within 2 months of approval from finance department.

HOSPITAL: PATIENT RELATED EXPENSES –

- The researcher upon approval will submit the details of Patient related expenses with R&D Clerk.
- R&D Clerk shall coordinate with the hospital finance office for procuring the rates of procedures/ investigations and total amount required for the whole project, which will be approved by the R&D. The time limit for this working shall not exceed 7 working days. The amount shall not exceed the sanctioned budget.
- R&D shall submit the approved budget with the estimated cost of patient related expenses to designated accountant under finance officer for the said purpose, who shall maintain a separated ledger of individual research project. The researcher will be allotted the "patient vouchers" signed by the competent authority for the allotted work by the accountant which can be redeemed for the said patient related expenses. (ex- for a research involving 15 CT scans worth RS 15000, the researcher shall be allotted 15 CT scan free vouchers signed by COE hospital which he/ she can avail during the duration of the research project only)
- The Researcher shall maintain the details of the utilization of vouchers in terms of receipt no and submit the same during the final submission of the work.

CASH (WITH JUSTIFICATION)

- The Scrutiny committee will justify the nature of work to be conducted by the researcher requiring the Cash amount (ex- investigations to be done outside not possible in AVBRH, certain work to be done at some higher center etc).
- R& D shall submit such proposals to the competent authority, who shall approve the cash disbursement for the said research work.
- Upon approval by the competent authority the sanctioned list shall be maintained by the designated accountant under finance officer for the said purpose, who shall maintain a separated ledger of individual research project. 70% of the Sanctioned amount shall be released within three months of the commencement of the project.

- Remaining 30% shall be released after the submission of report/ manuscript and the utilization certificate by the research along with the necessary documents.

Annexure – 3

ETHICAL CONSIDERATIONS

i. A researcher should obtain a clearance/approval from the Institutional Ethics Committee (IEC), if the proposal involves research on human participants and from Institutional Animal Ethics Committee (IAEC) if the work involves use of animals.

ii. Ethics committee approval can be obtained necessarily before beginning of research work.

iii. IEC/IAEC approval can be obtained from the IEC of DMIMS. In case the study involves collaboration with another institute/college, an ethics committee approval from all collaborating institutions needs to be obtained.

iv. IEC and IAEC submission at the time of application submission is optional however mandatory for availing the sanctioned grant as well as for final report.

v. Ethics committee approval is needed for all kinds of biomedical research involving human and animal participants or their samples or stored data/clinical records.

vi. Research should not be done if ethics committee has not given the clearance. If the ethics committee is not holding a meeting, the researcher will be unable to carry out the research. Any research carried out without IEC/IAEC approval will be automatically rejected.

vii. In case, it is felt that research belongs to exempt category a "certificate of exemption" may be obtained from the IEC and submitted along with report.

viii. Informed consent is to be obtained for any research on human participants.

ix. Original document should be safely kept by the researcher. It may also be required later when the researcher would try to publish the research in a journal.

x. For more information please refer to ICMR "Ethical guidelines for Biomedical Research on Human participants" available on http://icmr.nic.in/ethical guidelines in addition to other key documents related to ethics.

Annexure – 4

APPLICATION FOR INTRA MURAL RESEARCH FUNDING

Date :

Please Tick :-

JNMC ☐ SPDC ☐ MGAC ☐ RNPC ☐ SRMMCON ☐

Please Tick :-

UG ☐ PG ☐ Ph. D ☐ Faculty ☐

1. **Name of Principal Investigator :**
2. **Designation : (If applicable) :**
3. **Department : (If applicable) :**
4. **To Be filed by UG student Only**

   Batch : Roll No.:
5. **Name of Supervisor / Guide (If applicable):**
6. **Project Title :**

7. **Mobile No: Email id :-**
8. **Applied to Inst. Ethics Comm. YES / No**
   (Research grant will be availed only after receiving IEC approval letter)

   Approval Letter No : _____

PART B: RESEARCH PROPOSAL

1. **Introduction:**

   - Background
   - Review of Research and Development in the subject area/Discipline specifically related to the proposed work:
     - ❖ International status
     - ❖ National status
     - ❖ Significance of the study
   - Objectives
   - Methodology
   - Year wise plan of work and targets to be achieved
   - Details of collaboration, if any intended

2. **Details of the facilities available for the proposed work:**

   i. Institutional level (if applicable):
   ii. Department level:
   iii. Equipment(s)
   iv. Other infrastructural facilities:
   v. Any other:

3. Detail the usefulness of the Project for the department/ Institution.
4. Any other information which the Principal Investigator may like to give in support of the proposal which may be helpful in evaluation.

Part C- Financial Assistance Required

Sr. No	Item	Name of Investigation / Procedure / Kits	Unit Cost	Total Number of Units	Total
1	Investigation/ Procedure /				
2	Consumables / Kit				
3	Special Assistance for Services Outside DMIMS (after approval)				
4	Other Specify for special approval				
				Grand Total (1+2+3+4) = Total)	**Rs.**

Part D: UNDERTAKING FROM PRINCIPAL INVESTIGATOR

Project Title:

It is certified that

1. We/I undertake that spare time on equipment procured in the project will be made available to other users.
2. We/I agree to submit ethical clearance certificate from the Institutional ethical committee, if the project involves field trials/experiments/exchange of specimens, human & animal materials etc.
3. The research work proposed in the scheme/project does not in any way duplicate the work already done or being carried out elsewhere on the subject.
4. We/I agree to abide by the terms and conditions of DMIMS Intramural grant.
5. We/I shall complete the project within stipulated period. If We/I fail to do so and if the Review Committee is not satisfied with the progress of the research project, the project may be terminated immediately and we/ I may have to refund the amount proportional to the recurring expenditure Incurred by us/me.

Name and signature of Principal Investigator:

Date:

Place:

Annexure – 5

PROGRESS REPORT

Important Points

1. Report should be sent even if project has not become fully operational. Please write "NIL"
2. Against items where there is nothing significant to report or if these Items are not relevant.
3. The first Progress Report should cover the work done during the first 06 months of the project implementation. Subsequent reports should cover the next 06 Months and so on.
4. Timely submission of report is essential to facilitate release of funds.
5. Report should be in the format given below.
6. The report should be discussed and finalized by the project team before sending it.

Instructions for preparing the Manuscript of the Report

i. Manuscripts should be neatly written/printed (with single spacing) in the enclosed format for direct reproduction by Xerox/ photo off set process. Any corrections should be redone on a separate slip & then pasted neatly. Don't erase or re type. Don't cut/cross.

ii. Matter should be first preferably typed on A4 size paper within the prescribed space leaving the same margin as in the enclosed format and then retyped cleanly after careful correction/changes.

iii. Diagrams & graphs should be accommodated. Within space provided for the text for direct reproduction.

iv. Please do not leave any item unanswered.

PROGRESS REPORT

1. Period of report : from_____to _____

2. (a) Name of the Principal Investigator _____

   (b) Department and Institution name where work has progressed

3. Title of Research/Product Development Work_____

4. Effective date of starting of the project _____

5. Total expenditure till date _____

REPORT OF THE WORK DONE:

i. Brief objective of the project:

ii. Work done so far and results achieved and publications, if any, resulting from the work (Give details of the papers and names of the journals in which it has been published or accepted for publication.

iii. Has the progress been according to original plan of work and towards achieving the objective? If yes, then major achievements and if not, state reasons:

iv. Please indicate the difficulties, if any, experienced in implementing the project.

v. Any other information which would help in evaluation of work done on the project (for ex. (a) Manpower trained (b) Ph.D. awarded (c) Publication of results (d) other impact, if any).

1. Signature of the Principal Investigator (on all pages):

2. HoD

Annexure- 6

PROJECT COMPLETION REPORT

1. Title of the project:
2. Principal Investigator(s) and Co-Investigator(s):
3. Implementing Institution(s) and other collaborating Institution(s):
4. Date of commencement:
5. Planned date of completion:
6. Actual date of completion:
7. Introduction (including rationale)
8. Objectives as stated in the project proposal:
9. Deviation made from original objectives if any, while implementing the project and reasons thereof:
10. Methodology
11. Results
12. Summary
13. Conclusions
14. References
15. Annexure:

    a) IEC letter
    b) Consent form
    c) Study tool
    d) Utilization certificate
    e) Translatory component (if any)
    Publications/Presentations/Copyrights/Patents/Monographs/Other (specify)

Signature of PI

Annexure- 7

UTILIZATION CERTIFICATE

Certified that out of Rs_____of grants-in-aid sanctioned during the year_____ in favour of_____ _____letter / order No_____dated _____and Rs_____on account of unspent balance of the previous year, a sum of Rs_____has been utilized for the purpose for which it was sanctioned and that the balance of Rs _____ remaining unutilized at the end of the year. **OR** will be adjusted towards the grants – in aid payable during the next year i.e. _____

Certified that we have satisfied ourselves that the conditions on which the grants – in-aid was sanctioned have been fulfilled / are being fulfilled and that we have exercised the following checks to see that the money was actually utilized for the purpose for which it was sanctioned.

Kinds of check exercised.

1.
2.

Signature of PI	Signature of Registrar / Account officer	Signature of Head of Institution
Date	Date	Date

RESEARCH INCENTIVE SCHEME

Datta Meghe Institute of Medical Sciences
(Deemed to be University), Wardha

RESEARCH INCENTIVE SCHEME

Datta Meghe Institute of Medical Sciences-Deemed to be University [DMIMS (DU)] – Research Incentive Scheme promote basic, translational, and clinical research.

Purpose:

DMIMS (DU) has formulated this Research Incentive Scheme which provides financial incentives for staff to promote research publications, research grants, consultancy, copyrights, and patents. This Research Incentive Scheme is to support the development of a strong research base and culture within the DMIMS (DU). To create research enabling environment and ecosystem more attractive to current and prospective staff, to provide staff with an incentive to make research part of daily routine and to boost innovative research and achieve successful outcomes in terms of research publications, quality competitive grants, consultancy and IPR. So also enhance the research performance of staff at the individual level.

The policy is intended to encourage greater effort and success in securing external research funding, to recognize the significant effort involved in running research grants and the need for departments and centers to provide appropriate support for grant holders.

GUIDELINES:

- Research publications in journals may have multiple authors; the incentive will be provided to the first author. Herein, if publication is a collaborative inter institutional publication, the author from DMIMS-DU will be considered irrespective of the position in the list of authorship

- Incentives for publication will be only given for affiliation of DMIMS DU and its constituent colleges.
- It is the responsibility of the faculty member to produce evidence of having published paper in the refereed journal and the impact factor of the journal. The staff has to produce a printed copy of the SCOPUS or other evidence. The researcher may use the multiple resources to identify the indexing of journals like researcher http://www.scimagojr.com/journalsearch.php; pubmed journal - https://www.ncbi.nlm.nih.gov/pubmed/
- The incentive will be for all publications in journals, books, chapters, monographs, copyright and patent received, research grants received.
- Plagiarism, and any irregularities shall attract severe disciplinary action, including recovery of incentives paid earlier.
- Any suggestions, opinions or appeals, relating to the application of the incentive system, will be addressed by R&D Director
- The criteria and modalities will be amended from time to time.

Period of inclusion Research Incentive Scheme: 1st January to 31st December of every year

Total Budget: Incentives for Publications/Copyright/Patents/Incentives for Guide: INR 15 Lakhs and INR 10 Lakhs for Processing fees for publications in Q1 ranking Journals. Incentives for extramural research grants and consultancy will be provided as per policy.

PROCESSING FEES

- Processing fees up to Rs. 10,000 /- per publication to be provided for publications in Scopus or web of science or PubMed. If journal is indexed in any two databases (Scopus/ PubMed / WoS) complete processing fees up to Rs.20,000 /- per publication to be provided.
- If the article is published in Q1 indexed journal **OR** having Impact Factor more than 2.0 (Thomson Reuter); full processing fees to be supported by University.
- As the special privileges for Research Ambassador's or publications from funded projects or ICMR - STS or ICMR PG Thesis Support - Full processing fees to be supported by University.
- The scheme will be applicable to all UG /PG Doctoral, fellowship, Staff and Faculty (including Adjunct Faculty) of all constituent colleges. This scheme will be applicable if proof is given and reflected in database of Scopus / web of science / PubMed with affiliation ID of Datta Meghe Institute of Medical Sciences.(Deemed to be University)
- Amount of processing fees if more than Rs. 20,000 /- will require special approval of Vice-Chancellor

INCENTIVES FOR PUBLICATIONS IN JOURNALS

Description		Original research (INR)	Review article ** (INR)	Case Report (INR)	Edited/Co-edited Journals (INR)
Publications indexed in renowned databases like Scopus/PubMed/Web of science journals	Q1	15000	10000	5000	10000
	Q2	7500	5000	2500	
	Q3	5000	2500	1500	
	Q4	2500	1500	1000	

INCENTIVES IN BOOKS/MONOGRAPHS/CHAPTERS:

Sr	Description	Published in database Book Citation Index (Thomson Reuters)	Renowned national and international publishers	Others
1	Edited/Co-edited/Authored - Full Book (like Text book/Reference book)/Edited volume of book	20000	5000	1000
2	Authors of Chapters	5000	3000	500

INCENTIVES FOR INTELLECTUAL PROPERTY RIGHTS (IPR):

Sr. No	Description	Amount
1	Copyrights Received	1000
2	Patent Received	25000

INCENTIVES FOR RESEARCH GRANTS

The incentive will be linked to the total amount of research grant received from the sponsoring agency. The incentive will be as per the guidelines set by the competent authority for the research grant.

Sr. No	Incentive for Research Grants for PI	
1	Incentive for Research Grants will include fundings received for Conferences and Workshops from external funding agencies	**Cash Incentives for PI on actual amount received by the university from external funding agencies:** Tier based incentives ● 1 Lakh 20% ● 1-5 Lakh 15% ● 5 -25 Lakh 05% >**25 Lakh** Amount of incentive to be decided by the Vice-Chancellor in consultation with the members of the finance committee. (**Special Note:** In case the research is not successfully completed or left in between which will be assessed by an expert committee to be appointed by the Vice Chancellor then in such case the university will recover from the concerned PI the amount of incentive given to him from his salary & remuneration.

Undertaking Consultancy Projects:

Sr No	Description of Incentive for consultancy	Amount
1.	Institutional/University Consultancy (If the resource of the university such as hospital services, investigations, laboratory facilities, computing and other facilities are utilized in the consultancy project)	As per Budget Guidelines and Agreement (If no agreement than ● 20% of amount to Consultants ● 80% to the University (Amount Shared if more than 1 consultant) (With due information to funding agency)
2	Individual Consultancy (If no resources of the University are utilized except consultant expertise in terms like intellectual inputs)	As per Budget Guidelines and Agreement (If no agreement than 80% of amount to consultants & 20% to the University. (Amount Shared if more than 1 consultant) (With due information to funding agency)

INCENTIVES FOR GUIDES

Datta Meghe Institute of Medical Sciences-Deemed to be University encourages its undergraduates and postgraduates to apply for the ICMR STS and MD/MS/DM/MCh/MDS THESIS fund respectively.

The guides promote interest and aptitude for research among medical undergraduates for Short Term Studentship Program and MD/MS/DM/MCh/MDS THESIS fund. The main objective of this incentive for guide is to reward the guide for encouraging the undergraduate & postgraduate medical students to familiarize themselves with research methodology and techniques by being associated for a short duration with their seniors on ongoing research program or by undertaking independent projects

The role of guide is of crucial in application and completion of the research projects of Undergraduate and Postgraduate students. Keeping this in mind the competent authority has decided to launch incentives of Rs 5000/- to the guides of the UG & PG students who have received extramural funds like from ICMR, RNTCP etc and have successfully completed the project.

Responsibilities of the Guide:

- Guide must take overall responsibility for mentoring and support for the research project.
- Guiding the student in selection of appropriate research topic
- Encouraging the student for timely application of the project to the funding agency
- Ensuring successful completion of the project in timely manner,
- Preparation and submission of complete report.

DATTA MEGHE INSTITUTE OF MEDICAL SCIENCES
[DEEMED UNIVERSITY]

Research Practice

Guidelines

Jan -2017

Research & Development

GOOD RESEARCH PRACTICE

The Department of Research and Development (R&D); Datta Meghe Institute of Medical Sciences Deemed University [DMIMS (DU)] Guidelines on Good Research Practice have been developed to emphasise the importance of integrity and rigor in all research carried out at and in partnership with the Centre. The policy covers integrity, openness, conflicts of interest, leadership, supervision & training, ethical practice, conducting the research, intellectual property and publications of research results.

1. General principales

The DMIMS (DU) is committed to conducting its business in accordance with seven principles: selflessness, integrity, objectivity, accountability, openness, honesty and leadership. The R&D expects all those engaged in research to observe these principles, whether they are employees of the Institute, or students, and irrespective of the sources of their funding, or their area of research. The R&D has an Honour code which states: “DMIMS (DU) operates on a principle of trust. Most research materials are kept in accessible locations.

Research at DMIMS (DU) depends critically on colleagues being able to trust each others data. Hence, any form of cheating or falsification of data is totally unacceptable and will invite appropriate consequences. “This document provides guidelines on good practice in research and is intended for all staff, including persons with honorary positions, and students carrying out research at or on behalf of DMIMS (DU). Research in the biomedical area involving humans and other animals raises specific ethical issues.

2. Integrity

Researchers should be honest in respect of their own actions in research and in their responses to the actions of other researchers. This applies to the whole range of research work, including designing experiments, generating and analyzing data, applying for funding, publishing results, and when peer reviewing the work of other researchers. The direct and indirect contributions of colleagues, collaborators and others should be acknowledged.

Researchers are accountable to society, their professions, the institutes where the research is taking place, the staff and students involved and, in particular, to the sponsor that is funding the research. Researchers are expected to understand and apply the following principles:

- Plagiarism, deception, or the fabrication or falsification of results is regarded asa serious disciplinary offence
- Researchers are encouraged to report cases of suspected misconduct, and to do soin a responsible and appropriate manner.

The DMIMS (DU) approach to managing these issues is described in detail in the policy document entitled "Misconduct in Research".

3. Openness

Whilst recognizing the need for researchers to protect their own academic and, where appropriate their intellectual property rights (IPR), the Centre encourages researchers to be as open as possible in discussing their work with other researchers and with the public. The aim in disseminating public-funded or Centre research is to increase knowledge and understanding: its purpose should not be primarily to seek publicity for the researcher, for DMIMS (DU) or for the sponsor. Once results have been published, DMIMS (DU) expects researchers to make available relevant data and materials to other researchers,

on request, provided that this is consistent with any ethical approvals and consents which cover the data and materials, and any intellectual property rights in them. Procedures for managing the transfer of materials in and out of DMIMS (DU) are available onrequest.Sponsors recognize that publication of the results of research may need to be delayed for a reasonable period pending protection of any intellectual property arising from the research. Any such periods of delay in publication should be kept to a minimum and this should normally be no more than six months. Researchers should be especially careful when discussing work that is not complete or has not been published, particularly if it has not undergone peer review. Exchange of confidential information bye-mail is not recommended especially if patent applications are anticipated.

4. Conflicts of interest

Conflicts of interest happen in all walks of life; scientific research is no exception. A conflict arises when a person's judgment concerning a primary interest, such as scientific knowledge, could be unduly influenced by a secondary interest, such as financial gain or personal advancement. There is nothing inherently unethical in finding oneself in a position of conflict of interest; what is required

is to recognize the fact and deal with it accordingly. Researchers must pay as much attention to perceived and potential conflicts of interest as to actual conflicts. How one is perceived to act influences the attitudes and actions of others, and the credibility of scientific research overall.

Conflicts of interest can occur at every stage of the research Endeavour – from planning the research to disseminating and exploiting the results – and in many forms. Apart from financial interests, conflicts might, for example, be personal, academic, or political. Researchers should automatically ask themselves "Would I feel comfortable if others learnt about my secondary interest in this matter or perceived that I had one?" If the answer is no, the interest must be disclosed and addressed appropriately, for example according to the policy of an employer, a peer-review body, or a journal. The Centre's approach to managing financial conflicts of interest is described in detail in the policy document entitled "Managing conflicts of interest".

5. Leadership

Senior colleagues at the Centre should ensure that a research climate of mutual cooperationis created in which all members of a research team are encouraged to develop their skills and in which the open exchange of ideas is fostered.

6. Supervision & Training

Although everyone involved in science must take personal responsibility for maintaining the highest standards of integrity, the head of a laboratory, who is necessarily a mentor or supervisor of research, has special responsibilities. The laboratory head should ensure that personnel for whom he or she has responsibility, including associates, students, and technical staff, receive appropriate supervision and instruction. In particular, the laboratory head should teach and encourage careful scrutiny and interpretation of results, emphasizing the importance of and reliance on sound primary data.

Careful review and evaluation of all primary data by the laboratory head is necessary and cannot be delegated to others unless it is clearly understood that the individuals concerned are conducting research in a largely independent manner, for example in the case of certain senior visiting scientists or other senior research staff. It is inadvisable for the investigator to delegate these important functions. The laboratory head must assume absolute responsibility for the validity of all communicated and published information from his or her laboratory and for the publication of the data that may ensue from work in the laboratory.

DMIMS (DU) offers courses to enable students and new researchers to understand and adopt best practice in research as quickly as possible. Supervisors should encourage students and colleagues to attend relevant courses as part of their overall career development.

7. Ethical practice

The legal and ethical requirements relating to human participants, animals, and stem cell research should be familiar to each person involved in the study, and they should know to whom to turn for advice. Since ethical issues, guidance, or requirements often change, research teams must have effective arrangements for disseminating knowledge and documents. Each person should also know when changes may call for new ethical/regulatory approval and should be able to recognise unforeseen results or incidents that need to be reported and discussed.

7.1 Research involving human participants

DMIMS (DU) and its sponsors require that all research involving human participants or human biological samples has approval from the Institutional Bio-safety and Bio-Ethics Committee. The mandate of the Committee is to:

- Conduct scientific review in respect of proposals that involve human subjects and samples
- Examine ethical issues involving human subjects and samples
- Examine and approve all proposals for research at DMIMS (DU) in conformity with Department of Bio-Technology (DBT) and Indian Council of Medical Research (ICMR) Bio-Safety and Bio-Ethics rules and guidelines.

7.2 Research involving animals

DMIMS (DU) and its sponsors require that all research involving animals has approval from the Institutional Animal Ethics Committee. The mandate of the Committee is to:

- Conduct scientific review in respect of proposals that involve animals
- Examine ethical issues involving experimentation on animals
- Examine and approve all proposals for research at **DMIMS (DU)** in conformity with the
- CPCSA Guidelines.

Researchers should consider, at an early stage in the design of any research involving animals, the opportunities for Reduction, Replacement and Refinement of animal involvement "The Three Rs".

7.3 Research involving stem cells

DMIMS (DU) is in the process of creating an Institutional Committee for Stem Cell Research and Therapy. The mandate of the Committee will be to:

- Conduct scientific review in respect of proposals that involve human stem cells
- Examine ethical issues involving experimentation with human stem cells
- Examine and approve all proposals for permissive stem-cell research at DMIMS (DU) in
- conformity with the DBT/ICMR Guidelines.
- Examine and approve all proposals for creation of new human stem cell lines at
- DMIMS (DU)
- Examine and approve the import/movement of established human stem cell lines
- into DMIMS (DU)
- Examine and approve all proposals involving clinical trials of human stem cell
- lines at DMIMS (DU)

8. Conducting the research

8.1 Use, calibration, and maintenance of equipment

Equipment used to generate data should be appropriately located, safe, suitable for the purpose, of appropriate design, and of adequate capacity. It should be calibrated and serviced regularly by trained staff so that performance is optimal and the results can be trusted. A designated person should be responsible for ensuring the proper use and maintenance of equipment and, where appropriate, for training staff in its use; when this is not possible, the users themselves should take on the responsibility. Records should be kept of calibration, servicing, faults, breakdowns, and misuse of equipment. There should be easily accessible instructions for the safe shutdown of equipment in case of emergency.

8.2 Hazardous processes and materials

Experiments should be conducted in accordance with local policies on training, and health and safety regulations and guidelines. Where appropriate, risk assessments should be prepared before the work is carried out. Where necessary, materials and equipment should be decontaminated according to specified health and safety practices including an approved risk assessment. Waste should be disposed of and recorded in accordance with these practices and the appropriate health, safety, and environmental regulations, and also in compliance with local rules for dealing with spillages. Where relevant, the appropriate authority should be notified. Staff should be properly trained and monitored so as not to endanger themselves, others, or the environment.

8.3 Standard operating procedures

Standard operating procedures (SOPs) should be documented for all routine methods and for individual items of equipment to ensure that data are collected consistently and accurately. When there is more than one approved technique for any given procedure, all should be covered by SOPs. SOPs should be written in simple language, readily accessible, and ideally in a standardized format. They should be updated as necessary, and only the current version should be available. Written protocols are likewise essential for ensuring strict adherence to regulations/ licenses, for example in research involving animals.

8.4 Gathering and storing data

- Data should be stored in a way that permits a complete retrospective audit if necessary.
- Data should be stored safely, with appropriate contingency plans.
- Data records should be monitored regularly to ensure their completeness and accuracy.
- Data should be backed-up regularly; duplicate copies should be held on disc or tape in a secure but readily accessible archive. The Centre provides secure and archived storage for electronic data.
- Where feasible, a hard copy should be made of particularly important data.
- Copies of relevant software, particularly the version used to process electronic data, must be retained along with the raw data to ensure future access. Software updates must be logged and stored as new formats and media are adopted.
- Raw (original) data/images should be recorded and retained; this is especially
- important where data/images are subsequently enhanced. If possible, both original and enhanced data/images should be stored, along with provenance tracking to record every manipulation done to images or data. Over enhancement or over- interpretation of images is inappropriate.
- Special attention should be paid to guaranteeing the security of electronic data.
- Confidentiality is also important where there is potential for commercial exploitation.

8.5 Notebooks and electronic records

The following basic policies apply:

- All raw data should be recorded and retained in indexed laboratory notebooks with permanent binding, or in electronic laboratory notebooks which maintain a full logging system so that all edits and comments on any entry are recorded.
- Machine print-outs, questionnaires, chart recordings, autoradiograph, etc which cannot be attached to the main record should be retained in a separate ring-binder/folder that is cross-indexed with the main record. Similarly, any digital data that cannot be incorporated into

physical or electronic notes must be fully referenced so that it can be easily accessed. Digital data should always be stored on lab or institution servers so that it is accessible to the lab and institute, and should have full backup and archival capabilities.

- Records in physical or electronic lab notebooks should be entered as soon as possible after the data are collected. Recorded data should be identified by date of the record and date of collection if the two do not coincide. Subsequent modifications or additions to records should also be clearly identified and dated.
- Special attention should be paid to recording accurately the use of potentially hazardous substances (eg, radioactive materials) in both laboratory notebooks and any central logbooks.
- In clinical studies, consent forms should be kept securely with the raw data, and normally for the same period of time.
- Supervisors should regularly (monthly or as appropriate to the nature of the work) review and "sign-off" notebooks of researchers to signify that records are complete and accurate. Electronic lab notes should also be marked by the supervisor as having been examined. Queries should be discussed immediately with the individual who recorded the data and any resultant changes to the records should be signed by both. In the case of electronic lab notes the changes must be logged by the system. Authentication of data collected and recorded electronically requires special consideration.
- All lab records should be placed in a standard location, known both to the laboratory head and to the Dean's office. This includes standard locations for electronic lab records on institute servers. This is mandated by the requirements that all results can be substantiated by the laboratory head and centre.
- All labs must have a policy for handover of original laboratory notes, and all supporting material, to the supervisor, at the time of departure/graduation of laboratory members. It is permissible and encouraged for a copy to be made for the departing laboratory member.

9. Dissemination and publication of results

DMIMS (DU) encourages the publication of and dissemination of results of high quality research but believes that researchers must do this responsibly and with an awareness of the consequences of any such dissemination in the wider media. DMIMS (DU) expects those it supports to play their part in disseminating balanced information on scientific advances and their potential implications for society to the health professionals and policy makers who will be involved in applying them,

and to the wider public. Researchers should take into account the following guidance when publishing or disseminating their research findings including any plans they may have to publish or publicise research at conferences or on web sites.

9.1 Publication policy

- The person with overall responsibility for the research programme should authorise publication of results; authorisation should cover both the content of the paper (integrity of results, adequacy of internal peer review, appropriate protection of intellectual property rights, appropriate authorship) and the intended place of publication.
- Open access and open source publishing of data is encouraged, to improve reuse of results and raw data. However, release of data on the internet must be approved by the leader of the research team, as this may compromise subsequent publication and intellectual property rights.
- All funding sources must be acknowledged in any publication or publicity.
- Research findings with substantial implications for clinical practice or which are likely to attract strong public interest should be drawn to the attention of the research funders before publication.
- Published reports should normally contain basic information about the ethical acceptability of the work and/or its legality, as well as information about the scientific method.
- Work should normally be published as a coherent entity rather than a series of small parts, unless there is a legitimate need to demonstrate first discovery by publishing preliminary data.
- Quality rather than quantity is paramount.
- Authors must not publish the same data in different journals.

9**.2 Authorship**

- Authorship of papers should include those individuals who have made a major contribution to the work and who are familiar with the entire contents of the paper. Authors should have participated sufficiently in the research to take public responsibility for the content.
- The contributions of formal collaborators and all others who directly assist or indirectly support the research should be both specified and properly acknowledged. Other contributions to the work should be acknowledged formally, as should financial support

from sponsors. Authors are responsible for obtaining written permission from persons acknowledged by name.

9.3 Correction of errors and retraction of published findings

- If an error is found that degrades the worth of published findings, the principal author must immediately discuss the matter with the research leader, with a view to notifying co- authors and publishing a correction as soon as possible setting out the basis of the reservations.
- Where the findings are found to be in serious doubt, a retraction should be published speedily.
- Where fraud is suspected, the procedure set out in the policy "Managing Research Misconduct" should be followed.

10. Commercial exploitation

DMIMS (DU) has in place an Intellectual Property Management Office (IPMO) and a Technology Transfer Office (TTO) to develop and implement strategies and procedures for the identification, protection, management and exploitation of institutional intellectual property (IP).The Centre's policy on Intellectual Property Rights ensures that institutional intellectual property is used for the benefit of wider society, and that institutional inventors are rewarded appropriately. Researchers are strongly encouraged to inform the IPMO of any intellectual property rights that may arise from externally funded research and also inform the sponsor, if they so request. Full details of the DMIMS (DU)' approach to managing intellectual property are available on request.

Other Useful Sources of Information

- The Office of Research Integrity (ORI), USA.
- MRC-Good Research Practice
- University of Cambridge-Good Research Practice
- HHMI Policy on Research Conduct
- WT/DBT India Alliance- Guidelines on Good Research Practice

RESEARCH MISCONDUCT

1. Research misconduct

1.1 Research misconduct is defined by the R&D DMIMS (DU) as:

1. Fabrication, falsification, plagiarism, self-plagiarism, or deception in proposing, carrying out or reporting results of research.
2. Deliberate, dangerous or negligent deviations from accepted practices in carrying out research.
3. It includes failure to follow established protocols if this failure results in unreasonable risk or harm to humans or the environment and facilitating of misconduct in research bycollusion in, or concealment of, such actions by others.
4. It also includes intentional, unauthorized use, disclosure or removal of, or damage to, research-related property of another,including apparatus, materials, writings, data, hardware or software or any other substances or devices used in or produced by the conduct of research.

2. Responsibilities of the DMIMS (DU)

2.1 The R&D DMIMS (DU) considers that it is the responsibility of the DMIMS (DU) to investigate all allegations of research misconduct made against its staff and students. Findings of research misconduct would be matters for consideration under the DMIMS (DU)'s disciplinary procedures.

2. 2 All DMIMS (DU)s supported by the R&D DMIMS (DU) are expected to have in place formal, publicly notified, processes for addressing the issue of research misconduct. It is advisable that these processes are in consonance with the spirit of this (i.e. R&D DMIMS (DU)’s) policy statement.

2.3 DMIMS (DU)s must ensure that these processes contain provisions thatapply to visiting researchers while based in the DMIMS (DU) and to the DMIMS (DU)'s staff while visiting elsewhere.

2.4 It is the responsibility of the DMIMS (DU) to inform the R&D DMIMS (DU), in confidence and without prejudice, at the earliest opportunity, about allegations of serious research misconduct that concern grant holders whenever there is prima facie credibility in allegations of a serious nature. It

is the responsibility of the DMIMS (DU) to determine what constitutes ‘serious misconduct' and to document it as part of its notified processes. The DMIMS (DU) is also responsible for informing the R&D DMIMS (DU) of the outcome of any such investigation.

2.5 It is the responsibility of the DMIMS (DU) to inform the R&D DMIMS (DU), in confidence, of all instances of research misconduct involving grant holders that have resulted in the allegations being substantiated, as well as of the outcome of the disciplinary process resultant there from.

2.6 The policy statement and process notification of the DMIMS (DU) should have in place components relating to the treatment of whistleblowers, including a clear statement that research misconduct is taken seriously in the DMIMS (DU) and that any member of staff raising bona fide concerns can do so confidentially, and without fear of suffering any detriment, as also
that mala fide allegations will invite disciplinary action. The statement should include a clear indication of the procedures in which such bona fide concerns by staff may be brought to the attention of a designated individual within theDMIMS (DU).

3. Principles for investigation by DMIMS (DU)s of allegations of researchmisconduct

3. 1 Each DMIMS (DU) must have in place formal written procedures for dealing with allegations of research misconduct against its staff and students and other researchers.

3.2 DMIMS (DU)s should, where appropriate, take legal advice on implementing these procedures to ensure that the procedures comply withal legal obligations for the conduct of such investigations from time to timein force.

3.3 DMIMS (DU)s should endorse the following principles when implementing these procedures:

1. The responsibilities of those dealing with the allegation should be clear and understood by all interested parties
2. Measures should be in place to ensure an impartial and independent investigation and to ensure that line-management obligations or other interests of those dealing with the allegation do not conflict with theseprocedures.
3. Those undertaking research at the DMIMS (DU) should be contractually obliged to participate in and comply with the procedure.
4. The DMIMS (DU) should consider the confidential nature of the investigation and how to safeguard the rights to confidentiality of the interested parties.

All interested parties should be informed of the allegation at an appropriate stage in the proceedings.

Anyone accused of misconduct should have the right to respond A policy should be in place to ensure that no employee who makes an allegation in good faith against another employee shall suffer a detriment, but equally that disciplinary procedures are in place to deal with malicious allegations.

The allegation should be dealt with in a fair and timely manner.

- Proper records of the proceedings should be kept.
- The outcome should be made known as quickly as possible to all interested parties.
- Anyone found guilty of misconduct should have the right to an appeal.
- Appropriate sanctions and disciplinary procedures should be in place for cases when the allegation is upheld
- If appropriate, efforts should be made to restore the reputation of the accused party if the allegation is dismissed.

4. Involvement of the R&D DMIMS (DU)

4. 1. Receipt of allegations

The R&D DMIMS (DU) recognises that there may be instances where an allegation of research misconduct is made directly to a member of the R&D DMIMS (DU)'s staff or the Secretary rather than to an individual within the DMIMS (DU). In such instances, the R&D DMIMS (DU) will contact an appropriate individual at the DMIMS (DU) and the DMIMS (DU) will then be responsible for taking suitable action in line with its formal written procedures for handling allegations of research
misconduct.

4.2 Investigations by the R&D DMIMS (DU)

As stated above, it is the DMIMS (DU)'s responsibility to investigate allegations of research misconduct made against its staff and students and this would be the R&D DMIMS (DU)'s preferred course of action in most cases. In exceptional cases, however, the R&D DMIMS (DU) may wish to undertake its own investigation into alleged cases of research misconduct that concern grant holders (for example where the R&D DMIMS (DU)'s reputation is at risk or where the R&D DMIMS (DU) is dissatisfied with the investigation undertaken by the DMIMS (DU)).

Any investigations by the R&D DMIMS (DU) would only be undertaken following consultation between the R&D DMIMS (DU) and the appropriate representative's of theDMIMS (DU).

5. Sanctions

5.1. Sanctions by the host DMIMS (DU) are expected to be according to its statement on research misconduct and its rules and regulations.

5.2 If the DMIMS (DU) or the R&D DMIMS (DU) determines that the allegation of research misconduct is substantiated, the R&D DMIMS (DU) may also consider appropriatesanctions.

These may include, but are not restricted to:

- A letter of reprimand.
- The withdrawal of funding.
- Requiring the withdrawal or correction of pending or published abstracts and papers emanating from the research in question.
- Changes to the staffing of the particular project.
- Special monitoring of future work.
- Barring of the grant holder from applying for R&D DMIMS (DU) funds for a given period
- Repayment of grant plus interest at the R&D DMIMS (DU)'s discretion.
- Discussion with the host DMIMS (DU) on its implementation of appropriate administrative disciplinary procedures.

5.3 At all times, in line with its grant conditions, the R&D DMIMS (DU) reserves the right to withdraw funding with immediate effect.

OPEN RESEARCH DATA: CLINICAL TRIALS AND PUBLIC HEALTH INTERVENTIONS

The R&D DMIMS (DU) strongly promotes the principles of open research data and aims to make the research process and findings as open, understandable and reproducible as possible. Sharing data can enhance the use of existing data, avoid duplication of research effort and stimulate new discoveries.

The DMIMS (DU) policy on open research data from clinical trials and public health interventions applies to the following types of IGP funded study:

Clinical trials and clinical intervention studies: studies that prospectively assign human participants to one or more health-related intervention to evaluate the effects on health outcomes, including all stages of clinical trials.

Public health intervention studies: studies of a public health intervention to promote or protect health, or prevent ill-health, in communities or populations.

Observational studies: studies that assess outcomes in groups of human participants according to a research protocol, in order to investigate the effects of lifestyle or behaviours, or interventions that are part of routine care.

The policy does not apply to studies that involve human tissue only.

Registration

Any IGP funded studies within the scope of this policy are required to register with the ISRCTN registry and to obtain a unique ISRCTN number. The IGP project reference must be included in the registration.

Publishing study findings

The R&D DMIMS (DU) requires the results from IGP funded studies (whether positive or negative) to be published without unreasonable delay following the conclusion of the study. Publications should include the IGP project reference and ISRCTN registration number.

Publishing the study protocol and statistical analyses

The IGP requires all funded studies to make the study protocol, analysis plan and all relevant statistical analyses publicly available prior to the start of the study Details of where and how the study protocol and analysis plan may be accessed should also be provided on the ISRCTN register.

Data sharing: Individual Participant Data

The R&D DMIMS (DU) expects valuable data arising from IGP-funded research to be made available to the scientific community with as few restrictions as possible so as to maximise the value of the data for research and for eventual patient and public benefit. Such data must be shared in a timely and responsible manner.

The R&D DMIMS (DU) is aware of the risks of fully open access to individual participant data (IPD), in particular the need to comply with participant consent and avoid inadvertent or deliberate identification of participants. The R&D DMIMS (DU) expects researchers to follow the guidance in Good Practice Principles for Sharing Individual Participant Data from Publicly Funded Clinical Trials opens in new window which details good practice principles and practical guidance on sharing IPD in a controlled way. A data sharing policy should be developed for each study.

Research involving the population health sciences, and population and patient cohorts should follow the R&D DMIMS (DU) policy on sharing of research data from population and patient studies.

The R&D DMIMS (DU) expects researchers to publish summary data about the data requests made, including the number of requests fulfilled and reasons for refusal.

Applications for IGP funding for clinical and public health intervention studies should include the costs of data curation, including the preparation of metadata, access management and data release, to support its availability for data-sharing and re-use.

Secondary use of data

This policy also applies to secondary users of data from IGP-funded clinical and public health intervention studies.

Secondary data analyses should not be registered as separate clinical trials on the ISRCTN, but it is considered good practice to make information about such studies available on a publicly accessible register. Researchers are required to include a reference or link to the original data and trial registration number with any published findings.

Contact:

If you have any queries about policies please contact us at rddmimsu@gmail.com

DATA SHARING POLICY

Contents

Introduction:

Research and Development, Datta Meghe Institute of Medical Sciences (Deemed University) want to maximise the research opportunities that such a diversity, richness and quantity of data provides. One of the best ways of achieving this is to ensure that data are properly preserved for sharing and informed use beyond the originating research teams.

Our data-sharing policy applies to all IGP -funded research. It does not prescribe when or how researchers should preserve and share data but requires them to make clear provision for doing so when planning and executing research.

2. Principles

1. The R&D DMIMS (DU) expects valuable data arising from IGP-funded research to be made available to the scientific community with as few restrictions as possible so as to maximise the value of the data for research and for eventual patient and public benefit. Such data must be shared in a timely and responsible manner.
2. The R&D DMIMS (DU) believes that data-sharers should receive full and appropriate recognition by funders, their academic institutions and new users for promoting secondary research.
3. New studies that result from this data-sharing should meet the high standards of all DMIMS research regarding scientific quality, ethical requirements and value for money. It should also add recognisable value to the original dataset.
4. Such research is often most fruitful when it is a collaboration between the new user and the original data creators or curators, with the responsibilities and rights of all parties agreed at the outset.

5. Data arising from IGP-funded research must be properly curated throughout its life-cycle and released with the appropriate high-quality metadata. This is the responsibility of the data custodians, who are often those individuals or organizations that received MRC funding to create or collect the data.
6. A limited, defined, period of exclusive use of data for primary research is reasonable according to the nature and value of the data and how they are generated and used.
7. On-going research contributing to the completion of datasets must not be compromised by premature or opportunistic sharing and analysis. Sharing should always take account of enhancing the long-term value of the data.
8. R&D DMIMS (DU) policy is not intended to discourage filing of patent applications in advance of publication and recognizes that it may be necessary on occasion to delay publication for a short period to allow time for applications to be drafted.
9. For medical research involving personal data, the appropriate regulatory permissions – ethical, legal and institutional – must be in place before the data can be shared.
10. Researchers, research participants and research regulators must ensure that within the regulatory requirements of the law, opportunities for new uses are maximized. Potential research benefits to patients and the public should outweigh identified risks. Risks such as inappropriate disclosure of personal information must be managed in a proportionate yet robust manner.
11. Access policies and practices for new and existing IGP-funded data collections must be transparent, equitable, practicable, and provide clear decisions consistent with R&D DMIMS (DU) datasharing policy.
12. All applicants submitting proposals under IGP are required to include a Data Management Plan (DMP) as an integral part of the application.

IPR Policy

Datta Meghe Institute of Medical Sciences
(Deemed to be University)

Table of Contents

ARTICLE 1 - PREFACE

1.1. Context and Institution Mission

1.1.1. The core mission of the Datta Meghe Institute of Medical Sciences (Deemed to be University) ["DMIMS(DU)"] is to develop competent, confident, concerned, compassionate and Globally relevant professionals by quality, learner, community and evidence centric 'competency-based model' of higher education with value orientation, through all its constituent units. It shall foster a conducive milieu for interdisciplinary research practices generating consequential and meaningful outcomes for the nation in general and the region in particular. It shall deliver comprehensive quality health care services to the rural, needy, marginalized and underprivileged populace. This shall be achieved through appropriate collaborative linkages and a proactive, transparent and accountable decentralized governance system.

1.1.2. The Institution is committed to ensuring that Intellectual Property (IP) emanating from its Research activities is used in support of the objectives set out and in accordance with its legal obligations, for the benefit of the Institution, the Creators and, most importantly, society-at-large.

1.2. Purpose of the IP Policy

1.2.1. **Promotion of IP utilization**. The intent of the IP Policy is to facilitate the widespread use of, through various modalities of access to, the Institution's IP.

1.2.2. **IP management**. The IP Policy seeks to set the framework for the translation of the IP arising from the Institution's Research into products, services and processes. It encourages Staff Members, Students and Visitors to become Creators and to identify IP with potential commercial value. It also establishes clear rules and procedures for the management and Commercialization of such IP generated at the Institution.

1.2.3. **Balance of interests**. The IP Policy seeks to ensure the legal protection, where applicable; effective management and Commercialization of Institution IP; while at the same time not impeding with the traditions of education and scholarship, academic freedom, open and timely publications, Institution sovereignty, and the Institution's mission serving the public interest.

1.3. Overall Principles

The Institution operates under the following overall principles:

1.3.1. **Responsible Commercialization**. Where IP arises that has commercial potential as a result of Research, the Institution intends to make such IP available in a form that will most effectively promote its development and use for economic and social benefit.

1.3.2. **Incentives**. The Institution wishes to recognize and reward Staff Members, Students and Visitors whose IP generates a demonstrable socio- and/or economic impact.

1.3.3. **Local development**. The Institution encourages Research that responds to the local, regional and national needs. In its efforts to Commercialize Institution IP, the Institution shall seek to optimize the economic and societal benefits.

ARTICLE 2 - DEFINITIONS

Without prejudice to any applicable laws, in this Policy the definitions set out below shall apply:

Appointment. A formal agreement for a Visitor at the Institution, which is a prerequisite to participate in or conduct Research, scholarship, creative work, or teaching at the Institution.

Author. Any person to whom this Policy is applicable, who individually or jointly with others makes a design, a mark or copyrightable work and who meets the criteria for authorship under the IP laws of India.

Background IP. Any pre-existing IP created before the execution of any Research Project, or prior to a Creator becoming subject to this IP Policy, by virtue of Appointment in the case of a Visitor, employment contract in the case of a Staff Member, or registration in the case of a Student.

Commercialization. Any form of utilisation of IP intended to generate value, which may be in the form of a marketable product, process or service, commercial returns, or other benefit to society. **Commercialize** is similarly defined.

Commercialization Entity. A company that has access to the IP of the Institution, through any one or more of the available Commercialization modes, to produce new products, processes or services. This can be a spin-off or start-up.

Conflict of Commitment (COC). Any situation in which an individual Staff Member's or Visitor's primary professional loyalty is not to the Institution because the time devoted to outside activities adversely affects their capacity to meet their responsibilities as set out in their employment contract of Appointment, respectively.

Conflict of Interest (COI). Any situation in which real or perceived interests of an individual Staff Member, Visitor or Student may run counter to the interests of the Institution or negatively affect their employment or duties.

Course Materials. All materials used in, or in connection with, and for the purpose of, teaching an education course through the provision of lectures, tutorials, seminars, workshops, field or laboratory classes, assessments, practicum and other teaching activities conducted by the Institution; and all IP in such materials.

Creator. Any person to whom this Policy is applicable, who creates, conceives, reduces to practice, authors, or otherwise makes a substantive intellectual contribution to the creation of IP and who meets the definition of 'inventor', 'author' or 'breeder' as generally implied in the IP laws of India.

Enabler. Any assistants, technicians, and other individuals who have indirectly contributed to the creation of IP by Creators - and as such may not be listed themselves as an author or inventor in terms of statutory IPRs - mainly through the execution of standard tasks or following through on specific instructions, but without whose practical contribution the Commercialization would not have been possible.

Genetic Resources (GRs). "Genetic material of actual or potential value." Genetic material is defined as "any material of plant, animal, microbial or other origin containing functional units of heredity".[1] Some GRs are linked to traditional knowledge (TK) through their use and conservation by indigenous peoples and local communities, often over generations, and through their widespread use in modern scientific Research. Examples include medicinal plants, agricultural crops and animal breeds.

Gross IP Revenue. All revenue received by the Institution on Commercialization of Institution IP before any deductions for IP Expenses, as defined in Article 10.

Institution. DMIMS(DU)

Institution IP. IP owned or co-owned by the Institution.

Intellectual Property (IP). All outputs of creative endeavour in any field at the Institution for which legal rights may be obtained or enforced pursuant to the law. IP may include:

a) literary works, including publications in respect of Research results, and associated materials, including drafts, data sets and laboratory notebooks;
b) teaching and learning materials;
c) other original literary, dramatic, musical or artistic works, sound recordings, films, broadcasts, and typographical arrangements, multimedia works, photographs, drawings, and other works created with the aid of Institution resources or facilities;
d) databases, tables or compilations, computer software, preparatory design material for a computer program, firmware, courseware, and related material;
e) patentable and non-patentable technical information;
g) designs including layout designs (topographies) of integrated circuits;
h) plant varieties and related information;
i) trade secrets;
j) know-how, information and data associated with the above; and
k) any other Institution-commissioned works not included above.

Intellectual Property Rights (IPRs). The proprietary rights that may be granted for an invention, mark, design, plant variety, or other type of IP, should the statutory requirements for protection be met to result in a patent, trade mark, registered design or plant breeders' right, respectively.

Invention. an Invention that has been implemented, or put to actual, practical use, that results in better products, processes, or services. Such Innovations result in new products, processes, or services that result in better solutions that meet new requirements, unarticulated needs, or existing market needs. The basic difference between an invention and an innovation is that the former is a laboratory creation, whereas an innovation is its actual application in the field.

Inventor. Any person to whom this Policy is applicable, who individually or jointly with others makes an Invention and who meets the criteria for inventorship under the Indian IP law.

IP Disclosure Form. The form to be completed by Creators and submitted to IPR CELL to document their creation.

IP Expenses. All expenses incurred by the Institution in the management and Commercialization of IP for which Gross IP Revenue has been received.

IP Committee. The body within the Institution, set up in terms of Article 4.1, which is responsible for overseeing the drafting, implementation, monitoring and evolution of the Policy, and for providing strategic oversight of the IPR CELL.

IPR Cell. The administrative unit established in terms of Article 4.2, responsible for day-to-day management of all IP-related activities of the Institution under DMIMS(DU).

Net IP Revenue. Gross IP Revenue less IP Expenses.

Open Educational Resources (OER). Teaching, learning and Research materials that reside in the Public Domain and that have been released under an open license that permits their free use or modification by others.

Policy. This DMIMS(DU) IPR policy

Public Disclosure. The communication of information, relating to IP, to external parties. Public Disclosure includes, but is not limited to, disclosure in written or oral form; communication by email; posting on a web blog; disclosure in a news report, press release or interview; publication in a journal, abstract, poster, or report; presentation at a conference; examination of a thesis; demonstration of an Invention at a trade show; or the industrial application of an Invention.

Public Domain. The freely accessible public realm in which works that are not protected by IPRs, either because the rights have been forfeited or because the rights have been expired, are thereby held by the public at large and available for all to use without permission from the Creator or owner.

Research. Any creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of man, culture and society, and the use of this stock of knowledge to devise new applications. It comprises three activities: basic research, applied research and experimental development.

Research Contract. Any type of agreement between the Institution and an external party or research sponsor, concerning Research, which could result in IP being created at the Institution. This shall include, but is not limited to, all sponsorships, donorships and collaborations with the external party or research sponsor.

Research Project. Any project that forms the basis of Research undertaken by the Institution and includes projects undertaken by a Student, under the supervision of a Staff Member or a Visitor, as part of a research degree program.

Scholarly Works. All copyright works which are the outputs of academic Staff Members, Students or Visitors, including Research, creative and other outputs in area(s) of his/her expertise.

Senior Responsible Officer. The person at the Institution who has the ultimate decision-making authority regarding IP.

Staff Member. Any person who is under a contract of employment with the Institution including academic, research, technical, administrative and adjunct staff, whether full-time or part-time or on a temporary basis.

Student. Any student registered for an approved course at the Institution.

Substantial Use. Extensive [unreimbursed] use of the Institution's resources which include but are not limited to facilities, equipment, human resources or funds.

Trade Secret. Confidential information not publicly available that has commercial value because of its confidential nature, and which the owner has taken reasonable efforts to keep secret.]

Traditional Knowledge (TK). A living body of knowledge resulting from intellectual activity in a traditional context, which includes know-how, practices, skills, and innovations. TK embodies the traditional lifestyles of indigenous peoples and local communities and is transmitted from generation to generation, often forming part of the cultural and spiritual identity of the community. TK is not limited to any specific technical field, and may include agricultural, environmental and medicinal knowledge. TK also often encompasses knowledge associated with Genetic Resources.

Visitor. Any person who is neither a Staff Member nor a Student of the Institution who engages in work at the Institution, including visiting professors, adjunct and conjoint professors, teachers, researchers, scholars and volunteers; and who concludes an Appointment agreement with the Institution.

ARTICLE 3 – SCOPE OF THE POLICY

3.1. **IP**. This Policy applies to all IP generated at the Institution, in particular by Staff Members, Students and Visitors.

3.2. **Background IP**. Upon commencing employment, enrolment or an Appointment, Staff Members, Students and Visitors must declare any existing IP they wish to exclude from the application of this Policy due to creation prior to their employment, enrolment or Appointment at the Institution.

3.3. **Applicability**. This Policy applies to all Staff Members, Students and Visitors who participate in a Research Project or produce Scholarly Works. Rights and obligations under this Policy shall survive any termination of employment, enrolment or Appointment at the Institution.

3.4. **Binding effect of the Policy**. This Policy constitutes an understanding that is binding on the Institution, Staff Members, Students and Visitors, once adopted by the Board or Senate of the Institution, on the following grounds:

3.4.1. **Staff Members**. The Institution shall ensure that the employment contract or other agreement establishing any type of employment relationship between the Institution and Staff Members includes a provision placing Staff Members under the scope of this Policy.

3.4.2. **Students participating in a Research Project**. The Institution shall ensure that Students participating in a Research Project sign an agreement before commencing the project, to the effect that they have read and will comply with the provisions of this Policy, according to Article 5.2.5.

3.4.3. **Visitors**. The Institution shall ensure that Visitors sign an Appointment agreement before commencing any activity at the Institution. Such agreement shall place the Visitor under the scope of this Policy and shall

make reference to this Policy, a copy of which will be made available to the Visitor.

3.4.4. **Informed consent**. This Policy shall be included on the Institution's website, the University research Policy Compendium.

ARTICLE 4 – GOVERNANCE AND OPERATION

4.1. IP Committee

4.1.1 **Purpose**. The Institution has established an IP Committee to oversee the implementation and evolution of this Policy and provide strategic guidance to the IPR CELL (according to Article 4.2 below).

4.1.2. **Composition**. The Expert Committee on IP, chaired by the Honourable Vice Chancellor, DMIMS(DU). And IPR Cell committee.

4.1.3. **Responsibilities**. The IP Committee is the ultimate decision-making body in the determination of an IP management and Commercialization strategy for a particular IP.

4.1.4. **Meetings**. The IP Committee shall establish regular meetings and also be available for *ad hoc* meetings.

4.2. The IPR Cell:

4.2.1. **Purpose**. The Institution shall establish an IPR Cell or designate a function within the Institution or another organisation to act as such, to assist the Institution in managing and Commercializing its IP in a form that will most effectively promote its development and use for economic and social benefit.

4.2.2. **Responsibilities**. The responsibilities of the IPR CELL shall include, but are not limited to:

a. Outreach/awareness to Creators;
b. Relationship management with Creators;
c. IP management;
d. Technology marketing and IP contract negotiation;
e. IP contract management; and
f. IP costs and revenue distribution.

ARTICLE 5 - OWNERSHIP OF IP AND RIGHTS OF USE

5.1. IP Created by Staff Members

5.1.1. **Institution ownership**. The Institution owns all IP created by a Staff Member:

a. in the course and scope of his/her employment; or
b. making Substantial Use of the Institution's resources.

5.1.2. **Staff Member ownership**. Staff Members will own/co-own the IP they have created when such IP:

a. is outside the course and scope of their employment and without Substantial Use[2] of the Institution's resources;
b. vests in Scholarly Works (see Article 5.5);
c. Other IPRs, as required by national law, or for which the Institution cannot or does not wish to claim ownership and the Institution has communicated such in writing.

5.1.3. **IP emanating from Research Contracts**. Where there is no Substantial Use of the Institution's resources, the terms of the Research Contract will regulate ownership of IP created by Staff Members in the course of a Research Project that forms part of a Research Contract, as set out in Article 7.

5.1.4. **Appointment of Staff Members at another Institution**.[3] It is the responsibility of each Staff Member that holds an honorary or other academic or research appointment at another institution (Host Institution) to bring to the attention of the Host Institution, including its IPR CELL, his/her obligations in terms of this Policy, prior to the tenure at the Host Institution. To the extent that the Host Institution's IP Policy makes a claim on IP created by the Staff Member pursuant to such appointment, the Staff Member shall ensure that the Host Institution negotiates a suitable IP arrangement with the Institution.

5.2. IP Created by Students

5.2.1. **Student ownership**. IP created by a Student in the course of study at the Institution (including theses, dissertations and other Scholarly Works) will be owned by the Student. This is in contrast to IP created by a Student in a Research Project, as per Article 5.2.3 below.

5.2.2. **Theses or dissertations**.
The Student must submit his/her final thesis or dissertation to the Institutional repository. The Student must grant a royalty-free licence to the Institution to reproduce his/her thesis or dissertation and to distribute copies thereof to the public.

5.2.3. **Institution ownership**. IP emanating from a Student's Research Project shall be owned by the Institution in the following circumstances:

a. if the IP is created by making Substantial Use of the Institution's resources (excluding supervision) and there is no re-imbursement agreement concluded between the Institution and the Student; or
b. if the Research carried out by the Student forms part of the Institution's Research Projects.

5.2.4. **IP emanating from Research Contracts**. [4] The terms of the Research Contract shall regulate the ownership of IP created by a Student in the course of such Research Contract, as set out in Article 8.

[2] Use will be deemed not Substantial if minimal overhead costs have been incurred by the Institution (such as the use of office space, the library, facilities or traditional desktop computers); only a minimal amount of time has been spent using significant Institution facilities; or the IP has been written or developed in the personal (unpaid) time of the Creator.
[3] This means that such Staff Members are a visitor at another institution.
[4] That is, if the Student is participating in a Research Project under a Research Contract between the Institution and an external entity or research sponsor.

5.2.5. **Institution ownership responsibilities**.[5] If the Institution is the owner of IP created by a Student, in terms of Article 5.2.3 or Article 5.2.4, and hence created in terms of a Research Project or Research Contract, respectively, the Institution shall:

a. provide the Student with an explanation of the reasons for the assignment of IP rights to the Institution;
b. advise the Student to seek independent advice regarding the assignment;
c. obtain a deed of assignment from the Student for all IPRs emanating from the Student's Research Contract or Research Project, where relevant, in return for revenue sharing as provided for in Article 10; and
d. withdraw the Student from the Research Project or Research Contract if a Student elects not to assign the relevant IPRs to the Institution.

5.2.6. **Bursaries/scholarships**. An external party that grants a bursary or scholarship to a Student may elect to own the IP created by that Student in the course of his/her study at the Institution provided the Student and the Institution have consented to the assignment of IP ownership in writing and such consent is not contrary to any applicable local or national law.

5.2.7. **Student Owned IP**. IPR CELL may, upon agreement, provide services to Students for their IP.

a. In the absence of an assignment of the IP to the Institution, the Students and IPR CELL may agree on the specific Commercialization services required, in exchange for an agreed fee being paid to the Institution and/or sharing of Commercialization revenues accruing to the Students.

5.3. IP Created by Visitors

5.3.1. **Institution ownership**. Unless otherwise agreed to in writing by the Institution and the Visitor's home institution prior to the tenure at the Institution, Visitors are required to assign to the Institution any IP:

a. created in the course and scope of their Appointment at the Institution; or
b. created by making Substantial Use of the Institution's resources.

5.3.2. **Institution IP**. On departure from the Institution, a Visitor must sign and submit to IPR CELL an IP Disclosure form disclosing any IP created, as per Article 5.3.1, whilst at the Institution.

5.4. Special Rules for Course Materials

5.4.1. **Institution ownership**. The Institution will own the IP in Course Materials created by a Staff Member or a Visitor, with the exclusion of Course Material that is created from or for Open Educational Resources, in accordance with Article 5.7.1.

5.4.2. **Licensed by the Institution**. The Institution grants the Creators of Course Materials a royalty-free, non-exclusive licence to use the Course Materials created by them for teaching and Research purposes at the Institution. With the express prior written permission of the Institution, such licence may be utilised for commercial purposes outside the Institution.

5.5. Special Rules for Scholarly Works

5.5.1. **Publication**. The Institution recognises and endorses the rights of Staff Members, Students and Visitors to publish their Scholarly Works, provided that any Scholarly

[5] See also Article 3.4.2 of this Policy.

Work which may disclose any possible Institutional IP shall first be cleared by IPR CELL after having an opportunity to protect such Institutional IP according to Article 8.

5.5.2. **Institutional repository**. Staff Members, Students and Visitors should endeavour to obtain publishers' permission to include published Scholarly Works in the Institutional repository [whether as a published edition or in pre-publication form].

5.5.3. **Licensed to the Institution**. Staff Members, Students and Visitors shall grant to the Institution a non-exclusive, royalty free license to use their Scholarly Works for the Institution's administrative, promotional, Research and teaching purposes.

5.6. Moral Rights

5.6.1. **Recognition**. The Institution undertakes to respect and protect the moral rights which copyright law confers on Authors of copyright works.

5.6.2. **Rights granted**. The Institution acknowledges that moral rights vest in Authors of copyright works irrespective of the copyright ownership thereof and include:
a. the right of attribution of authorship in respect of the copyright works;
b. the right not to have authorship of the copyright works falsely attributed; and
c. the right of integrity of authorship in respect of the copyright works.

5.6.3. **No waiver**. The Institution will not require Staff Members, Students or Visitors to waive their moral rights as a condition of employment, enrolment, Appointment or funding.

5.7. Public Domain

5.7.1. **Public Domain**. Institution IP forms part of the Public Domain in the following circumstances:
a. if a Research Contract provides that the Research results be placed into the Public Domain; or
b. if Staff Members or Visitors made use of OERs or resources licensed through Open Source or Creative Commons Licences and the licensing conditions require release of derivatives into the Public Domain.

5.7.2. **Release into the public domain**. The Institution will release IP into the Public Domain in the following circumstances:
a. where it is deemed to be in the public interest;
b. if the IP has low commercial or other development potential and low prospects of fostering the development of new products or services; or
c. if deemed necessary by the Institution.

ARTICLE 6 – PUBLICATION, NON-DISCLOSURE AND TRADE SECRETS

6.1. **Right of publication**. The Institution encourages and supports the right of Creators to decide if and when to publish their Research results, in accordance with Article 5.5 above.

6.2. **Non-disclosure for IP protection**. In conjunction with the right of publication, Creators should be aware that premature Public Disclosure may result in loss of IP protection rights. Therefore, they are strongly encouraged to make all reasonable

efforts to identify any protectable IP as early as possible, according to Article 8, and shall consult IPR CELL before making any Public Disclosure of potential Institution IP.

6.3. **Trade Secrets**. The Institution may designate certain confidential information as a Trade Secret, owned by the Institution. In that event, all Creators will be obligated to maintain secrecy of the Trade Secret and to follow the direction for management of the Trade Secret by IPR CELL.

ARTICLE 7 – RESEARCH CONTRACTS

7.1. **Authority**. Staff Members, Students and Visitors shall not have the right to enter into a Research Contract with external parties on behalf of the Institution unless they are authorized to do so by an official representative of the Institution.

7.2. **Research Policy**. All Research Contracts must be executed and performed in compliance with the Institution's Research Policy (where available).[6]

7.3. **Due diligence**. Persons acting for and on behalf of the Institution shall exercise all due diligence and consult IPR CELL when negotiating and signing contracts that may affect the Institution's IPRs.

7.4. **Ownership and rights to use**. Subject to any provisions in law to the contrary, ownership and rights to use shall be agreed upon with the external entity, in accordance with contracts/MOU's signed with external entity.

7.5. **Government rules**. Research Contracts shall comply with any applicable law and/or Government regulations and/or rules, which may be applicable to Research undertaken by the Institution, in particular, as far as it relates to the ownership of IP resulting from such Research.

7.6. **Approval**. Proposed Research Contract and other legal statements concerning the Institution's IPRs shall comply with the provisions of this Policy. Any variance from this Policy must be approved by the Senior Responsible Officer.

7.7. **Basic Principles**. The IP clauses in all Research Contracts shall the governed by the following basic principles:

7.7.1. **Concluded from the outset**. A Research Contract must be executed in writing and signed by the Institution and the external party(ies)/sponsor(s) prior to the commencement of any Research Project and, as appropriate and without limitation, must contain terms relating to ownership, management and use of IP arising from the Research Project as well as any Background IP.

7.7.2. **Background IP**. All Institution Background IP must be properly recorded and declared prior to the commencement of a Research Contract and belongs to the Institution. Similarly, Background IP of the external party/sponsor, belongs to such party or sponsor. Use of such Background IP requires express written permission.

[6] In general, Research Contracts must be managed in terms of a specific research contract policy. Article 8 of the policy only deals with the IP ownership clauses and the possible options for contract, sponsorship or donor funding.

7.7.3. **Foreground IP** (**IP arising from the Research Contract)**. IP generated pursuant to a Research Contract by Staff Members, Students or Visitors shall be governed in terms of the above provisions relating to IP generated by these parties. The general rule is that such IP shall be owned by the Institution.

7.7.4. **Co-owned Foreground IP**.

a. **Terms for co-ownership**. Co-ownership of IP generated pursuant to a Research Contract shall be in accordance with national legislative provisions, failing which, as mutually agreed contractually.

b. **Costs for protecting and maintaining co-owned IP**. The costs for protecting and maintaining any IPRs shall be shared between the Institution and the external party(ies)/sponsor(s) as mutually agreed contractually.

7.7.5. **Serendipitous IP**[7] . Any IP created during the course of the Research Contract which falls outside of scope of the Research Contract shall be owned by the Institution or the external party(ies)/sponsor(s) which developed such IP, unless agreed contractually otherwise in the Research Contract.

7.7.6. **Right of first refusal to the IP**. The Research Contract may include provisions giving the external party(ies)/sponsors, a right of first refusal to Commercialize the IP emanating from the Research Contract, through a license or joint venture arrangement or assignment.

7.7.7. **Publication delay**. It is the strict policy of the Institution to allow Creators freedom to publish their work. However, the Institution acknowledges that delays in publication for the purpose of initiating statutory protection of the IP is often necessary. In this regard, the Institution will agree, on a case-by-case basis, to a contractual delay in publication by Creators.

7.7.8. **Use of the IP for Research and teaching**. In instances, where the Institution IP is licensed exclusively or assigned as part of the Research Contract, all efforts should be made to secure a royalty-free license for use of the IP for on-going Research and teaching purposes.

7.8. **Exceptions to the Policy**. In certain cases, it may be necessary and/or beneficial to the Institution to enter into a Research Contract that contains exceptions to the provisions of this Policy. Any such exceptions require prior, written approval from the Senior Responsible Officer.

ARTICLE 8 – DETERMINATIONS BY THE IPR CELL

8.1. Responsibility to Disclose IP

8.1.1. **Recording**. Creators shall keep appropriate records of their Research in accordance with the Institution's applicable policy procedures and make reasonable efforts to ensure that only those individuals within the Institution who have a need to have access to such records for the performance of their duties are granted such access.

[7] Results are serendipitous when research that was originally funded for one purpose turns out to be useful for another purpose.

8.1.2. **IP Disclosure**. Where a Creator identifies potential IP resulting from his/her Research [or that of his/her team], he/she shall disclose such potential IP to IPR CELL promptly by means of an IP Disclosure Form.

8.1.3. **Complete disclosure**. Creators must provide to IPR CELL such full, complete and accurate information as IPR CELL may reasonably require to enable it to sufficiently assess the technical and related features and functions, ownership, commercial potential and IP protection that might be applicable to such IP. Upon complete disclosure, the IP Disclosure will be registered and assigned a reference number and IPR CELL will share this reference number with the Creators to signify that the IP Disclosure has been formally received by the Institution.

8.2. Creatorship and Ownership

8.2.1. **Creatorship**. Creators shall, upon request, sign the appropriate legal documents provided by IPR CELL that attest to creatorship. Where there is more than one Creator, and there is a dispute as to the contribution to creatorship, IPR CELL shall in consultation with the Creators, assist in the determination of the percentage IP creatorship, failing which it shall be assumed that there was an equal undivided contribution.

8.2.2 **Ownership.** Once creatorship has been determined, the Creators shall be required to formally assign any right, title or interest they may have in that IP to the Institution in the form of a contract that specifies the rights that will accrue to the Creator(s) and the Institution and the obligations they will have to assist the Institution with the Commercialization of that IP. Article 9.3 will apply.

8.3. Determination as to IP Protection and Commercialization

8.3.1. **Evaluation and recommendation**. IPR CELL will analyse the information disclosed in the IP Disclosure within 90 days of formal receipt. The analysis will include: whether or not the subject matter is protectable as IP; an assessment of economic viability or marketability; and determination of any rights of external parties, such as a funder or collaborator. After evaluation, IPR CELL will prepare a preliminary report with findings that enable the Institution to decide if it will proceed with IP protection and Commercialization. IPR CELL shall share the preliminary report with the Creator(s), and seek their input.

8.3.2. **Decision to protect/Commercialize**. The Institution will decide, as soon as reasonably practicable, whether or not it wishes to protect and/or Commercialize the IP. IPR CELL will use all reasonable efforts to notify the Creator(s) of the Institution's decision within of formal receipt of the IP Disclosure. IPR CELL will also make a determination in relation to the validity of any claim made by a Staff Member, a Visitor or a Student that they are the true Creator(s) of that IP and in relation to their rights under this Policy.

8.3.3. **Institution's obligation to notify Creators of its decision.** Within no more than 90 days IPR CELL will notify the Creator(s) of the decision of whether the Institution will or will not pursue IP protection and Commercialization of their IP Disclosure.

8.4. Institution Elects not to Protect /Commercialize the IP

8.4.1. **IP abandoned or not Commercialized**. The Institution reserves the right not to protect or Commercialize IP that it owns if after consultation with the Creators:
   a. there is no reasonable prospect of commercial success;
   b. it is not deemed to be in the best interest of the Institution; or
   c. it is not deemed to be in the public interest.

8.4.2 **Transfer of Ownership**. In the event the Institution decides not to pursue IP protection and/or Commercialization, it will take steps to return said IPRs to the Creator(s), contingent on any other superseding contract rights of external party(ies)/sponsor(s).

8.4.3. **Written notification**. If the Institution is unable to or decides not to protect or Commercialize the Institution IP, it should notify the relevant Creator(s) of its decision in writing and in a timely manner.

8.4.4. **No prejudice to IP protection**. The Creator(s) should receive the written notification in a timely manner that enables the relevant Creator(s) to take any formal steps to ensure the protection of IP, should they so desire.

8.4.5. **Assignment**. If the Creator elects to take assignment of the IP, the Institution shall ensure that a deed of assignment is executed without delay.

8.4.6. **Terms and conditions**. If the Institution assigns IPRs to the Creator in terms of this Article 8.4.5, the assignment may be subject to one or more of the following terms and conditions:
   a. that upon Commercialization, the Institution be compensated for any expenditure it may have incurred in connection with the protection and/or Commercialization of such IP; and/or
   b. that the Institution be granted a non-exclusive, royalty-free licence to use the IP for Research and teaching purposes.

ARTICLE 9 - COMMERCIALIZATION OF IP

9.1. **Determination of the Commercialization Strategy**. Within 6 months of the decision to protect or Commercialise the IP under Article 8.3.2, the Institution will determine, with input from the Creators, the most appropriate Commercialization strategy.

9.2. **Assistance to IPR CELL**. Creators of IP which has been selected for IP protection and Commercialization by the Institution must provide IPR CELL with all reasonable support in the assessment, protection (including preventing premature disclosure and execution of any documents including deeds of assignment and deeds attesting to creatorship), and Commercialization of the IP.

9.3. **Sovereignty and Cooperation**. The Institution shall have the sole discretion regarding the Commercialization of IP owned by it. Notwithstanding, the Institution will ensure that reasonable efforts are made to keep the Creators informed and, where appropriate, involved in the Commercialization of the IP to which they contributed. The Commercialization of Institution IP will be monitored by IPR CELL.

9.4. **Commercialization Pathways**. Modes of IP Commercialization may include:
   a. license, either exclusive or non-exclusive, and variations thereof;
   b. assignment (sale);

c. formation of a Commercialization Entity to which the IP is licensed or assigned in terms of this Policy;
d. non-profit use or donation;
e. joint ventures;
f. royalty free access on humanitarian or other grounds; or
g. various combinations of the above.

9.5. **Guidelines**. Regardless of the mode of IP Commercialization, the transaction will be executed in a contract which:
a. protects the interests of the Institution, its Staff Members, Students and Visitors;
b. retains rights for the Institution to use the IP for educational and research purposes;
c. assures that the IP will be utilized in a manner which will serve the public good;
d. assures that the IP will be developed and brought to the marketplace as useful goods and services; and
e. prohibits the "shelving" or "mothballing" [8] of the IP or its use in any illegal or unethical manner.

9.6. The Institution will endeavour to Commercialize IP in a manner that enhances local, regional, and national economic development.

9.7. The Institution will endeavour to Commercialize IP in a manner that encourages and fosters entrepreneurship by Staff Members and others and which supports Commercialization Entities.

ARTICLE 10 - INCENTIVES AND DISTRIBUTION OF REVENUES

10.1. The Institution's Incentive Structure

10.1.1. **Purpose and scope**. The Institution, in the interest of promoting knowledge transfer, will give due consideration to incentives to researchers to foster Research that has socio-economic impact; such incentives may be financial or non-financial. A Creator/Enabler may receive incentives from each IP they created/enabled which is Commercialized.

10.2. Sharing of Revenues

10.2.1. **General**. The Institution, in line with the minimum requirements set out in relevant national legislation, will award Creators/Enablers in the sharing of monetary benefits that may accrue to the Institution from the Commercialization of Institution IP.

10.2.2. **Calculation of revenues for distribution**. Calculation of Gross IP Revenue, IP Expenses, and Net IP Revenue shall be in accordance with the following rules:

10.2.2.1. **Calculation of Gross IP Revenue**. "Gross IP Revenue" is defined in Article 2 as "*all revenue received by the Institution for Commercialization of Institutional IP before any cost recovery or deductions for IP Expenses*" and includes, but is not limited to, outright sale of IP, option payments received, licence fees received, evaluation fees received, upfront and

[8] Shelving or mothballing of academic IP refers to IP and invention disclosure bundles that remain unexplored, unlicensed or unused.

milestone payments received, royalty payments received, share of profits received, dividends received, commissions, income through disposal of equity, and direct sale of products or services.

10.2.2.2. **IP Expenses**. "IP Expenses" is defined in Article 2 as "*all expenses incurred by the Institution in the management of IP for which Gross IP Revenue has been received*" and includes, but is not limited to, those expenses that relate to (i) the Institution's expenses incurred by payment to external entities for securing, maintaining and enforcing IP protection, such as patenting and litigation expenses; (ii) costs incurred by the Institution in the licensing/assignment of IP, including marketing costs, contract negotiation and drafting costs; and (iii) costs in making, shipping or otherwise distributing products, processes or services that embody the particular IPl.

10.2.2.3. **Calculation of Net IP Revenue**. Finance Department of DMIMS(DU) shall maintain accurate and transparent documentation of IP Expenses incurred for a particular IP and shall be entitled to cover all IP Expenses it has incurred, as set out in 10.2.2.2 above. The "Net IP Revenue" is calculated as the Gross IP Revenue less IP Expenses.

10.2.2.4. **Co-owned IP**. Where the IP is co-owned by the Institution and an outside organization, the Gross IP Revenue received by the Institution will be shared in accordance with a pre-determined formula as per a contractual arrangement. Thereafter, the Gross IP Revenue received by the Institution and the Net IP Revenue will be determined, and revenues will be shared in accordance with section 10.2.3.1 and 10.2.3.2 below.

10.2.3. Sharing of revenues – Creators/Enablers

10.2.3.1. **Standard Creator's share**.
The Standard Creator's share of IP Revenue will be distributed as per the decisions of Competent authorities.

10.2.3.2. **Standard Enabler's share**.
The Standard Creator's share of IP Revenue will be distributed as per the decisions of Competent authorities**.**

10.2.3.3. **Disputes**. In the event of a dispute or uncertainty regarding the Creators'/Enablers' share of the Gross or Net IP Revenue from a specific IP, the issue shall be brought for resolution to the IP Committee.

10.2.3.4. **Payment**. Payment to the Creators/Enablers will be made by the Institution on a periodic basis as agreed in writing, but no later than 12 months after receipt of the Gross IP Revenue by the Institution.

10.2.3.5. **Taxes**. Payments made as per 10.2.3.4 are subject to personal tax. The Institution may, make any applicable tax deductions before making payments to the Creators/ Enablers.

10.2.3.6. **Entitlement**. Creators/Enablers and their heirs will be entitled to IP revenue sharing for as long as the Institution receives Gross IP Revenues from Commercialization of the Institution IP.

10.2.3.7. **Banking details**. The onus is upon each Creator/Enabler to ensure that the Institution has their current banking details for the purpose of revenue sharing. The Institution will keep the relevant IP revenue amounts in reserve for a maximum period of 3 (three) years after which all rights of Creators/Enablers to receive such payments will be forfeited. If the Institution pays an amount into an incorrect account as a result of information supplied to it being outdated or incorrect, the Institution will not have any further obligation or liability in respect of such payment, which will be deemed to have been duly and properly made.

10.2.4. **Sharing of revenues – Institution**. The Institution's share of Net IP Revenue is distributed as per the decisions of Competent authorities.

10.3. Other Incentives

10.3.1. **General.** As a default position, the Institution will refrain from accepting non-monetary benefits for the Commercialization of its IP or from offering incentives other than revenue sharing, unless they are in addition to the revenue sharing as per 10.2.3.1 and 10.2.3.2, as appropriate. The Institution will thus give consideration, on a case-by-case basis, to the provision of other incentives, where monetary benefits (revenues) are not available or where the Creator/Enabler elects to choose other benefits *in lieu of* revenue sharing, which may only be realized in due course. Other incentives will include, but are not limited to, the incentives described in Article 10.3.2. – 10.3.4.

10.3.2. **Growth, development and acknowledgement**. A framework for growth and development of the Creator/Enabler in their professional and personal capacity shall be developed including (i) recognition of IP generation and Commercialization performance in appraisal procedures; and (ii) opportunities for enterprise development or capacity development through, for example, specific training opportunities, sabbaticals, and local and international exchanges in their relevant Research field or in the field of IP management and knowledge transfer.

10.3.3. **Research funds**. The Institution will actively promote, source and/or facilitate collaborative arrangements with industry partners to secure funding for further Research for the Creators/Enablers.

10.3.4. **Creator/Enabler receiving shares in a Commercialization Entity or other licensee**.

10.3.4.1. In the case where a Creator/Enabler is granted equity in a Commercialization Entity that licences the Institution IP which the Creator/Enabler has created, [9] such Creator's/Enabler's portion in the standard revenue sharing formula of Article 10.2.3.1 or 10.2.3.2 will be adjusted accordingly, taking into account the shares held in the company by the Creator/ Enabler. All other Creators/Enablers will be rewarded in accordance with the formula in Article 10.2.3.1 or 10.2.3.2.

10.3.4.2. Where the Institution receives shares in a licensee company, which company may be a Commercialization Entity, as consideration for an IP

[9] The institutional policy regulating Conflict of Interests must be consulted to assess additional measures that should be put in place especially when the researcher outsources research to the spin-off or start-up company, in which the researcher has a material interest.

license, the Institution will hold all the shares until liquidation, at which time the income will be considered Gross IP Revenue and the Creators/Enablers will receive their share according to the revenue sharing formula in Article 10.2.3.1 or 10.2.3.2.

10.3.4.3. Notwithstanding the benefit sharing in respect of shares in terms of this Article 10.3.4, the Creators/Enablers will still be entitled to their share of any other revenues under the IP license.

10.4. Contact Details

10.4.1. **Contact details**. The onus is upon each Creator/Enabler to ensure that the Institution is in receipt of their current address details for the purpose of revenue sharing. Unless contrary to law, should the Institution be unable to locate the Creators/Enablers through reasonable efforts, in order to effect payment of the revenue share amount, and a period of five years has passed since an initial attempt, then the portion owed to that Creator/Enabler or his/her heirs will be paid to the Institution's central fund to be used to support Research and innovation activities.

ARTICLE 11 - IP PORTFOLIO MAINTENANCE

11.1. **Recording and monitoring**. IPR CELL [or an external entity designated by the IPR CELL] shall maintain records of the Institution's IP in an appropriate form and in sufficient detail. It shall monitor the deadlines for the payment obligations related to the maintenance or annuity fees of protected IP, and shall, within a reasonable time, inform the person or department designated to make such payments.

11.2. **Accounting**. Finance department of DMIMS(DU) shall maintain income/expense accounting records on each IP so that revenue sharing allocations can be calculated.

ARTICLE 12 - TRADITIONAL KNOWLEDGE AND GENETIC RESOURCES

12.1. When Research is conducted at the Institution using TK and/or GRs, provisions of national legislation must be observed,[10] which provisions may include prior informed consent, and access and benefit-sharing, and the need to obtain any relevant permits.

12.2. The Institution shall formulate procedures and mechanisms for access to GRs/TK in order to comply with national legislation.

12.3. The Institution shall make provision in all Research Contracts concluded for the protection of any IP which may arise from the use of TK and/or GRs.

[10] For instance, when a member of the Institution needs to access and use GRs for the purpose of the research or when it is envisaged to share samples of GRs with partners from other countries, the Institution shall abide by the national laws in place.

ARTICLE 13 - CONFLICTS OF INTEREST AND CONFLICTS OF COMMITMENT

13.1. **Commitment to the Institution**. Staff Members' and Visitors' primary commitment of time and intellectual contributions should be to the education, research and academic programs of the Institution.

13.2. **Best Interests of the Institution**. Staff Members and Visitors have a primary professional obligation to act in the best interests of the Institution; they should avoid situations where external interests could significantly and negatively affect their work ethic and research integrity.

13.3. **Agreements with External Parties**. It is the responsibility of all Staff Members and Visitors to ensure that their agreements with external parties do not conflict with their duties and responsibilities in terms of this Policy. This provision shall apply in particular to private consultancy and other research service agreements concluded with external parties. Each individual should make his/her duties and responsibilities clear to those with whom such agreements may be made and should ensure that they are provided with a copy of this Policy.

13.4. **Disclosure of External Activities and Financial Interests**. Staff Members and Visitors shall promptly report all potential and existing Conflict of Interest (COI) or Conflict of Commitment (COC) to the appropriate Institutional authority, in compliance with applicable COI/COC policies. The authority will be responsible for resolving the conflict or reaching a solution satisfactory to all parties concerned. The decision must be approved by a high level academic functionary (e.g., Vice Chancellor or Registrar of DMIMS(DU)).

ARTICLE 14 - DISPUTE

14.1. **Violation.** Breach of the provisions of this Policy shall be dealt with under the normal procedures of the Institution, and in accordance with the relevant provisions of laws and regulations in force.

14.2. **Dispute Resolution**.

14.2.1. Any internal disputes or questions of interpretation arising under this Policy must in the first instance be referred to IPR CELL for consideration and mediation by the IP Committee.

14.2.2. If the matter cannot be resolved by the IP Committee within two months, then the dispute or question of interpretation must be referred to the Senior Responsible Officer for mediation.

14.2.3. The Senior Responsible Officer may at their sole discretion refer the matter to Institution's Executive Committee and/or an independent committee for arbitration as final arbiter of any disputed issues or for final determination.

14.3. **Appeal**. Individuals covered by this Policy shall have the right to appeal the application of any aspect of this Policy to the IP Committee.

ARTICLE 15 - AMENDMENT

15.1. **Revision**. This Policy may be amended at any time by a decision of the IP Committee. In this case:

a. all IP disclosed on or *after* the effective date of such amendment shall be governed by the Policy as amended; and

b. all IP disclosed *prior* to the effective date of the amendment shall be governed by the Policy prior to such amendment, provided that the provisions of the Policy (as amended) shall apply to all IP licensed or otherwise Commercialized on or after the effective date of any such amendment regardless of when the IP is disclosed.

ARTICLE 16 -SOP for Application of Patents and Copy Rights

The document is intended to develop a Plan for Total Quality Management of the process of Application of the Copyrights and Patents at DMIMSDU.
The proposed steps and the time duration intended towards the same are as follows

Patent

S No	Step	Person	Duration
01	Application Received From the inventor in soft copy	Inventor	
02	Confirmation Email sent to the inventor towards the receipt of the proposal in prescribed format and Forwarding the proposal to the attorney for the initial search	Secretary IPR	Within 48 hrs of receipt of the proposal
03	Initial search towards establishing innovation	Attorney	6 weeks
04	If application is found innovative the confirmation email to be sent to the inventor along with the suggestions of the attorney	Secretary IPR	48 hrs from the receipt of the report of the attorney
05	Release of Payment for Search	Finance Department	Within 48hrs
06	Submission of final Draft	Inventor	4 weeks
07	Approval of final draft	Attorney	2 weeks
08	Approval Email be sent to finance department for release of payment of the attorney and processing fees	Secretary IPR	Within 48 hrs
09	Release of payment	Finance Department	Within 48hrs
10	Submission of draft and issuance of diary no	Secretary IPR	2 weeks
11	Publication of Patent in the Gazette	Patent office	12-18months
	Receipt of Patent		1 year

Copyright

S No	Step	Person	Duration
01	Application Received From the inventor in soft copy	Inventor	
02	Confirmation Email sent to the inventor towards the receipt of the proposal in prescribed format and Forwarding the proposal to the attorney for the initial search	Secretary IPR	Within 48 hrs of receipt of the proposal
03	Initial search towards establishing innovation	Attorney	3 weeks
04	If application is found innovative the confirmation email to be sent to the inventor along with the suggestions of the attorney	Secretary IPR	48 hrs from the receipt of the report of the attorney
05	Submission of final Draft	Inventor	3 weeks
06	Approval of final draft	Attorney	2 weeks
07	Approval Email be sent to finance department for release of payment of the attorney and processing fees	Secretary IPR	Within 48 hrs
08	Release of payment	Finance Department	Within 48 hrs
09	Submission of draft and issuance of diary no	Secretary IPR	2 weeks
10	Final issuance of Copyright	Copyright office	6 -8 months

DATTA MEGHE INSTITUTE OF MEDICAL SCIENCES
[DEEMED UNIVERSITY]

Accredited by NAAC with 'A' Grade (CGPA 3.36 on 4 point scale)
Conferred 'A' Grade status by H.R.D. Ministry Govt. of India.

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CORRIGENDUM NOTIFICATION

No. - **25 of 2017** ***Date- 19th Aug. 2017***

In supersession of Notification No. 22 of 2017 dated 10TH Aug. 2017, , it is notified for information of all concerned that the Intellectual Property Cell of Datta Meghe Institute of Medical Sciences (Deemed University), has been reconstituted as under and shall be headed by Dr. Sandeep Shrivastava, Professor, Deptt. of Orthopaedics, Jawaharlal Nehru Medical College, Sawangi (Meghe) Wardha in his capacity as the Hon. Director-cum-Convenor of the IPR Cell w.e.f. 11th Aug. 2017

1	Dr. Sandeep Shrivastava, Professor Deptt. of Orthopaedics	Hon. Director –cum-Convener IPR Cell
2	Adv. Khurana M/s Khurana & Khurana a legal advisory company for Patent filing & IPR matters	Technical Member
3	Dr.Swanand Pathak, I/c CRL	Member
4	Dr.S.Z.Quazi, Director (R & D)	Member
5.	Dr. Tripti Shrivastava (Representative for Educational Research)	Member
6.	Dr.C.Mahakalkar (Representative for Device Developments & Technological Interventions.)	Member
7.	Dr.Manish Deshmukh (representative for Drug Development)	Member
8.	Mrs.Vaishalli Tendulkar (representative for Literary & others)	Member
9	Dr.Punit Fulzele, Asst.Prof., Deptt. of Pedodontics, SPDC	Member-Secretary

(Dr. A.J. Anjankar)
Registrar

Copy to:

1. Hon'ble Pro Chancellor & Chief Advisor, DMIMS (DU)
2. Hon'ble Vice Chancellor, DMIMS (DU)
3. Hon'ble Pro Vice Chancellor, DMIMS (DU)
4. Dr. Sandeep Shrivastava Hon. Director-cum-Convener IPR Cell
5. All the members of the IPR Cell ,
6. The Chief Coordinator, DMIMS (DU)
7. The Dean, JNMC, Sawangi(Meghe), Wardha
8. The Dean, SPDC, Sawangi(Meghe), Wardha
9. The Dean, MGACH &RC, Sawangi(Meghe), Wardha
10. The Principal, SRMMCON, Sawangi(Meghe), Wardha
11. The Principal, RNPC, Sawangi(Meghe), Wardha
12. The Dean, Examinations, DMIMS (DU)
13. The Dean, Interdisciplinary Health Sciences, DMIMS (DU)
14. The Director, SHPER & All the Heads of the Depts. Of SHPER.
15. The Dean (Acad), Faculty of Medicine, DMIMS (DU)
16. The Dean (Acad), Faculty of Dentistry, DMIMS (DU)
17. The Dean (Acad), Faculty of Ayurveda, DMIMS (DU)
18. The Dean (Acad), Faculty of Nursing, DMIMS (DU)
19. The Dean (Acad), Faculty of Para Medical Sciences.
20. The Director, (Personal & Planning), DMIMS (DU)
21. The Director, (II & Stratigic Planning), DMIMS (DU)
22. The Director, IQAC, DMIMS (DU)
23. The Dierctor, Nursing, SRMMCON
24. The OSD, DMIMS (DU)
25. The Nursing Coordinator, SRMMCON, Sawangi (Meghe)
26. The Controller of Examinations, DMIMS (DU)
27. The OSD, AVBRH
28. The Finance Officer, DMIMS (DU)
29. The Manager, HR, Sawangi (Meghe)
30. Asst. Registrar (Admin), DMIMS (DU)
31. Asst. Registrar, (Acad and Dev), DMIMS (DU)
32. Asst. Registrar (Confidential), DMIMS(DU)
33. All the AOs/AAOs of constituent colleges, DMISM (DU)
34. Website Incharge, DMIMS (DU)

GOOD CLINICAL PRACTICE GUIDELINES

Datta Meghe Institute of Medical Sciences
(Deemed to be University)

INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE

ICH HARMONISED TRIPARTITE GUIDELINE

GUIDELINE FOR GOOD CLINICAL PRACTICE
E6(R1)

Current *Step 4* version

dated 10 June 1996

(including the Post Step 4 corrections)

This Guideline has been developed by the appropriate ICH Expert Working Group and has been subject to consultation by the regulatory parties, in accordance with the ICH Process. At Step 4 of the Process the final draft is recommended for adoption to the regulatory bodies of the European Union, Japan and USA.

E6(R1)
Document History

First Codification	History	Date	New Codification **November 2005**
E6	Approval by the Steering Committee under *Step 2* and release for public consultation.	27 April 1995	E6
E6	Approval by the Steering Committee under *Step 4* and recommended for adoption to the three ICH regulatory bodies.	1 May 1996	E6

Current *Step 4* version

E6	Approval by the Steering Committee of *Post-Step 4* editorial corrections.	10 June 1996	E6(R1)

GUIDELINE FOR GOOD CLINICAL PRACTICE

ICH Harmonised Tripartite Guideline

Having reached *Step 4* of the ICH Process at the ICH Steering Committee meeting on 1 May 1996, this guideline is recommended for adoption to the three regulatory parties to ICH

(This document includes the Post Step 4 corrections agreed by the Steering Committee on 10 June 1996)

TABLE OF CONTENTS

GUIDELINE FOR GOOD CLINICAL PRACTICE

INTRODUCTION

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.

The objective of this ICH GCP Guideline is to provide a unified standard for the European Union (EU), Japan and the United States to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions.

The guideline was developed with consideration of the current good clinical practices of the European Union, Japan, and the United States, as well as those of Australia, Canada, the Nordic countries and the World Health Organization (WHO).

This guideline should be followed when generating clinical trial data that are intended to be submitted to regulatory authorities.

The principles established in this guideline may also be applied to other clinical investigations that may have an impact on the safety and well-being of human subjects.

1. GLOSSARY

1.1 Adverse Drug Reaction (ADR)

In the pre-approval clinical experience with a new medicinal product or its new usages, particularly as the therapeutic dose(s) may not be established: all noxious and unintended responses to a medicinal product related to any dose should be considered adverse drug reactions. The phrase responses to a medicinal product means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility, i.e. the relationship cannot be ruled out.

Regarding marketed medicinal products: a response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of diseases or for modification of physiological function (see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).

1.2 Adverse Event (AE)

Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product (see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).

1.3 Amendment (to the protocol)

See Protocol Amendment.

1.4 Applicable Regulatory Requirement(s)

Any law(s) and regulation(s) addressing the conduct of clinical trials of investigational products.

1.5 Approval (in relation to Institutional Review Boards)

The affirmative decision of the IRB that the clinical trial has been reviewed and may be conducted at the institution site within the constraints set forth by the IRB, the institution, Good Clinical Practice (GCP), and the applicable regulatory requirements.

1.6 Audit

A systematic and independent examination of trial related activities and documents to determine whether the evaluated trial related activities were conducted, and the data were recorded, analyzed and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).

1.7 Audit Certificate

A declaration of confirmation by the auditor that an audit has taken place.

1.8 Audit Report

A written evaluation by the sponsor's auditor of the results of the audit.

1.9 Audit Trail

Documentation that allows reconstruction of the course of events.

1.10 Blinding/Masking

A procedure in which one or more parties to the trial are kept unaware of the treatment assignment(s). Single-blinding usually refers to the subject(s) being unaware, and double-blinding usually refers to the subject(s), investigator(s), monitor, and, in some cases, data analyst(s) being unaware of the treatment assignment(s).

1.11 Case Report Form (CRF)

A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject.

1.12 Clinical Trial/Study

Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous.

1.13 Clinical Trial/Study Report

A written description of a trial/study of any therapeutic, prophylactic, or diagnostic agent conducted in human subjects, in which the clinical and statistical description, presentations, and analyses are fully integrated into a single report (see the ICH Guideline for Structure and Content of Clinical Study Reports).

1.14 Comparator (Product)

An investigational or marketed product (i.e., active control), or placebo, used as a reference in a clinical trial.

1.15 Compliance (in relation to trials)

Adherence to all the trial-related requirements, Good Clinical Practice (GCP) requirements, and the applicable regulatory requirements.

1.16 Confidentiality

Prevention of disclosure, to other than authorized individuals, of a sponsor's proprietary information or of a subject's identity.

1.17 Contract

A written, dated, and signed agreement between two or more involved parties that sets out any arrangements on delegation and distribution of tasks and obligations and, if appropriate, on financial matters. The protocol may serve as the basis of a contract.

1.18 Coordinating Committee

A committee that a sponsor may organize to coordinate the conduct of a multicentre trial.

1.19 Coordinating Investigator

An investigator assigned the responsibility for the coordination of investigators at different centres participating in a multicentre trial.

1.20 Contract Research Organization (CRO)

A person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions.

1.21 Direct Access

Permission to examine, analyze, verify, and reproduce any records and reports that are important to evaluation of a clinical trial. Any party (e.g., domestic and foreign regulatory authorities, sponsor's monitors and auditors) with direct access should take all reasonable precautions within the constraints of the applicable regulatory requirement(s) to maintain the confidentiality of subjects' identities and sponsor's proprietary information.

1.22 Documentation

All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records, and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken.

1.23 Essential Documents

Documents which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced (see 8. Essential Documents for the Conduct of a Clinical Trial).

1.24 Good Clinical Practice (GCP)

A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

1.25 Independent Data-Monitoring Committee (IDMC) (Data and Safety Monitoring Board, Monitoring Committee, Data Monitoring Committee)

An independent data-monitoring committee that may be established by the sponsor to assess at intervals the progress of a clinical trial, the safety data, and the critical efficacy endpoints, and to recommend to the sponsor whether to continue, modify, or stop a trial.

1.26 Impartial Witness

A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or the subject's legally acceptable representative cannot read, and who reads the informed consent form and any other written information supplied to the subject.

1.27 Independent Ethics Committee (IEC)

An independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical professionals and non-medical members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, reviewing and approving / providing favourable

opinion on, the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

The legal status, composition, function, operations and regulatory requirements pertaining to Independent Ethics Committees may differ among countries, but should allow the Independent Ethics Committee to act in agreement with GCP as described in this guideline.

1.28 Informed Consent

A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.

1.29 Inspection

The act by a regulatory authority(ies) of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authority(ies) to be related to the clinical trial and that may be located at the site of the trial, at the sponsor's and/or contract research organization's (CRO's) facilities, or at other establishments deemed appropriate by the regulatory authority(ies).

1.30 Institution (medical)

Any public or private entity or agency or medical or dental facility where clinical trials are conducted.

1.31 Institutional Review Board (IRB)

An independent body constituted of medical, scientific, and non-scientific members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trial protocol and amendments and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

1.32 Interim Clinical Trial/Study Report

A report of intermediate results and their evaluation based on analyses performed during the course of a trial.

1.33 Investigational Product

A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

1.34 Investigator

A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator. See also Subinvestigator.

1.35 Investigator / Institution

An expression meaning "the investigator and/or institution, where required by the applicable regulatory requirements".

1.36 Investigator's Brochure

A compilation of the clinical and nonclinical data on the investigational product(s) which is relevant to the study of the investigational product(s) in human subjects (see 7. Investigator's Brochure).

1.37 Legally Acceptable Representative

An individual or juridical or other body authorized under applicable law to consent, on behalf of a prospective subject, to the subject's participation in the clinical trial.

1.38 Monitoring

The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).

1.39 Monitoring Report

A written report from the monitor to the sponsor after each site visit and/or other trial-related communication according to the sponsor's SOPs.

1.40 Multicentre Trial

A clinical trial conducted according to a single protocol but at more than one site, and therefore, carried out by more than one investigator.

1.41 Nonclinical Study

Biomedical studies not performed on human subjects.

1.42 Opinion (in relation to Independent Ethics Committee)

The judgement and/or the advice provided by an Independent Ethics Committee (IEC).

1.43 Original Medical Record

See Source Documents.

1.44 Protocol

A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents. Throughout the ICH GCP Guideline the term protocol refers to protocol and protocol amendments.

1.45 Protocol Amendment

A written description of a change(s) to or formal clarification of a protocol.

1.46 Quality Assurance (QA)

All those planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented (recorded), and reported in compliance with Good Clinical Practice (GCP) and the applicable regulatory requirement(s).

1.47 Quality Control (QC)

The operational techniques and activities undertaken within the quality assurance system to verify that the requirements for quality of the trial-related activities have been fulfilled.

1.48 Randomization

The process of assigning trial subjects to treatment or control groups using an element of chance to determine the assignments in order to reduce bias.

1.49 Regulatory Authorities

Bodies having the power to regulate. In the ICH GCP guideline the expression Regulatory Authorities includes the authorities that review submitted clinical data and those that conduct inspections (see 1.29). These bodies are sometimes referred to as competent authorities.

1.50 Serious Adverse Event (SAE) or Serious Adverse Drug Reaction (Serious ADR)

Any untoward medical occurrence that at any dose:

- results in death,

- is life-threatening,

- requires inpatient hospitalization or prolongation of existing hospitalization,

- results in persistent or significant disability/incapacity,

or

- is a congenital anomaly/birth defect

(see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).

1.51 Source Data

All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies).

1.52 Source Documents

Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial).

1.53 Sponsor

An individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial.

1.54 Sponsor-Investigator

An individual who both initiates and conducts, alone or with others, a clinical trial, and under whose immediate direction the investigational product is administered to, dispensed to, or used by a subject. The term does not include any person other than an individual (e.g., it does not include a corporation or an agency). The obligations of a sponsor-investigator include both those of a sponsor and those of an investigator.

1.55 Standard Operating Procedures (SOPs)

Detailed, written instructions to achieve uniformity of the performance of a specific function.

1.56 Subinvestigator

Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows). See also Investigator.

1.57 Subject/Trial Subject

An individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control.

1.58 Subject Identification Code

A unique identifier assigned by the investigator to each trial subject to protect the subject's identity and used in lieu of the subject's name when the investigator reports adverse events and/or other trial related data.

1.59 Trial Site

The location(s) where trial-related activities are actually conducted.

1.60 Unexpected Adverse Drug Reaction

An adverse reaction, the nature or severity of which is not consistent with the applicable product information (e.g., Investigator's Brochure for an unapproved investigational product or package insert/summary of product characteristics for an approved product) (see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).

1.61 Vulnerable Subjects

Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.

1.62 Well-being (of the trial subjects)

The physical and mental integrity of the subjects participating in a clinical trial.

2. THE PRINCIPLES OF ICH GCP

2.1 Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with GCP and the applicable regulatory requirement(s).

2.2 Before a trial is initiated, foreseeable risks and inconveniences should be weighed against the anticipated benefit for the individual trial subject and society. A trial should be initiated and continued only if the anticipated benefits justify the risks.

2.3 The rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society.

2.4 The available nonclinical and clinical information on an investigational product should be adequate to support the proposed clinical trial.

2.5 Clinical trials should be scientifically sound, and described in a clear, detailed protocol.

2.6 A trial should be conducted in compliance with the protocol that has received prior institutional review board (IRB)/independent ethics committee (IEC) approval/favourable opinion.

2.7 The medical care given to, and medical decisions made on behalf of, subjects should always be the responsibility of a qualified physician or, when appropriate, of a qualified dentist.

2.8 Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s).

2.9 Freely given informed consent should be obtained from every subject prior to clinical trial participation.

2.10 All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.

2.11 The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).

2.12 Investigational products should be manufactured, handled, and stored in accordance with applicable good manufacturing practice (GMP). They should be used in accordance with the approved protocol.

2.13 Systems with procedures that assure the quality of every aspect of the trial should be implemented.

3. INSTITUTIONAL REVIEW BOARD/INDEPENDENT ETHICS COMMITTEE (IRB/IEC)

3.1 Responsibilities

3.1.1 An IRB/IEC should safeguard the rights, safety, and well-being of all trial subjects. Special attention should be paid to trials that may include vulnerable subjects.

3.1.2 The IRB/IEC should obtain the following documents:

trial protocol(s)/amendment(s), written informed consent form(s) and consent form updates that the investigator proposes for use in the trial, subject recruitment procedures (e.g. advertisements), written information to be provided to subjects, Investigator's Brochure (IB), available safety information, information about payments and compensation available to subjects, the investigator's current curriculum vitae and/or other documentation evidencing qualifications, and any other documents that the IRB/IEC may need to fulfil its responsibilities.

The IRB/IEC should review a proposed clinical trial within a reasonable time and document its views in writing, clearly identifying the trial, the documents reviewed and the dates for the following:

- approval/favourable opinion;

- modifications required prior to its approval/favourable opinion;

- disapproval / negative opinion; and

- termination/suspension of any prior approval/favourable opinion.

3.1.3 The IRB/IEC should consider the qualifications of the investigator for the proposed trial, as documented by a current curriculum vitae and/or by any other relevant documentation the IRB/IEC requests.

3.1.4 The IRB/IEC should conduct continuing review of each ongoing trial at intervals appropriate to the degree of risk to human subjects, but at least once per year.

3.1.5 The IRB/IEC may request more information than is outlined in paragraph 4.8.10 be given to subjects when, in the judgement of the IRB/IEC, the additional information would add meaningfully to the protection of the rights, safety and/or well-being of the subjects.

3.1.6 When a non-therapeutic trial is to be carried out with the consent of the subject's legally acceptable representative (see 4.8.12, 4.8.14), the IRB/IEC should determine that the proposed protocol and/or other document(s) adequately addresses relevant ethical concerns and meets applicable regulatory requirements for such trials.

3.1.7 Where the protocol indicates that prior consent of the trial subject or the subject's legally acceptable representative is not possible (see 4.8.15), the IRB/IEC should determine that the proposed protocol and/or other document(s) adequately addresses relevant ethical concerns and meets applicable regulatory requirements for such trials (i.e. in emergency situations).

3.1.8 The IRB/IEC should review both the amount and method of payment to subjects to assure that neither presents problems of coercion or undue influence on the trial subjects. Payments to a subject should be prorated and not wholly contingent on completion of the trial by the subject.

3.1.9 The IRB/IEC should ensure that information regarding payment to subjects, including the methods, amounts, and schedule of payment to trial subjects, is set forth in the written informed consent form and any other written information to be provided to subjects. The way payment will be prorated should be specified.

3.2 Composition, Functions and Operations

3.2.1 The IRB/IEC should consist of a reasonable number of members, who collectively have the qualifications and experience to review and evaluate the science, medical aspects, and ethics of the proposed trial. It is recommended that the IRB/IEC should include:

(a) At least five members.

(b) At least one member whose primary area of interest is in a nonscientific area.

(c) At least one member who is independent of the institution/trial site.

Only those IRB/IEC members who are independent of the investigator and the sponsor of the trial should vote/provide opinion on a trial-related matter.

A list of IRB/IEC members and their qualifications should be maintained.

3.2.2 The IRB/IEC should perform its functions according to written operating procedures, should maintain written records of its activities and minutes of its meetings, and should comply with GCP and with the applicable regulatory requirement(s).

3.2.3 An IRB/IEC should make its decisions at announced meetings at which at least a quorum, as stipulated in its written operating procedures, is present.

3.2.4 Only members who participate in the IRB/IEC review and discussion should vote/provide their opinion and/or advise.

3.2.5 The investigator may provide information on any aspect of the trial, but should not participate in the deliberations of the IRB/IEC or in the vote/opinion of the IRB/IEC.

3.2.6 An IRB/IEC may invite nonmembers with expertise in special areas for assistance.

3.3 Procedures

The IRB/IEC should establish, document in writing, and follow its procedures, which should include:

3.3.1 Determining its composition (names and qualifications of the members) and the authority under which it is established.

3.3.2 Scheduling, notifying its members of, and conducting its meetings.

3.3.3 Conducting initial and continuing review of trials.

3.3.4 Determining the frequency of continuing review, as appropriate.

3.3.5 Providing, according to the applicable regulatory requirements, expedited review and approval/favourable opinion of minor change(s) in ongoing trials that have the approval/favourable opinion of the IRB/IEC.

3.3.6 Specifying that no subject should be admitted to a trial before the IRB/IEC issues its written approval/favourable opinion of the trial.

3.3.7 Specifying that no deviations from, or changes of, the protocol should be initiated without prior written IRB/IEC approval/favourable opinion of an appropriate amendment, except when necessary to eliminate immediate hazards to the subjects or when the change(s) involves only logistical or

administrative aspects of the trial (e.g., change of monitor(s), telephone number(s)) (see 4.5.2).

3.3.8 Specifying that the investigator should promptly report to the IRB/IEC:

(a) Deviations from, or changes of, the protocol to eliminate immediate hazards to the trial subjects (see 3.3.7, 4.5.2, 4.5.4).

(b) Changes increasing the risk to subjects and/or affecting significantly the conduct of the trial (see 4.10.2).

(c) All adverse drug reactions (ADRs) that are both serious and unexpected.

(d) New information that may affect adversely the safety of the subjects or the conduct of the trial.

3.3.9 Ensuring that the IRB/IEC promptly notify in writing the investigator/institution concerning:

(a) Its trial-related decisions/opinions.

(b) The reasons for its decisions/opinions.

(c) Procedures for appeal of its decisions/opinions.

3.4 Records

The IRB/IEC should retain all relevant records (e.g., written procedures, membership lists, lists of occupations/affiliations of members, submitted documents, minutes of meetings, and correspondence) for a period of at least 3 years after completion of the trial and make them available upon request from the regulatory authority(ies).

The IRB/IEC may be asked by investigators, sponsors or regulatory authorities to provide its written procedures and membership lists.

4. INVESTIGATOR

4.1 Investigator's Qualifications and Agreements

4.1.1 The investigator(s) should be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial, should meet all the qualifications specified by the applicable regulatory requirement(s), and should provide evidence of such qualifications through up-to-date curriculum vitae and/or other relevant documentation requested by the sponsor, the IRB/IEC, and/or the regulatory authority(ies).

4.1.2 The investigator should be thoroughly familiar with the appropriate use of the investigational product(s), as described in the protocol, in the current Investigator's Brochure, in the product information and in other information sources provided by the sponsor.

4.1.3 The investigator should be aware of, and should comply with, GCP and the applicable regulatory requirements.

4.1.4 The investigator/institution should permit monitoring and auditing by the sponsor, and inspection by the appropriate regulatory authority(ies).

4.1.5 The investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties.

4.2 Adequate Resources

4.2.1 The investigator should be able to demonstrate (e.g., based on retrospective data) a potential for recruiting the required number of suitable subjects within the agreed recruitment period.

4.2.2 The investigator should have sufficient time to properly conduct and complete the trial within the agreed trial period.

4.2.3 The investigator should have available an adequate number of qualified staff and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely.

4.2.4 The investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions.

4.3 Medical Care of Trial Subjects

4.3.1 A qualified physician (or dentist, when appropriate), who is an investigator or a sub-investigator for the trial, should be responsible for all trial-related medical (or dental) decisions.

4.3.2 During and following a subject's participation in a trial, the investigator/institution should ensure that adequate medical care is provided to a subject for any adverse events, including clinically significant laboratory values, related to the trial. The investigator/institution should inform a subject when medical care is needed for intercurrent illness(es) of which the investigator becomes aware.

4.3.3 It is recommended that the investigator inform the subject's primary physician about the subject's participation in the trial if the subject has a primary physician and if the subject agrees to the primary physician being informed.

4.3.4 Although a subject is not obliged to give his/her reason(s) for withdrawing prematurely from a trial, the investigator should make a reasonable effort to ascertain the reason(s), while fully respecting the subject's rights.

4.4 Communication with IRB/IEC

4.4.1 Before initiating a trial, the investigator/institution should have written and dated approval/favourable opinion from the IRB/IEC for the trial protocol, written informed consent form, consent form updates, subject recruitment procedures (e.g., advertisements), and any other written information to be provided to subjects.

4.4.2 As part of the investigator's/institution's written application to the IRB/IEC, the investigator/institution should provide the IRB/IEC with a current copy of the Investigator's Brochure. If the Investigator's Brochure is updated during the trial, the investigator/institution should supply a copy of the updated Investigator's Brochure to the IRB/IEC.

4.4.3 During the trial the investigator/institution should provide to the IRB/IEC all documents subject to review.

4.5 Compliance with Protocol

4.5.1 The investigator/institution should conduct the trial in compliance with the protocol agreed to by the sponsor and, if required, by the regulatory authority(ies) and which was given approval/favourable opinion by the

IRB/IEC. The investigator/institution and the sponsor should sign the protocol, or an alternative contract, to confirm agreement.

4.5.2 The investigator should not implement any deviation from, or changes of the protocol without agreement by the sponsor and prior review and documented approval/favourable opinion from the IRB/IEC of an amendment, except where necessary to eliminate an immediate hazard(s) to trial subjects, or when the change(s) involves only logistical or administrative aspects of the trial (e.g., change in monitor(s), change of telephone number(s)).

4.5.3 The investigator, or person designated by the investigator, should document and explain any deviation from the approved protocol.

4.5.4 The investigator may implement a deviation from, or a change of, the protocol to eliminate an immediate hazard(s) to trial subjects without prior IRB/IEC approval/favourable opinion. As soon as possible, the implemented deviation or change, the reasons for it, and, if appropriate, the proposed protocol amendment(s) should be submitted:

(a) to the IRB/IEC for review and approval/favourable opinion,

(b) to the sponsor for agreement and, if required,

(c) to the regulatory authority(ies).

4.6 Investigational Product(s)

4.6.1 Responsibility for investigational product(s) accountability at the trial site(s) rests with the investigator/institution.

4.6.2 Where allowed/required, the investigator/institution may/should assign some or all of the investigator's/institution's duties for investigational product(s) accountability at the trial site(s) to an appropriate pharmacist or another appropriate individual who is under the supervision of the investigator/institution..

4.6.3 The investigator/institution and/or a pharmacist or other appropriate individual, who is designated by the investigator/institution, should maintain records of the product's delivery to the trial site, the inventory at the site, the use by each subject, and the return to the sponsor or alternative disposition of unused product(s). These records should include dates, quantities, batch/serial numbers, expiration dates (if applicable), and the unique code numbers assigned to the investigational product(s) and trial subjects. Investigators should maintain records that document adequately that the subjects were provided the doses specified by the protocol and reconcile all investigational product(s) received from the sponsor.

4.6.4 The investigational product(s) should be stored as specified by the sponsor (see 5.13.2 and 5.14.3) and in accordance with applicable regulatory requirement(s).

4.6.5 The investigator should ensure that the investigational product(s) are used only in accordance with the approved protocol.

4.6.6 The investigator, or a person designated by the investigator/institution, should explain the correct use of the investigational product(s) to each subject and should check, at intervals appropriate for the trial, that each subject is following the instructions properly.

4.7 Randomization Procedures and Unblinding

The investigator should follow the trial's randomization procedures, if any, and should ensure that the code is broken only in accordance with the protocol. If the trial is blinded, the investigator should promptly document and explain to the sponsor any premature unblinding (e.g., accidental unblinding, unblinding due to a serious adverse event) of the investigational product(s).

4.8 Informed Consent of Trial Subjects

4.8.1 In obtaining and documenting informed consent, the investigator should comply with the applicable regulatory requirement(s), and should adhere to GCP and to the ethical principles that have their origin in the Declaration of Helsinki. Prior to the beginning of the trial, the investigator should have the IRB/IEC's written approval/favourable opinion of the written informed consent form and any other written information to be provided to subjects.

4.8.2 The written informed consent form and any other written information to be provided to subjects should be revised whenever important new information becomes available that may be relevant to the subject's consent. Any revised written informed consent form, and written information should receive the IRB/IEC's approval/favourable opinion in advance of use. The subject or the subject's legally acceptable representative should be informed in a timely manner if new information becomes available that may be relevant to the subject's willingness to continue participation in the trial. The communication of this information should be documented.

4.8.3 Neither the investigator, nor the trial staff, should coerce or unduly influence a subject to participate or to continue to participate in a trial.

4.8.4 None of the oral and written information concerning the trial, including the written informed consent form, should contain any language that causes the subject or the subject's legally acceptable representative to waive or to appear to waive any legal rights, or that releases or appears to release the investigator, the institution, the sponsor, or their agents from liability for negligence.

4.8.5 The investigator, or a person designated by the investigator, should fully inform the subject or, if the subject is unable to provide informed consent, the subject's legally acceptable representative, of all pertinent aspects of the trial including the written information and the approval/ favourable opinion by the IRB/IEC.

4.8.6 The language used in the oral and written information about the trial, including the written informed consent form, should be as non-technical as practical and should be understandable to the subject or the subject's legally acceptable representative and the impartial witness, where applicable.

4.8.7 Before informed consent may be obtained, the investigator, or a person designated by the investigator, should provide the subject or the subject's legally acceptable representative ample time and opportunity to inquire about details of the trial and to decide whether or not to participate in the trial. All questions about the trial should be answered to the satisfaction of the subject or the subject's legally acceptable representative.

4.8.8 Prior to a subject's participation in the trial, the written informed consent form should be signed and personally dated by the subject or by the subject's legally

acceptable representative, and by the person who conducted the informed consent discussion.

4.8.9 If a subject is unable to read or if a legally acceptable representative is unable to read, an impartial witness should be present during the entire informed consent discussion. After the written informed consent form and any other written information to be provided to subjects, is read and explained to the subject or the subject's legally acceptable representative, and after the subject or the subject's legally acceptable representative has orally consented to the subject's participation in the trial and, if capable of doing so, has signed and personally dated the informed consent form, the witness should sign and personally date the consent form. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject or the subject's legally acceptable representative, and that informed consent was freely given by the subject or the subject's legally acceptable representative.

4.8.10 Both the informed consent discussion and the written informed consent form and any other written information to be provided to subjects should include explanations of the following:

(a) That the trial involves research.

(b) The purpose of the trial.

(c) The trial treatment(s) and the probability for random assignment to each treatment.

(d) The trial procedures to be followed, including all invasive procedures.

(e) The subject's responsibilities.

(f) Those aspects of the trial that are experimental.

(g) The reasonably foreseeable risks or inconveniences to the subject and, when applicable, to an embryo, fetus, or nursing infant.

(h) The reasonably expected benefits. When there is no intended clinical benefit to the subject, the subject should be made aware of this.

(i) The alternative procedure(s) or course(s) of treatment that may be available to the subject, and their important potential benefits and risks.

(j) The compensation and/or treatment available to the subject in the event of trial-related injury.

(k) The anticipated prorated payment, if any, to the subject for participating in the trial.

(l) The anticipated expenses, if any, to the subject for participating in the trial.

(m) That the subject's participation in the trial is voluntary and that the subject may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled.

(n) That the monitor(s), the auditor(s), the IRB/IEC, and the regulatory authority(ies) will be granted direct access to the subject's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the

applicable laws and regulations and that, by signing a written informed consent form, the subject or the subject's legally acceptable representative is authorizing such access.

(o) That records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the subject's identity will remain confidential.

(p) That the subject or the subject's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the subject's willingness to continue participation in the trial.

(q) The person(s) to contact for further information regarding the trial and the rights of trial subjects, and whom to contact in the event of trial-related injury.

(r) The foreseeable circumstances and/or reasons under which the subject's participation in the trial may be terminated.

(s) The expected duration of the subject's participation in the trial.

(t) The approximate number of subjects involved in the trial.

4.8.11 Prior to participation in the trial, the subject or the subject's legally acceptable representative should receive a copy of the signed and dated written informed consent form and any other written information provided to the subjects. During a subject's participation in the trial, the subject or the subject's legally acceptable representative should receive a copy of the signed and dated consent form updates and a copy of any amendments to the written information provided to subjects.

4.8.12 When a clinical trial (therapeutic or non-therapeutic) includes subjects who can only be enrolled in the trial with the consent of the subject's legally acceptable representative (e.g., minors, or patients with severe dementia), the subject should be informed about the trial to the extent compatible with the subject's understanding and, if capable, the subject should sign and personally date the written informed consent.

4.8.13 Except as described in 4.8.14, a non-therapeutic trial (i.e. a trial in which there is no anticipated direct clinical benefit to the subject), should be conducted in subjects who personally give consent and who sign and date the written informed consent form.

4.8.14 Non-therapeutic trials may be conducted in subjects with consent of a legally acceptable representative provided the following conditions are fulfilled:

(a) The objectives of the trial can not be met by means of a trial in subjects who can give informed consent personally.

(b) The foreseeable risks to the subjects are low.

(c) The negative impact on the subject's well-being is minimized and low.

(d) The trial is not prohibited by law.

(e) The approval/favourable opinion of the IRB/IEC is expressly sought on the inclusion of such subjects, and the written approval/ favourable opinion covers this aspect.

Such trials, unless an exception is justified, should be conducted in patients having a disease or condition for which the investigational product is intended. Subjects in these trials should be particularly closely monitored and should be withdrawn if they appear to be unduly distressed.

4.8.15 In emergency situations, when prior consent of the subject is not possible, the consent of the subject's legally acceptable representative, if present, should be requested. When prior consent of the subject is not possible, and the subject's legally acceptable representative is not available, enrolment of the subject should require measures described in the protocol and/or elsewhere, with documented approval/favourable opinion by the IRB/IEC, to protect the rights, safety and well-being of the subject and to ensure compliance with applicable regulatory requirements. The subject or the subject's legally acceptable representative should be informed about the trial as soon as possible and consent to continue and other consent as appropriate (see 4.8.10) should be requested.

4.9 Records and Reports

4.9.1 The investigator should ensure the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor in the CRFs and in all required reports.

4.9.2 Data reported on the CRF, that are derived from source documents, should be consistent with the source documents or the discrepancies should be explained.

4.9.3 Any change or correction to a CRF should be dated, initialed, and explained (if necessary) and should not obscure the original entry (i.e. an audit trail should be maintained); this applies to both written and electronic changes or corrections (see 5.18.4 (n)). Sponsors should provide guidance to investigators and/or the investigators' designated representatives on making such corrections. Sponsors should have written procedures to assure that changes or corrections in CRFs made by sponsor's designated representatives are documented, are necessary, and are endorsed by the investigator. The investigator should retain records of the changes and corrections.

4.9.4 The investigator/institution should maintain the trial documents as specified in Essential Documents for the Conduct of a Clinical Trial (see 8.) and as required by the applicable regulatory requirement(s). The investigator/institution should take measures to prevent accidental or premature destruction of these documents.

4.9.5 Essential documents should be retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents should be retained for a longer period however if required by the applicable regulatory requirements or by an agreement with the sponsor. It is the responsibility of the sponsor to inform the investigator/institution as to when these documents no longer need to be retained (see 5.5.12).

4.9.6 The financial aspects of the trial should be documented in an agreement between the sponsor and the investigator/institution.

4.9.7 Upon request of the monitor, auditor, IRB/IEC, or regulatory authority, the investigator/institution should make available for direct access all requested trial-related records.

4.10 Progress Reports

4.10.1 The investigator should submit written summaries of the trial status to the IRB/IEC annually, or more frequently, if requested by the IRB/IEC.

4.10.2 The investigator should promptly provide written reports to the sponsor, the IRB/IEC (see 3.3.8) and, where applicable, the institution on any changes significantly affecting the conduct of the trial, and/or increasing the risk to subjects.

4.11 Safety Reporting

4.11.1 All serious adverse events (SAEs) should be reported immediately to the sponsor except for those SAEs that the protocol or other document (e.g., Investigator's Brochure) identifies as not needing immediate reporting. The immediate reports should be followed promptly by detailed, written reports. The immediate and follow-up reports should identify subjects by unique code numbers assigned to the trial subjects rather than by the subjects' names, personal identification numbers, and/or addresses. The investigator should also comply with the applicable regulatory requirement(s) related to the reporting of unexpected serious adverse drug reactions to the regulatory authority(ies) and the IRB/IEC.

4.11.2 Adverse events and/or laboratory abnormalities identified in the protocol as critical to safety evaluations should be reported to the sponsor according to the reporting requirements and within the time periods specified by the sponsor in the protocol.

4.11.3 For reported deaths, the investigator should supply the sponsor and the IRB/IEC with any additional requested information (e.g., autopsy reports and terminal medical reports).

4.12 Premature Termination or Suspension of a Trial

If the trial is prematurely terminated or suspended for any reason, the investigator/institution should promptly inform the trial subjects, should assure appropriate therapy and follow-up for the subjects, and, where required by the applicable regulatory requirement(s), should inform the regulatory authority(ies). In addition:

4.12.1 If the investigator terminates or suspends a trial without prior agreement of the sponsor, the investigator should inform the institution where applicable, and the investigator/institution should promptly inform the sponsor and the IRB/IEC, and should provide the sponsor and the IRB/IEC a detailed written explanation of the termination or suspension.

4.12.2 If the sponsor terminates or suspends a trial (see 5.21), the investigator should promptly inform the institution where applicable and the investigator/institution should promptly inform the IRB/IEC and provide the IRB/IEC a detailed written explanation of the termination or suspension.

4.12.3 If the IRB/IEC terminates or suspends its approval/favourable opinion of a trial (see 3.1.2 and 3.3.9), the investigator should inform the institution where applicable and the investigator/institution should promptly notify the sponsor and provide the sponsor with a detailed written explanation of the termination or suspension.

4.13 Final Report(s) by Investigator

Upon completion of the trial, the investigator, where applicable, should inform the institution; the investigator/institution should provide the IRB/IEC with a summary of the trial's outcome, and the regulatory authority(ies) with any reports required.

5. SPONSOR

5.1 Quality Assurance and Quality Control

5.1.1 The sponsor is responsible for implementing and maintaining quality assurance and quality control systems with written SOPs to ensure that trials are conducted and data are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirement(s).

5.1.2 The sponsor is responsible for securing agreement from all involved parties to ensure direct access (see 1.21) to all trial related sites, source data/documents , and reports for the purpose of monitoring and auditing by the sponsor, and inspection by domestic and foreign regulatory authorities.

5.1.3 Quality control should be applied to each stage of data handling to ensure that all data are reliable and have been processed correctly.

5.1.4 Agreements, made by the sponsor with the investigator/institution and any other parties involved with the clinical trial, should be in writing, as part of the protocol or in a separate agreement.

5.2 Contract Research Organization (CRO)

5.2.1 A sponsor may transfer any or all of the sponsor's trial-related duties and functions to a CRO, but the ultimate responsibility for the quality and integrity of the trial data always resides with the sponsor. The CRO should implement quality assurance and quality control.

5.2.2 Any trial-related duty and function that is transferred to and assumed by a CRO should be specified in writing.

5.2.3 Any trial-related duties and functions not specifically transferred to and assumed by a CRO are retained by the sponsor.

5.2.4 All references to a sponsor in this guideline also apply to a CRO to the extent that a CRO has assumed the trial related duties and functions of a sponsor.

5.3 Medical Expertise

The sponsor should designate appropriately qualified medical personnel who will be readily available to advise on trial related medical questions or problems. If necessary, outside consultant(s) may be appointed for this purpose.

5.4 Trial Design

5.4.1 The sponsor should utilize qualified individuals (e.g. biostatisticians, clinical pharmacologists, and physicians) as appropriate, throughout all stages of the trial process, from designing the protocol and CRFs and planning the analyses to analyzing and preparing interim and final clinical trial reports.

5.4.2 For further guidance: Clinical Trial Protocol and Protocol Amendment(s) (see 6.), the ICH Guideline for Structure and Content of Clinical Study Reports, and other appropriate ICH guidance on trial design, protocol and conduct.

5.5 Trial Management, Data Handling, and Record Keeping

5.5.1 The sponsor should utilize appropriately qualified individuals to supervise the overall conduct of the trial, to handle the data, to verify the data, to conduct the statistical analyses, and to prepare the trial reports.

5.5.2 The sponsor may consider establishing an independent data-monitoring committee (IDMC) to assess the progress of a clinical trial, including the safety data and the critical efficacy endpoints at intervals, and to recommend to the sponsor whether to continue, modify, or stop a trial. The IDMC should have written operating procedures and maintain written records of all its meetings.

5.5.3 When using electronic trial data handling and/or remote electronic trial data systems, the sponsor should:

(a) Ensure and document that the electronic data processing system(s) conforms to the sponsor's established requirements for completeness, accuracy, reliability, and consistent intended performance (i.e. validation).

(b) Maintains SOPs for using these systems.

(c) Ensure that the systems are designed to permit data changes in such a way that the data changes are documented and that there is no deletion of entered data (i.e. maintain an audit trail, data trail, edit trail).

(d) Maintain a security system that prevents unauthorized access to the data.

(e) Maintain a list of the individuals who are authorized to make data changes (see 4.1.5 and 4.9.3).

(f) Maintain adequate backup of the data.

(g) Safeguard the blinding, if any (e.g. maintain the blinding during data entry and processing).

5.5.4 If data are transformed during processing, it should always be possible to compare the original data and observations with the processed data.

5.5.5 The sponsor should use an unambiguous subject identification code (see 1.58) that allows identification of all the data reported for each subject.

5.5.6 The sponsor, or other owners of the data, should retain all of the sponsor- specific essential documents pertaining to the trial (see 8. Essential Documents for the Conduct of a Clinical Trial).

5.5.7 The sponsor should retain all sponsor-specific essential documents in conformance with the applicable regulatory requirement(s) of the country(ies) where the product is approved, and/or where the sponsor intends to apply for approval(s).

5.5.8 If the sponsor discontinues the clinical development of an investigational product (i.e. for any or all indications, routes of administration, or dosage forms), the sponsor should maintain all sponsor-specific essential documents for at least 2 years after formal discontinuation or in conformance with the applicable regulatory requirement(s).

5.5.9 If the sponsor discontinues the clinical development of an investigational product, the sponsor should notify all the trial investigators/institutions and all the regulatory authorities.

5.5.10 Any transfer of ownership of the data should be reported to the appropriate authority(ies), as required by the applicable regulatory requirement(s).

5.5.11 The sponsor specific essential documents should be retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents should be retained for a longer period however if required by the applicable regulatory requirement(s) or if needed by the sponsor.

5.5.12 The sponsor should inform the investigator(s)/institution(s) in writing of the need for record retention and should notify the investigator(s)/institution(s) in writing when the trial related records are no longer needed.

5.6 Investigator Selection

5.6.1 The sponsor is responsible for selecting the investigator(s)/institution(s). Each investigator should be qualified by training and experience and should have adequate resources (see 4.1, 4.2) to properly conduct the trial for which the investigator is selected. If organization of a coordinating committee and/or selection of coordinating investigator(s) are to be utilized in multicentre trials, their organization and/or selection are the sponsor's responsibility.

5.6.2 Before entering an agreement with an investigator/institution to conduct a trial, the sponsor should provide the investigator(s)/institution(s) with the protocol and an up-to-date Investigator's Brochure, and should provide sufficient time for the investigator/institution to review the protocol and the information provided.

5.6.3 The sponsor should obtain the investigator's/institution's agreement:

(a) to conduct the trial in compliance with GCP, with the applicable regulatory requirement(s) (see 4.1.3), and with the protocol agreed to by the sponsor and given approval/favourable opinion by the IRB/IEC (see 4.5.1);

(b) to comply with procedures for data recording/reporting;

(c) to permit monitoring, auditing and inspection (see 4.1.4) and

(d) to retain the trial related essential documents until the sponsor informs the investigator/institution these documents are no longer needed (see 4.9.4 and 5.5.12).

The sponsor and the investigator/institution should sign the protocol, or an alternative document, to confirm this agreement.

5.7 Allocation of Responsibilities

Prior to initiating a trial, the sponsor should define, establish, and allocate all trial-related duties and functions.

5.8 Compensation to Subjects and Investigators

5.8.1 If required by the applicable regulatory requirement(s), the sponsor should provide insurance or should indemnify (legal and financial coverage) the investigator/the institution against claims arising from the trial, except for claims that arise from malpractice and/or negligence.

5.8.2 The sponsor's policies and procedures should address the costs of treatment of trial subjects in the event of trial-related injuries in accordance with the applicable regulatory requirement(s).

5.8.3 When trial subjects receive compensation, the method and manner of compensation should comply with applicable regulatory requirement(s).

5.9 Financing

The financial aspects of the trial should be documented in an agreement between the sponsor and the investigator/institution.

5.10 Notification/Submission to Regulatory Authority(ies)

Before initiating the clinical trial(s), the sponsor (or the sponsor and the investigator, if required by the applicable regulatory requirement(s)) should submit any required application(s) to the appropriate authority(ies) for review, acceptance, and/or permission (as required by the applicable regulatory requirement(s)) to begin the trial(s). Any notification/submission should be dated and contain sufficient information to identify the protocol.

5.11 Confirmation of Review by IRB/IEC

5.11.1 The sponsor should obtain from the investigator/institution:

(a) The name and address of the investigator's/institution's IRB/IEC.

(b) A statement obtained from the IRB/IEC that it is organized and operates according to GCP and the applicable laws and regulations.

(c) Documented IRB/IEC approval/favourable opinion and, if requested by the sponsor, a current copy of protocol, written informed consent form(s) and any other written information to be provided to subjects, subject recruiting procedures, and documents related to payments and compensation available to the subjects, and any other documents that the IRB/IEC may have requested.

5.11.2 If the IRB/IEC conditions its approval/favourable opinion upon change(s) in any aspect of the trial, such as modification(s) of the protocol, written informed consent form and any other written information to be provided to subjects, and/or other procedures, the sponsor should obtain from the investigator/institution a copy of the modification(s) made and the date approval/favourable opinion was given by the IRB/IEC.

5.11.3 The sponsor should obtain from the investigator/institution documentation and dates of any IRB/IEC reapprovals/re-evaluations with favourable opinion, and of any withdrawals or suspensions of approval/favourable opinion.

5.12 Information on Investigational Product(s)

5.12.1 When planning trials, the sponsor should ensure that sufficient safety and efficacy data from nonclinical studies and/or clinical trials are available to support human exposure by the route, at the dosages, for the duration, and in the trial population to be studied.

5.12.2 The sponsor should update the Investigator's Brochure as significant new information becomes available (see 7. Investigator's Brochure).

5.13 Manufacturing, Packaging, Labelling, and Coding Investigational Product(s)

5.13.1 The sponsor should ensure that the investigational product(s) (including active comparator(s) and placebo, if applicable) is characterized as appropriate to the stage of development of the product(s), is manufactured in accordance with any applicable GMP, and is coded and labelled in a manner that protects the blinding, if applicable. In addition, the labelling should comply with applicable regulatory requirement(s).

5.13.2 The sponsor should determine, for the investigational product(s), acceptable storage temperatures, storage conditions (e.g. protection from light), storage times, reconstitution fluids and procedures, and devices for product infusion, if any. The sponsor should inform all involved parties (e.g. monitors, investigators, pharmacists, storage managers) of these determinations.

5.13.3 The investigational product(s) should be packaged to prevent contamination and unacceptable deterioration during transport and storage.

5.13.4 In blinded trials, the coding system for the investigational product(s) should include a mechanism that permits rapid identification of the product(s) in case of a medical emergency, but does not permit undetectable breaks of the blinding.

5.13.5 If significant formulation changes are made in the investigational or comparator product(s) during the course of clinical development, the results of any additional studies of the formulated product(s) (e.g. stability, dissolution rate, bioavailability) needed to assess whether these changes would significantly alter the pharmacokinetic profile of the product should be available prior to the use of the new formulation in clinical trials.

5.14 Supplying and Handling Investigational Product(s)

5.14.1 The sponsor is responsible for supplying the investigator(s)/institution(s) with the investigational product(s).

5.14.2 The sponsor should not supply an investigator/institution with the investigational product(s) until the sponsor obtains all required documentation (e.g. approval/favourable opinion from IRB/IEC and regulatory authority(ies)).

5.14.3 The sponsor should ensure that written procedures include instructions that the investigator/institution should follow for the handling and storage of investigational product(s) for the trial and documentation thereof. The procedures should address adequate and safe receipt, handling, storage, dispensing, retrieval of unused product from subjects, and return of unused investigational product(s) to the sponsor (or alternative disposition if authorized by the sponsor and in compliance with the applicable regulatory requirement(s)).

5.14.4 The sponsor should:

(a) Ensure timely delivery of investigational product(s) to the investigator(s).

(b) Maintain records that document shipment, receipt, disposition, return, and destruction of the investigational product(s) (see 8. Essential Documents for the Conduct of a Clinical Trial).

(c) Maintain a system for retrieving investigational products and documenting this retrieval (e.g. for deficient product recall, reclaim after trial completion, expired product reclaim).

(d) Maintain a system for the disposition of unused investigational product(s) and for the documentation of this disposition.

5.14.5 The sponsor should:

(a) Take steps to ensure that the investigational product(s) are stable over the period of use.

(b) Maintain sufficient quantities of the investigational product(s) used in the trials to reconfirm specifications, should this become necessary, and maintain records of batch sample analyses and characteristics. To the extent stability permits, samples should be retained either until the analyses of the trial data are complete or as required by the applicable regulatory requirement(s), whichever represents the longer retention period.

5.15 Record Access

5.15.1 The sponsor should ensure that it is specified in the protocol or other written agreement that the investigator(s)/institution(s) provide direct access to source data/documents for trial-related monitoring, audits, IRB/IEC review, and regulatory inspection.

5.15.2 The sponsor should verify that each subject has consented, in writing, to direct access to his/her original medical records for trial-related monitoring, audit, IRB/IEC review, and regulatory inspection.

5.16 Safety Information

5.16.1 The sponsor is responsible for the ongoing safety evaluation of the investigational product(s).

5.16.2 The sponsor should promptly notify all concerned investigator(s)/institution(s) and the regulatory authority(ies) of findings that could affect adversely the

safety of subjects, impact the conduct of the trial, or alter the IRB/IEC's approval/favourable opinion to continue the trial.

5.17 Adverse Drug Reaction Reporting

5.17.1 The sponsor should expedite the reporting to all concerned investigator(s)/institutions(s), to the IRB(s)/IEC(s), where required, and to the regulatory authority(ies) of all adverse drug reactions (ADRs) that are both serious and unexpected.

5.17.2 Such expedited reports should comply with the applicable regulatory requirement(s) and with the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting.

5.17.3 The sponsor should submit to the regulatory authority(ies) all safety updates and periodic reports, as required by applicable regulatory requirement(s).

5.18 Monitoring

5.18.1 Purpose

The purposes of trial monitoring are to verify that:

(a) The rights and well-being of human subjects are protected.

(b) The reported trial data are accurate, complete, and verifiable from source documents.

(c) The conduct of the trial is in compliance with the currently approved protocol/amendment(s), with GCP, and with the applicable regulatory requirement(s).

5.18.2 Selection and Qualifications of Monitors

(a) Monitors should be appointed by the sponsor.

(b) Monitors should be appropriately trained, and should have the scientific and/or clinical knowledge needed to monitor the trial adequately. A monitor's qualifications should be documented.

(c) Monitors should be thoroughly familiar with the investigational product(s), the protocol, written informed consent form and any other written information to be provided to subjects, the sponsor's SOPs, GCP, and the applicable regulatory requirement(s).

5.18.3 Extent and Nature of Monitoring

The sponsor should ensure that the trials are adequately monitored. The sponsor should determine the appropriate extent and nature of monitoring. The determination of the extent and nature of monitoring should be based on considerations such as the objective, purpose, design, complexity, blinding, size, and endpoints of the trial. In general there is a need for on-site monitoring, before, during, and after the trial; however in exceptional circumstances the sponsor may determine that central monitoring in conjunction with procedures such as investigators' training and meetings, and extensive written guidance can assure appropriate conduct of the trial in accordance with GCP. Statistically controlled sampling may be an acceptable method for selecting the data to be verified.

5.18.4 Monitor's Responsibilities

The monitor(s) in accordance with the sponsor's requirements should ensure that the trial is conducted and documented properly by carrying out the following activities when relevant and necessary to the trial and the trial site:

(a) Acting as the main line of communication between the sponsor and the investigator.

(b) Verifying that the investigator has adequate qualifications and resources (see 4.1, 4.2, 5.6) and remain adequate throughout the trial period, that facilities, including laboratories, equipment, and staff, are adequate to safely and properly conduct the trial and remain adequate throughout the trial period.

(c) Verifying, for the investigational product(s):

  (i) That storage times and conditions are acceptable, and that supplies are sufficient throughout the trial.

  (ii) That the investigational product(s) are supplied only to subjects who are eligible to receive it and at the protocol specified dose(s).

  (iii) That subjects are provided with necessary instruction on properly using, handling, storing, and returning the investigational product(s).

  (iv) That the receipt, use, and return of the investigational product(s) at the trial sites are controlled and documented adequately.

  (v) That the disposition of unused investigational product(s) at the trial sites complies with applicable regulatory requirement(s) and is in accordance with the sponsor.

(d) Verifying that the investigator follows the approved protocol and all approved amendment(s), if any.

(e) Verifying that written informed consent was obtained before each subject's participation in the trial.

(f) Ensuring that the investigator receives the current Investigator's Brochure, all documents, and all trial supplies needed to conduct the trial properly and to comply with the applicable regulatory requirement(s).

(g) Ensuring that the investigator and the investigator's trial staff are adequately informed about the trial.

(h) Verifying that the investigator and the investigator's trial staff are performing the specified trial functions, in accordance with the protocol and any other written agreement between the sponsor and the investigator/institution, and have not delegated these functions to unauthorized individuals.

(i) Verifying that the investigator is enroling only eligible subjects.

(j) Reporting the subject recruitment rate.

(k) Verifying that source documents and other trial records are accurate, complete, kept up-to-date and maintained.

(l) Verifying that the investigator provides all the required reports, notifications, applications, and submissions, and that these documents are accurate, complete, timely, legible, dated, and identify the trial.

(m) Checking the accuracy and completeness of the CRF entries, source documents and other trial-related records against each other. The monitor specifically should verify that:

(i) The data required by the protocol are reported accurately on the CRFs and are consistent with the source documents.

(ii) Any dose and/or therapy modifications are well documented for each of the trial subjects.

(iii) Adverse events, concomitant medications and intercurrent illnesses are reported in accordance with the protocol on the CRFs.

(iv) Visits that the subjects fail to make, tests that are not conducted, and examinations that are not performed are clearly reported as such on the CRFs.

(v) All withdrawals and dropouts of enrolled subjects from the trial are reported and explained on the CRFs.

(n) Informing the investigator of any CRF entry error, omission, or illegibility. The monitor should ensure that appropriate corrections, additions, or deletions are made, dated, explained (if necessary), and initialled by the investigator or by a member of the investigator's trial staff who is authorized to initial CRF changes for the investigator. This authorization should be documented.

(o) Determining whether all adverse events (AEs) are appropriately reported within the time periods required by GCP, the protocol, the IRB/IEC, the sponsor, and the applicable regulatory requirement(s).

(p) Determining whether the investigator is maintaining the essential documents (see 8. Essential Documents for the Conduct of a Clinical Trial).

(q) Communicating deviations from the protocol, SOPs, GCP, and the applicable regulatory requirements to the investigator and taking appropriate action designed to prevent recurrence of the detected deviations.

5.18.5 Monitoring Procedures

The monitor(s) should follow the sponsor's established written SOPs as well as those procedures that are specified by the sponsor for monitoring a specific trial.

5.18.6 Monitoring Report

(a) The monitor should submit a written report to the sponsor after each trial-site visit or trial-related communication.

(b) Reports should include the date, site, name of the monitor, and name of the investigator or other individual(s) contacted.

(c) Reports should include a summary of what the monitor reviewed and the monitor's statements concerning the significant findings/facts, deviations and deficiencies, conclusions, actions taken or to be taken and/or actions recommended to secure compliance.

(d) The review and follow-up of the monitoring report with the sponsor should be documented by the sponsor's designated representative.

5.19 Audit

If or when sponsors perform audits, as part of implementing quality assurance, they should consider:

5.19.1 Purpose

The purpose of a sponsor's audit, which is independent of and separate from routine monitoring or quality control functions, should be to evaluate trial conduct and compliance with the protocol, SOPs, GCP, and the applicable regulatory requirements.

5.19.2 Selection and Qualification of Auditors

(a) The sponsor should appoint individuals, who are independent of the clinical trials/systems, to conduct audits.

(b) The sponsor should ensure that the auditors are qualified by training and experience to conduct audits properly. An auditor's qualifications should be documented.

5.19.3 Auditing Procedures

(a) The sponsor should ensure that the auditing of clinical trials/systems is conducted in accordance with the sponsor's written procedures on what to audit, how to audit, the frequency of audits, and the form and content of audit reports.

(b) The sponsor's audit plan and procedures for a trial audit should be guided by the importance of the trial to submissions to regulatory authorities, the number of subjects in the trial, the type and complexity of the trial, the level of risks to the trial subjects, and any identified problem(s).

(c) The observations and findings of the auditor(s) should be documented.

(d) To preserve the independence and value of the audit function, the regulatory authority(ies) should not routinely request the audit reports. Regulatory authority(ies) may seek access to an audit report on a case by case basis when evidence of serious GCP non-compliance exists, or in the course of legal proceedings.

(e) When required by applicable law or regulation, the sponsor should provide an audit certificate.

5.20 Noncompliance

5.20.1 Noncompliance with the protocol, SOPs, GCP, and/or applicable regulatory requirement(s) by an investigator/institution, or by member(s) of the sponsor's staff should lead to prompt action by the sponsor to secure compliance.

5.20.2 If the monitoring and/or auditing identifies serious and/or persistent noncompliance on the part of an investigator/institution, the sponsor should terminate the investigator's/institution's participation in the trial. When an investigator's/institution's participation is terminated because of noncompliance, the sponsor should notify promptly the regulatory authority(ies).

5.21 Premature Termination or Suspension of a Trial

If a trial is prematurely terminated or suspended, the sponsor should promptly inform the investigators/institutions, and the regulatory authority(ies) of the termination or suspension and the reason(s) for the termination or suspension. The IRB/IEC should also be informed promptly and provided the reason(s) for the termination or suspension by the sponsor or by the investigator/institution, as specified by the applicable regulatory requirement(s).

5.22 Clinical Trial/Study Reports

Whether the trial is completed or prematurely terminated, the sponsor should ensure that the clinical trial reports are prepared and provided to the regulatory agency(ies) as required by the applicable regulatory requirement(s). The sponsor should also ensure that the clinical trial reports in marketing applications meet the standards of the ICH Guideline for Structure and Content of Clinical Study Reports. (NOTE: The ICH Guideline for Structure and Content of Clinical Study Reports specifies that abbreviated study reports may be acceptable in certain cases.)

5.23 Multicentre Trials

For multicentre trials, the sponsor should ensure that:

5.23.1 All investigators conduct the trial in strict compliance with the protocol agreed to by the sponsor and, if required, by the regulatory authority(ies), and given approval/favourable opinion by the IRB/IEC.

5.23.2 The CRFs are designed to capture the required data at all multicentre trial sites. For those investigators who are collecting additional data, supplemental CRFs should also be provided that are designed to capture the additional data.

5.23.3 The responsibilities of coordinating investigator(s) and the other participating investigators are documented prior to the start of the trial.

5.23.4 All investigators are given instructions on following the protocol, on complying with a uniform set of standards for the assessment of clinical and laboratory findings, and on completing the CRFs.

5.23.5 Communication between investigators is facilitated.

6. CLINICAL TRIAL PROTOCOL AND PROTOCOL AMENDMENT(S)

The contents of a trial protocol should generally include the following topics. However, site specific information may be provided on separate protocol page(s), or addressed in a separate agreement, and some of the information listed below may be contained in other protocol referenced documents, such as an Investigator's Brochure.

6.1 General Information

6.1.1 Protocol title, protocol identifying number, and date. Any amendment(s) should also bear the amendment number(s) and date(s).

6.1.2 Name and address of the sponsor and monitor (if other than the sponsor).

6.1.3 Name and title of the person(s) authorized to sign the protocol and the protocol amendment(s) for the sponsor.

6.1.4 Name, title, address, and telephone number(s) of the sponsor's medical expert (or dentist when appropriate) for the trial.

6.1.5 Name and title of the investigator(s) who is (are) responsible for conducting the trial, and the address and telephone number(s) of the trial site(s).

6.1.6 Name, title, address, and telephone number(s) of the qualified physician (or dentist, if applicable), who is responsible for all trial-site related medical (or dental) decisions (if other than investigator).

6.1.7 Name(s) and address(es) of the clinical laboratory(ies) and other medical and/or technical department(s) and/or institutions involved in the trial.

6.2 Background Information

6.2.1 Name and description of the investigational product(s).

6.2.2 A summary of findings from nonclinical studies that potentially have clinical significance and from clinical trials that are relevant to the trial.

6.2.3 Summary of the known and potential risks and benefits, if any, to human subjects.

6.2.4 Description of and justification for the route of administration, dosage, dosage regimen, and treatment period(s).

6.2.5 A statement that the trial will be conducted in compliance with the protocol, GCP and the applicable regulatory requirement(s).

6.2.6 Description of the population to be studied.

6.2.7 References to literature and data that are relevant to the trial, and that provide background for the trial.

6.3 Trial Objectives and Purpose

A detailed description of the objectives and the purpose of the trial.

6.4 Trial Design

The scientific integrity of the trial and the credibility of the data from the trial depend substantially on the trial design. A description of the trial design, should include:

6.4.1 A specific statement of the primary endpoints and the secondary endpoints, if any, to be measured during the trial.

6.4.2 A description of the type/design of trial to be conducted (e.g. double-blind, placebo-controlled, parallel design) and a schematic diagram of trial design, procedures and stages.

6.4.3 A description of the measures taken to minimize/avoid bias, including:

(a) Randomization.

(b) Blinding.

6.4.4 A description of the trial treatment(s) and the dosage and dosage regimen of the investigational product(s). Also include a description of the dosage form, packaging, and labelling of the investigational product(s).

6.4.5 The expected duration of subject participation, and a description of the sequence and duration of all trial periods, including follow-up, if any.

6.4.6 A description of the "stopping rules" or "discontinuation criteria" for individual subjects, parts of trial and entire trial.

6.4.7 Accountability procedures for the investigational product(s), including the placebo(s) and comparator(s), if any.

6.4.8 Maintenance of trial treatment randomization codes and procedures for breaking codes.

6.4.9 The identification of any data to be recorded directly on the CRFs (i.e. no prior written or electronic record of data), and to be considered to be source data.

6.5 Selection and Withdrawal of Subjects

6.5.1 Subject inclusion criteria.

6.5.2 Subject exclusion criteria.

6.5.3 Subject withdrawal criteria (i.e. terminating investigational product treatment/trial treatment) and procedures specifying:

(a) When and how to withdraw subjects from the trial/ investigational product treatment.

(b) The type and timing of the data to be collected for withdrawn subjects.

(c) Whether and how subjects are to be replaced.

(d) The follow-up for subjects withdrawn from investigational product treatment/trial treatment.

6.6 Treatment of Subjects

6.6.1 The treatment(s) to be administered, including the name(s) of all the product(s), the dose(s), the dosing schedule(s), the route/mode(s) of administration, and the treatment period(s), including the follow-up period(s) for subjects for each investigational product treatment/trial treatment group/arm of the trial.

6.6.2 Medication(s)/treatment(s) permitted (including rescue medication) and not permitted before and/or during the trial.

6.6.3 Procedures for monitoring subject compliance.

6.7 Assessment of Efficacy

6.7.1 Specification of the efficacy parameters.

6.7.2 Methods and timing for assessing, recording, and analysing of efficacy parameters.

6.8 Assessment of Safety

6.8.1 Specification of safety parameters.

6.8.2 The methods and timing for assessing, recording, and analysing safety parameters.

6.8.3 Procedures for eliciting reports of and for recording and reporting adverse event and intercurrent illnesses.

6.8.4 The type and duration of the follow-up of subjects after adverse events.

6.9 Statistics

6.9.1 A description of the statistical methods to be employed, including timing of any planned interim analysis(ses).

6.9.2 The number of subjects planned to be enrolled. In multicentre trials, the numbers of enrolled subjects projected for each trial site should be specified. Reason for choice of sample size, including reflections on (or calculations of) the power of the trial and clinical justification.

6.9.3 The level of significance to be used.

6.9.4 Criteria for the termination of the trial.

6.9.5 Procedure for accounting for missing, unused, and spurious data.

6.9.6 Procedures for reporting any deviation(s) from the original statistical plan (any deviation(s) from the original statistical plan should be described and justified in protocol and/or in the final report, as appropriate).

6.9.7 The selection of subjects to be included in the analyses (e.g. all randomized subjects, all dosed subjects, all eligible subjects, evaluable subjects).

6.10 Direct Access to Source Data/Documents

The sponsor should ensure that it is specified in the protocol or other written agreement that the investigator(s)/institution(s) will permit trial-related monitoring, audits, IRB/IEC review, and regulatory inspection(s), providing direct access to source data/documents.

6.11 Quality Control and Quality Assurance

6.12 Ethics

Description of ethical considerations relating to the trial.

6.13 Data Handling and Record Keeping

6.14 Financing and Insurance

Financing and insurance if not addressed in a separate agreement.

6.15 Publication Policy

Publication policy, if not addressed in a separate agreement.

6.16 Supplements

(NOTE: Since the protocol and the clinical trial/study report are closely related, further relevant information can be found in the ICH Guideline for Structure and Content of Clinical Study Reports.)

7. INVESTIGATOR'S BROCHURE

7.1 Introduction

The Investigator's Brochure (IB) is a compilation of the clinical and nonclinical data on the investigational product(s) that are relevant to the study of the product(s) in human subjects. Its purpose is to provide the investigators and others involved in the trial with the information to facilitate their understanding of the rationale for, and their compliance with, many key features of the protocol, such as the dose, dose frequency/interval, methods of administration: and safety monitoring procedures. The IB also provides insight to support the clinical management of the study subjects during the course of the clinical trial. The information should be presented in a concise, simple, objective, balanced, and non-promotional form that enables a clinician, or potential investigator, to understand it and make his/her own unbiased risk-benefit assessment of the appropriateness of the proposed trial. For this reason, a medically qualified person should generally participate in the editing of an IB, but the contents of the IB should be approved by the disciplines that generated the described data.

This guideline delineates the minimum information that should be included in an IB and provides suggestions for its layout. It is expected that the type and extent of information available will vary with the stage of development of the investigational product. If the investigational product is marketed and its pharmacology is widely understood by medical practitioners, an extensive IB may not be necessary. Where permitted by regulatory authorities, a basic product information brochure, package leaflet, or labelling may be an appropriate alternative, provided that it includes current, comprehensive, and detailed information on all aspects of the investigational product that might be of importance to the investigator. If a marketed product is being studied for a new use (i.e., a new indication), an IB specific to that new use should be prepared. The IB should be reviewed at least annually and revised as necessary in compliance with a sponsor's written procedures. More frequent revision may be appropriate depending on the stage of development and the generation of relevant new information. However, in accordance with Good Clinical Practice, relevant new information may be so important that it should be communicated to the investigators, and possibly to the Institutional Review Boards (IRBs)/Independent Ethics Committees (IECs) and/or regulatory authorities before it is included in a revised IB.

Generally, the sponsor is responsible for ensuring that an up-to-date IB is made available to the investigator(s) and the investigators are responsible for providing the up-to-date IB to the responsible IRBs/IECs. In the case of an investigator sponsored trial, the sponsor-investigator should determine whether a brochure is available from the commercial manufacturer. If the investigational product is provided by the sponsor-investigator, then he or she should provide the necessary information to the trial personnel. In cases where preparation of a formal IB is impractical, the sponsor-investigator should provide, as a substitute, an expanded background information section in the trial protocol that contains the minimum current information described in this guideline.

7.2 General Considerations

The IB should include:

7.2.1 Title Page

This should provide the sponsor's name, the identity of each investigational product (i.e., research number, chemical or approved generic name, and trade name(s) where legally permissible and desired by the sponsor), and the release date. It is also suggested that an edition number, and a reference to the number and date of the edition it supersedes, be provided. An example is given in Appendix 1.

7.2.2 Confidentiality Statement

The sponsor may wish to include a statement instructing the investigator/recipients to treat the IB as a confidential document for the sole information and use of the investigator's team and the IRB/IEC.

7.3 Contents of the Investigator's Brochure

The IB should contain the following sections, each with literature references where appropriate:

7.3.1 Table of Contents

An example of the Table of Contents is given in Appendix 2

7.3.2 Summary

A brief summary (preferably not exceeding two pages) should be given, highlighting the significant physical, chemical, pharmaceutical, pharmacological, toxicological, pharmacokinetic, metabolic, and clinical information available that is relevant to the stage of clinical development of the investigational product.

7.3.3 Introduction

A brief introductory statement should be provided that contains the chemical name (and generic and trade name(s) when approved) of the investigational product(s), all active ingredients, the investigational product (s) pharmacological class and its expected position within this class (e.g. advantages), the rationale for performing research with the investigational product(s), and the anticipated prophylactic, therapeutic, or diagnostic indication(s). Finally, the introductory statement should provide the general approach to be followed in evaluating the investigational product.

7.3.4 Physical, Chemical, and Pharmaceutical Properties and Formulation

A description should be provided of the investigational product substance(s) (including the chemical and/or structural formula(e)), and a brief summary should be given of the relevant physical, chemical, and pharmaceutical properties.

To permit appropriate safety measures to be taken in the course of the trial, a description of the formulation(s) to be used, including excipients, should be provided and justified if clinically relevant. Instructions for the storage and handling of the dosage form(s) should also be given.

Any structural similarities to other known compounds should be mentioned.

7.3.5 Nonclinical Studies

Introduction:

The results of all relevant nonclinical pharmacology, toxicology, pharmacokinetic, and investigational product metabolism studies should be provided in summary form. This summary should address the methodology used, the results, and a discussion of the relevance of the findings to the investigated therapeutic and the possible unfavourable and unintended effects in humans.

The information provided may include the following, as appropriate, if known/available:

- Species tested
- Number and sex of animals in each group
- Unit dose (e.g., milligram/kilogram (mg/kg))
- Dose interval
- Route of administration
- Duration of dosing
- Information on systemic distribution
- Duration of post-exposure follow-up
- Results, including the following aspects:
  - Nature and frequency of pharmacological or toxic effects
  - Severity or intensity of pharmacological or toxic effects
  - Time to onset of effects
  - Reversibility of effects
  - Duration of effects
  - Dose response

Tabular format/listings should be used whenever possible to enhance the clarity of the presentation.

The following sections should discuss the most important findings from the studies, including the dose response of observed effects, the relevance to humans, and any aspects to be studied in humans. If applicable, the effective and nontoxic dose findings in the same animal species should be compared (i.e., the therapeutic index should be discussed). The relevance of this information to the proposed human dosing should be addressed. Whenever possible, comparisons should be made in terms of blood/tissue levels rather than on a mg/kg basis.

(a) Nonclinical Pharmacology

A summary of the pharmacological aspects of the investigational product and, where appropriate, its significant metabolites studied in animals, should be included. Such a summary should incorporate studies that assess potential therapeutic activity (e.g. efficacy models, receptor binding, and specificity) as well as those that assess safety (e.g., special studies to assess pharmacological actions other than the intended therapeutic effect(s)).

(b) Pharmacokinetics and Product Metabolism in Animals

A summary of the pharmacokinetics and biological transformation and disposition of the investigational product in all species studied should be given. The discussion of the findings should address the absorption and the local and systemic bioavailability of the investigational product and its metabolites, and their relationship to the pharmacological and toxicological findings in animal species.

(c) Toxicology

A summary of the toxicological effects found in relevant studies conducted in different animal species should be described under the following headings where appropriate:

- Single dose
- Repeated dose
- Carcinogenicity
- Special studies (e.g. irritancy and sensitisation)
- Reproductive toxicity
- Genotoxicity (mutagenicity)

7.3.6 Effects in Humans

Introduction:

A thorough discussion of the known effects of the investigational product(s) in humans should be provided, including information on pharmacokinetics, metabolism, pharmacodynamics, dose response, safety, efficacy, and other pharmacological activities. Where possible, a summary of each completed clinical trial should be provided. Information should also be provided regarding results of any use of the investigational product(s) other than from in clinical trials, such as from experience during marketing.

(a) Pharmacokinetics and Product Metabolism in Humans

- A summary of information on the pharmacokinetics of the investigational product(s) should be presented, including the following, if available:
- Pharmacokinetics (including metabolism, as appropriate, and absorption, plasma protein binding, distribution, and elimination).
- Bioavailability of the investigational product (absolute, where possible, and/or relative) using a reference dosage form.
- Population subgroups (e.g., gender, age, and impaired organ function).
- Interactions (e.g., product-product interactions and effects of food).
- Other pharmacokinetic data (e.g., results of population studies performed within clinical trial(s).

(b) Safety and Efficacy

A summary of information should be provided about the investigational product's/products' (including metabolites, where appropriate) safety, pharmacodynamics, efficacy, and dose response that were obtained from preceding trials in humans (healthy volunteers and/or patients). The implications of this information should be discussed. In cases where a number of clinical trials have been completed, the use of summaries of safety and efficacy across multiple trials by indications in subgroups may provide a clear presentation of the data. Tabular summaries of adverse drug reactions for all the clinical trials (including those for all the studied indications) would be useful. Important differences in adverse drug

reaction patterns/incidences across indications or subgroups should be discussed.

The IB should provide a description of the possible risks and adverse drug reactions to be anticipated on the basis of prior experiences with the product under investigation and with related products. A description should also be provided of the precautions or special monitoring to be done as part of the investigational use of the product(s).

(c) Marketing Experience

The IB should identify countries where the investigational product has been marketed or approved. Any significant information arising from the marketed use should be summarised (e.g., formulations, dosages, routes of administration, and adverse product reactions). The IB should also identify all the countries where the investigational product did not receive approval/registration for marketing or was withdrawn from marketing/registration.

7.3.7 Summary of Data and Guidance for the Investigator

This section should provide an overall discussion of the nonclinical and clinical data, and should summarise the information from various sources on different aspects of the investigational product(s), wherever possible. In this way, the investigator can be provided with the most informative interpretation of the available data and with an assessment of the implications of the information for future clinical trials.

Where appropriate, the published reports on related products should be discussed. This could help the investigator to anticipate adverse drug reactions or other problems in clinical trials.

The overall aim of this section is to provide the investigator with a clear understanding of the possible risks and adverse reactions, and of the specific tests, observations, and precautions that may be needed for a clinical trial. This understanding should be based on the available physical, chemical, pharmaceutical, pharmacological, toxicological, and clinical information on the investigational product(s). Guidance should also be provided to the clinical investigator on the recognition and treatment of possible overdose and adverse drug reactions that is based on previous human experience and on the pharmacology of the investigational product.

7.4 APPENDIX 1:

TITLE PAGE *(Example)*

SPONSOR'S NAME

Product:

Research Number:

Name(s): Chemical, Generic (if approved)

Trade Name(s) (if legally permissible and desired by the sponsor)

INVESTIGATOR'S BROCHURE

Edition Number:

Release Date:

Replaces Previous Edition Number:

Date:

7.5 APPENDIX 2:

TABLE OF CONTENTS OF INVESTIGATOR'S BROCHURE *(Example)*

NB: References on 1. Publications
2. Reports

These references should be found at the end of each chapter

Appendices (if any)

8. ESSENTIAL DOCUMENTS FOR THE CONDUCT OF A CLINICAL TRIAL

8.1 Introduction

Essential Documents are those documents which individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor and monitor with the standards of Good Clinical Practice and with all applicable regulatory requirements.

Essential Documents also serve a number of other important purposes. Filing essential documents at the investigator/institution and sponsor sites in a timely manner can greatly assist in the successful management of a trial by the investigator, sponsor and monitor. These documents are also the ones which are usually audited by the sponsor's independent audit function and inspected by the regulatory authority(ies) as part of the process to confirm the validity of the trial conduct and the integrity of data collected.

The minimum list of essential documents which has been developed follows. The various documents are grouped in three sections according to the stage of the trial during which they will normally be generated: 1) before the clinical phase of the trial commences, 2) during the clinical conduct of the trial, and 3) after completion or termination of the trial. A description is given of the purpose of each document, and whether it should be filed in either the investigator/institution or sponsor files, or both. It is acceptable to combine some of the documents, provided the individual elements are readily identifiable.

Trial master files should be established at the beginning of the trial, both at the investigator/institution’s site and at the sponsor's office. A final close-out of a trial can only be done when the monitor has reviewed both investigator/institution and sponsor files and confirmed that all necessary documents are in the appropriate files.

Any or all of the documents addressed in this guideline may be subject to, and should be available for, audit by the sponsor’s auditor and inspection by the regulatory authority(ies).

8.2 Before the Clinical Phase of the Trial Commences

During this planning stage the following documents should be generated and should be on file before the trial formally starts

	Title of Document	Purpose	Located in Files of	
			Investigator/ Institution	**Sponsor**
8.2.1	**INVESTIGATOR'S BROCHURE**	To document that relevant and current scientific information about the investigational product has been provided to the investigator	X	X
8.2.2	**SIGNED PROTOCOL AND AMENDMENTS, IF ANY, AND SAMPLE CASE REPORT FORM (CRF)**	To document investigator and sponsor agreement to the protocol/amendment(s) and CRF	X	X
8.2.3	**INFORMATION GIVEN TO TRIAL SUBJECT**		X	X
	- INFORMED CONSENT FORM (including all applicable translations)	To document the informed consent		
	- ANY OTHER WRITTEN INFORMATION	To document that subjects will be given appropriate written information (content and wording) to support their ability to give fully informed consent	X	X
	- ADVERTISEMENT FOR SUBJECT RECRUITMENT (if used)	To document that recruitment measures are appropriate and not coercive	X	
8.2.4	**FINANCIAL ASPECTS OF THE TRIAL**	To document the financial agreement between the investigator/institution and the sponsor for the trial	X	X

	Title of Document	Purpose	Located in Files of	
			Investigator/ Institution	**Sponsor**
8.2.5	**INSURANCE STATEMENT** (where required)	To document that compensation to subject(s) for trial-related injury will be available	X	X
8.2.6	**SIGNED AGREEMENT BETWEEN INVOLVED PARTIES,** e.g.:	To document agreements		
	- investigator/institution and sponsor		X	X
	- investigator/institution and CRO		X	X (where required)
	- sponsor and CRO			X
	- investigator/institution and authority(ies) (where required)		X	X
8.2.7	**DATED, DOCUMENTED APPROVAL/FAVOURABLE OPINION OF INSTITUTIONAL REVIEW BOARD (IRB) /INDEPENDENT ETHICS COMMITTEE (IEC) OF THE FOLLOWING:** - protocol and any amendments - CRF (if applicable) - informed consent form(s) - any other written information to be provided to the subject(s) - advertisement for subject recruitment (if used) - subject compensation (if any) - any other documents given approval/ favourable opinion	To document that the trial has been subject to IRB/IEC review and given approval/favourable opinion. To identify the version number and date of the document(s)	X	X

	Title of Document	Purpose	Located in Files of	
			Investigator/ Institution	**Sponsor**
8.2.8	**INSTITUTIONAL REVIEW BOARD/INDEPENDENT ETHICS COMMITTEE COMPOSITION**	To document that the IRB/IEC is constituted in agreement with GCP	X	X (where required)
8.2.9	**REGULATORY AUTHORITY(IES) AUTHORISATION/APPROVAL/ NOTIFICATION OF PROTOCOL** (where required)	To document appropriate authorisation/approval/notification by the regulatory authority(ies) has been obtained prior to initiation of the trial in compliance with the applicable regulatory requirement(s)	X (where required)	X (where required)
8.2.10	**CURRICULUM VITAE AND/OR OTHER RELEVANT DOCUMENTS EVIDENCING QUALIFICATIONS OF INVESTIGATOR(S) AND SUB-INVESTIGATOR(S)**	To document qualifications and eligibility to conduct trial and/or provide medical supervision of subjects	X	X
8.2.11	**NORMAL VALUE(S)/RANGE(S) FOR MEDICAL/ LABORATORY/TECHNICAL PROCEDURE(S) AND/OR TEST(S) INCLUDED IN THE PROTOCOL**	To document normal values and/or ranges of the tests	X	X
8.2.12	**MEDICAL/LABORATORY/TECHNICAL PROCEDURES /TESTS** - certification or - accreditation or - established quality control and/or external quality assessment or - other validation (where required)	To document competence of facility to perform required test(s) , and support reliability of results	X (where required)	X

	Title of Document	Purpose	Located in Files of	
			Investigator/ Institution	**Sponsor**
8.2.13	**SAMPLE OF LABEL(S) ATTACHED TO INVESTIGATIONAL PRODUCT CONTAINER(S)**	To document compliance with applicable labelling regulations and appropriateness of instructions provided to the subjects		X
8.2.14	**INSTRUCTIONS FOR HANDLING OF INVESTIGATIONAL PRODUCT(S) AND TRIAL-RELATED MATERIALS** (if not included in protocol or Investigator's Brochure)	To document instructions needed to ensure proper storage, packaging, dispensing and disposition of investigational products and trial-related materials	X	X
8.2.15	**SHIPPING RECORDS FOR INVESTIGATIONAL PRODUCT(S) AND TRIAL-RELATED MATERIALS**	To document shipment dates, batch numbers and method of shipment of investigational product(s) and trial-related materials. Allows tracking of product batch, review of shipping conditions, and accountability	X	X
8.2.16	**CERTIFICATE(S) OF ANALYSIS OF INVESTIGATIONAL PRODUCT(S) SHIPPED**	To document identity, purity, and strength of investigational product(s) to be used in the trial		X
8.2.17	**DECODING PROCEDURES FOR BLINDED TRIALS**	To document how, in case of an emergency, identity of blinded investigational product can be revealed without breaking the blind for the remaining subjects' treatment	X	X (third party if applicable)

	Title of Document	Purpose	Located in Files of	
			Investigator/ Institution	**Sponsor**
8.2.18	**MASTER RANDOMISATION LIST**	To document method for randomisation of trial population		X (third party if applicable)
8.2.19	**PRE-TRIAL MONITORING REPORT**	To document that the site is suitable for the trial (may be combined with 8.2.20)		X
8.2.20	**TRIAL INITIATION MONITORING REPORT**	To document that trial procedures were reviewed with the investigator and the investigator's trial staff (may be combined with 8.2.19)	X	X

8.3 During the Clinical Conduct of the Trial

In addition to having on file the above documents, the following should be added to the files during the trial as evidence that all new relevant information is documented as it becomes available

8.3.1	**INVESTIGATOR'S BROCHURE UPDATES**	To document that investigator is informed in a timely manner of relevant information as it becomes available	X	X

	Title of Document	Purpose	Located in Files of	
			Investigator/ Institution	**Sponsor**
8.3.2	**ANY REVISION TO:** - protocol/amendment(s) and CRF - informed consent form - any other written information provided to subjects - advertisement for subject recruitment (if used)	To document revisions of these trial related documents that take effect during trial	X	X

8.3.3	**DATED, DOCUMENTED APPROVAL/FAVOURABLE OPINION OF INSTITUTIONAL REVIEW BOARD (IRB) /INDEPENDENT ETHICS COMMITTEE (IEC) OF THE FOLLOWING:**
	- protocol amendment(s)
	- revision(s) of:
	  - informed consent form
	  - any other written information to be provided to the subject
	  - advertisement for subject recruitment (if used)
	- any other documents given approval/favourable opinion
	- continuing review of trial (where required)
		To document that the amendment(s) and/or revision(s) have been subject to IRB/IEC review and were given approval/favourable opinion. To identify the version number and date of the document(s).	X	X

	Title of Document	Purpose	Located in Files of	
			Investigator/ Institution	**Sponsor**
8.3.4	**REGULATORY AUTHORITY(IES) AUTHORISATIONS/APPROVALS/NOTIFICATIONS WHERE REQUIRED FOR:** - protocol amendment(s) and other documents	To document compliance with applicable regulatory requirements	X (where required)	X
8.3.5	**CURRICULUM VITAE FOR NEW INVESTIGATOR(S) AND/OR SUB-INVESTIGATOR(S)**	(see 8.2.10)	X	X
8.3.6	**UPDATES TO NORMAL VALUE(S)/RANGE(S) FOR MEDICAL/ LABORATORY/ TECHNICAL PROCEDURE(S)/TEST(S) INCLUDED IN THE PROTOCOL**	To document normal values and ranges that are revised during the trial (see 8.2.11)	X	X
8.3.7	**UPDATES OF MEDICAL/LABORATORY/ TECHNICAL PROCEDURES/TESTS** - certification or - accreditation or - established quality control and/or external quality assessment or - other validation (where required)	To document that tests remain adequate throughout the trial period (see 8.2.12)	X (where required)	X
8.3.8	**DOCUMENTATION OF INVESTIGATIONAL PRODUCT(S) AND TRIAL-RELATED MATERIALS SHIPMENT**	(see 8.2.15.)	X	X

	Title of Document	Purpose	Located in Files of	
			Investigator/ Institution	**Sponsor**
8.3.9	**CERTIFICATE(S) OF ANALYSIS FOR NEW BATCHES OF INVESTIGATIONAL PRODUCTS**	(see 8.2.16)		X
8.3.10	**MONITORING VISIT REPORTS**	To document site visits by, and findings of, the monitor		X
8.3.11	**RELEVANT COMMUNICATIONS OTHER THAN SITE VISITS** - letters - meeting notes - notes of telephone calls	To document any agreements or significant discussions regarding trial administration, protocol violations, trial conduct, adverse event (AE) reporting	X	X
8.3.12	**SIGNED INFORMED CONSENT FORMS**	To document that consent is obtained in accordance with GCP and protocol and dated prior to participation of each subject in trial. Also to document direct access permission (see 8.2.3)	X	
8.3.13	**SOURCE DOCUMENTS**	To document the existence of the subject and substantiate integrity of trial data collected. To include original documents related to the trial, to medical treatment, and history of subject	X	

	Title of Document	Purpose	Located in Files of	
			Investigator/ Institution	**Sponsor**
8.3.14	**SIGNED, DATED AND COMPLETED CASE REPORT FORMS (CRF)**	To document that the investigator or authorised member of the investigator's staff confirms the observations recorded	X (copy)	X (original)
8.3.15	**DOCUMENTATION OF CRF CORRECTIONS**	To document all changes/additions or corrections made to CRF after initial data were recorded	X (copy)	X (original)
8.3.16	**NOTIFICATION BY ORIGINATING INVESTIGATOR TO SPONSOR OF SERIOUS ADVERSE EVENTS AND RELATED REPORTS**	Notification by originating investigator to sponsor of serious adverse events and related reports in accordance with 4.11	X	X
8.3.17	**NOTIFICATION BY SPONSOR AND/OR INVESTIGATOR, WHERE APPLICABLE, TO REGULATORY AUTHORITY(IES) AND IRB(S)/IEC(S) OF UNEXPECTED SERIOUS ADVERSE DRUG REACTIONS AND OF OTHER SAFETY INFORMATION**	Notification by sponsor and/or investigator, where applicable, to regulatory authorities and IRB(s)/IEC(s) of unexpected serious adverse drug reactions in accordance with 5.17 and 4.11.1 and of other safety information in accordance with 5.16.2 and 4.11.2	X (where required)	X
8.3.18	**NOTIFICATION BY SPONSOR TO INVESTIGATORS OF SAFETY INFORMATION**	Notification by sponsor to investigators of safety information in accordance with 5.16.2	X	X
8.3.19	**INTERIM OR ANNUAL REPORTS TO IRB/IEC AND AUTHORITY(IES)**	Interim or annual reports provided to IRB/IEC in accordance with 4.10 and to authority(ies) in accordance with 5.17.3	X	X (where required)

	Title of Document	Purpose	Located in Files of	
			Investigator/ Institution	Sponsor
8.3.20	**SUBJECT SCREENING LOG**	To document identification of subjects who entered pre-trial screening	X	X (where required)
8.3.21	**SUBJECT IDENTIFICATION CODE LIST**	To document that investigator/institution keeps a confidential list of names of all subjects allocated to trial numbers on enrolling in the trial. Allows investigator/institution to reveal identity of any subject	X	
8.3.22	**SUBJECT ENROLMENT LOG**	To document chronological enrolment of subjects by trial number	X	
8.3.23	**INVESTIGATIONAL PRODUCTS ACCOUNTABILITY AT THE SITE**	To document that investigational product(s) have been used according to the protocol	X	X
8.3.24	**SIGNATURE SHEET**	To document signatures and initials of all persons authorised to make entries and/or corrections on CRFs	X	X
8.3.25	**RECORD OF RETAINED BODY FLUIDS/ TISSUE SAMPLES (IF ANY)**	To document location and identification of retained samples if assays need to be repeated	X	X

8.4 After Completion or Termination of the Trial

After completion or termination of the trial, all of the documents identified in sections 8.2 and 8.3 should be in the file together with the following

	Title of Document	Purpose	Located in Files of	
			Investigator/ Institution	**Sponsor**
8.4.1	**INVESTIGATIONAL PRODUCT(S) ACCOUNTABILITY AT SITE**	To document that the investigational product(s) have been used according to the protocol. To documents the final accounting of investigational product(s) received at the site, dispensed to subjects, returned by the subjects, and returned to sponsor	X	X
8.4.2	**DOCUMENTATION OF INVESTIGATIONAL PRODUCT DESTRUCTION**	To document destruction of unused investigational products by sponsor or at site	X (if destroyed at site)	X
8.4.3	**COMPLETED SUBJECT IDENTIFICATION CODE LIST**	To permit identification of all subjects enrolled in the trial in case follow-up is required. List should be kept in a confidential manner and for agreed upon time	X	
8.4.4	**AUDIT CERTIFICATE** (if available)	To document that audit was performed		X
8.4.5	**FINAL TRIAL CLOSE-OUT MONITORING REPORT**	To document that all activities required for trial close-out are completed, and copies of essential documents are held in the appropriate files		X
8.4.6	**TREATMENT ALLOCATION AND DECODING DOCUMENTATION**	Returned to sponsor to document any decoding that may have occurred		X

	Title of Document	Purpose	Located in Files of	
			Investigator/ Institution	**Sponsor**
8.4.7	**FINAL REPORT BY INVESTIGATOR TO IRB/IEC WHERE REQUIRED, AND WHERE APPLICABLE, TO THE REGULATORY AUTHORITY(IES)**	To document completion of the trial	X	
8.4.8	**CLINICAL STUDY REPORT**	To document results and interpretation of trial	X (if applicable)	X

NAAC Accredited Grade A+

POLICY FOR PROMOTION OF ACADEMIC INTEGRITY & PREVENTION OF PLAGIARISM

POLICY FOR PROMOTION OF ACADEMIC INTEGRITY & PREVENTION OF PLAGIARISM

In terms of the notification no D.O. No F-1-18/2010 (CCP-II) dated 6th August 2018 pertaining to Promotion of Academic Integrity & Prevention of Plagiarism the DMIMS DU, after adopting the same, has issued this notification for the **PROMOTION OF ACADEMIC INTEGRITY & PREVENTION OF PLAGIARISM** for DMIMS (DU) and all its constituent units.

The notification has 2 operational parts, the Part I deals with undertaking the steps to subject all research documents for plagiarism check through the ***Turn it in*** software prior to its submission/ publication so that the researcher is given forewarning and an opportunity to rectify the same.

The Part II deals with evoking disciplinary jurisdiction and process for lodging complaint pertaining to plagiarism by the academic person.

Part -I

1. **All the** thesis, dissertation, or any other such documents such as research papers published in theofficial journals published by the university or sent for publication shall be thoroughly scrutinized using appropriate technology prior to the submission so that it is properly filtered and the researcher/ author is provided an opportunity to make desired modification before final submission to the university or he journal. All the concerned stake holders shall be sensitized and awareness shll be created amongst the researchers/ authors towards the plagiarism policy and its mandate.

2. **Awareness Programs and Trainings:**

2.a) DMIMS(DU) shall instruct students, faculty, researcher and staff about proper attribution, seeking permission of the author wherever necessary, acknowledgement of source compatible with the needs and specificities of disciplines and in accordance with rules, international conventions and regulations governing the source.

2.b) DMIMS(DU) shall conduct sensitization seminars/ awareness programs every semester on responsible conduct of research, thesis, dissertation, promotion of academic integrity and ethics in education for students, faculty, researcher and staff at an appropriate occasion (such as during PG orientation, Doctoral scholars workshop on research methodology, faculty development program etc) which will be included as a scheduled activity in the annual comprehensive calendar.

(2.c) the wider dissemination of the information pertaining to plagiarism policy shall be ensured by circulation, display on the kiosks, display at the library and on the website.

The modalities are presented in concise manner in Table 2.1.

Undergraduate (UG) Postgraduate (PG)Master's degree etc.	Masters and Research Scholars.	Faculty and staff members of the University.
Include the cardinal principles of academic integrity in the curricula as compulsory course work/module.	Include elements of responsible conduct of research and publication ethics as a compulsory course work/module	Include elements of responsible conduct of research and publication ethics and organise Orientation and Refresher Courses
Wider dessimination of information pertaining to plagiarism by circulation, display on kiosks and website	Widerdessimination of information pertaining to plagiarism by circulation, display on kiosks and website	nformation pertaining to plagiarism by circulation, display on kiosks and website
Train student, faculty, researcher and staff for using plagiarism detection tools and reference management tools by conducting training sessions/ workshops at an appropriate occasion (orientation programs at the beginning of course or during faculty development program)		
Establish facility equipped with modern technologies for detection of plagiarism.		
Encourage student, faculty, researcher and staff to register on international researcher's Registry systems.		

Table (2.1) – depicting various sensitization and facilitation modalities

3. Guidelines for CurbingPlagiarism

3.a) DMIMS(DU) shall **declare** and **implement** the technology based mechanism using appropriate software so as to ensure that documents such as thesis, dissertation, publications or any other such documents are free of plagiarism at the time of their submission. The software procured for this purpose shall be Turn it in.

3.b) The mechanism as defined at (a) above shall be **made accessible** to all engaged in research work including student, faculty, researcher and staff etc.

3.c) Every student submitting a thesis, dissertation, or any other such documents to the DMIMS(DU) shall **submit an undertaking** indicating that the document has been prepared by him or her and that the document is his/her original work and free of any plagiarism.

3.d) The undertaking shall include the fact that the document has been **duly checked** through a Plagiarism detection tool approved by the DMIMS(DU).

3.e) DMIMS(DU) has **developed this policy on plagiarism and get it approved** by its relevant statutory bodies/authorities. The approved policy shall be **placed on the homepage** of the HEI website.

3.f) **Each supervisor** shall s**ubmit a certificate** indicating that the work done by the researcher under him / her is plagiarism free.

3.g) DMIMS(DU) shall submit to **INFLIBNET soft copies** of all Masters, Research program's dissertations and thesis **within a month** after the award of degrees for hosting in the digital repository under the "*Shodh Ganga e-repository"*.

3.h) DMIMS(DU) shall create **Institutional Repository on institute website** which shall include dissertation / thesis / paper / publication and other in-house publications.

4. Similarity checks for exclusion from Plagiarism

The similarity checks for plagiarism shall exclude the following:

4.i. Allquoted work reproduced with allnecessarypermission and/or attribution.

4.ii. All references, bibliography, table of content, preface and acknowledgements.

4.iii. All generic terms, laws, standard symbols and standards equations.

4. iv. The research work carried out by the student, faculty, researcher and staff shall be based on original ideas, which shall include abstract, summary, hypothesis, observations, results, conclusions and recommendations only and shall not have any similarities. It shall exclude a common knowledge or coincidental terms, up to fourteen (14) consecutive words.

5. Procedure for submitting the thesis/ research papers for plagiarism check prior to submission.

All the scientific data, literature, thesis, project work shall be subjected to calculation of similarity index (Plagiarism check) prior to submission as per the following SOP

5.a.) All the Ph D , Post Graduate thesis, M Phil , Fellowship projects, scientific publications shall be subjected to calculation of the similarity index, prior to submission.

5.b.) The permissible similarity index shall be not more than 20%

5.c). Review of literature in case of PhD thesis shall be in the form of systematic review.

5.d.) The review of literature in case of other thesis and project work is a compilation of literature wherein proper citations are made, under these circumstances the review of literature shall be exempted form the similarity index calculation.

5.e.) The Introduction. Material & methods, discussion, summary and conclusion shall be essentially subjected to calculation of similarity index,

5.f.) To calculate the similarity index the following chronology shall be followed for different submissions

S no	**Nature of submission**	**Duration of course**	**Submission for similarity index check**	**Resubmission after making corrections**	**Final Submission to the university for evaluation**
1	PhD thesis	Min 3 years	2 months prior to mock open defence viva	1 month prior to mock open defence viva	1 month prior to open defence viva
2	MD/ MS/ MDS/ McH thesis	3 years	2 months prior to final submission	1 month prior to final submission	6 months prior to exam
3	MSc nursing thesis/ Fellowship project	2 years	1 months prior to final submission	15 days prior to final submission	3 months prior to exam
4	Fellowship project	1 year	1 month prior to final submission	15 days prior to final submission	1 month prior to exam
5	Research papers	-	1 month prior to submission for publication	15 days prior to submission for publication	--

5.g) The submission for similarity index shall be done in soft copy only, with the certificate from the concerned supervisor.

5.h) The similarity index shall be calculated twice, first upon submission and second upon incorporating corrections.

5.i)Those submissions which have similarity index beyond the permissible limits, shall not be accepted. Similarly each researcher sending his / her work for publication must posses certificate of permissible similarity index.

5.j) Each institute is provided with scrutiny for generating the similarity index through a soft ware. The software shall be installed centrally in the research cell and these scrutinizers shall dispense their job in the research cell for better administrative control and monitoring.
5.k) There shall be one verifying officer who shall verify the process of calculating the similarity index, before and after corrections.
5.l) There shall be one certifying officer who shall be certifying the similarity index is in permissible limits.
5.m) The similarity index certificate shall be embodied in each submission along with IEC clearance certificate.

Part –II

6. Detection reporting and handling plagiarism

In the event of any member of academic community suspects with appropriate proof, that a case of plagiarism has happened in any document, the same can be reported to the Departmental academic Integrity Panel (DAIP). The DAIP, upon receipt of the complaint or allegation shall undertake investigation in the matter and submit its report to the Institutional Academic Integrity Panel (IAIP) of the DMIMS(DU).

The DMIMS(DU) can also take the *suomotu* notice of any act of plagiarism brought to its notice and can start proceedings under these regulations. The DMIMS(DU) shall also initiate the proceedings on the basis of findings of an examiner.All such cases shall be investigated by the IAIP constituted by the university.

7 . **Departmental Academic Integrity Panel (DAIP)**

The DMIMS(DU) shall constitute DAIP at the level of its each constituent unit. The composition of the DAIP shall be as Under:

i. Chairman – Head of the constituent Unit
ii. Member-Senior Academician from out side the institution nominated by the DMIMS(DU)
iii. Member-Person well versed with the anti plagiarism tool, nominated by the Head of the Constituent unit
The tenure of the member mentioned at s no 2 & 3 shall be of 2 years and the quorum shall be 2 out of the 3 members(including the Chairman).

7.a) Tasks assignable to the DAIP

i. The DAIP shall follow the principle of natural justice while dealing with the complaints / allegations of plagiarism against the student, Faculty, researcher or staff.

ii. The DAIP shall have powers to assss the level of plagiarism committed and recommend penalty (ies) accordingly..

iii. The DAIP after investigation shall submit its report with recommendations on penalties to be imposed to the IAIP within 45 days from the date of receipt of complaint/ initiation of proceedings.

8. Institutional Academic Integrity Panel

The DMIMS(DU) shall notify the IAIP with following composition

i. Chairman- Pro – Vice Chancellor/ Senior Academician of the University
ii. Member- Senior academician other than Chairman nominated by the University
iii. Member- one member nominated by the Vice Chancellor from outside the university
iv. Member- Person well versed with the ani-plagiarism tolls, nominated by the University.

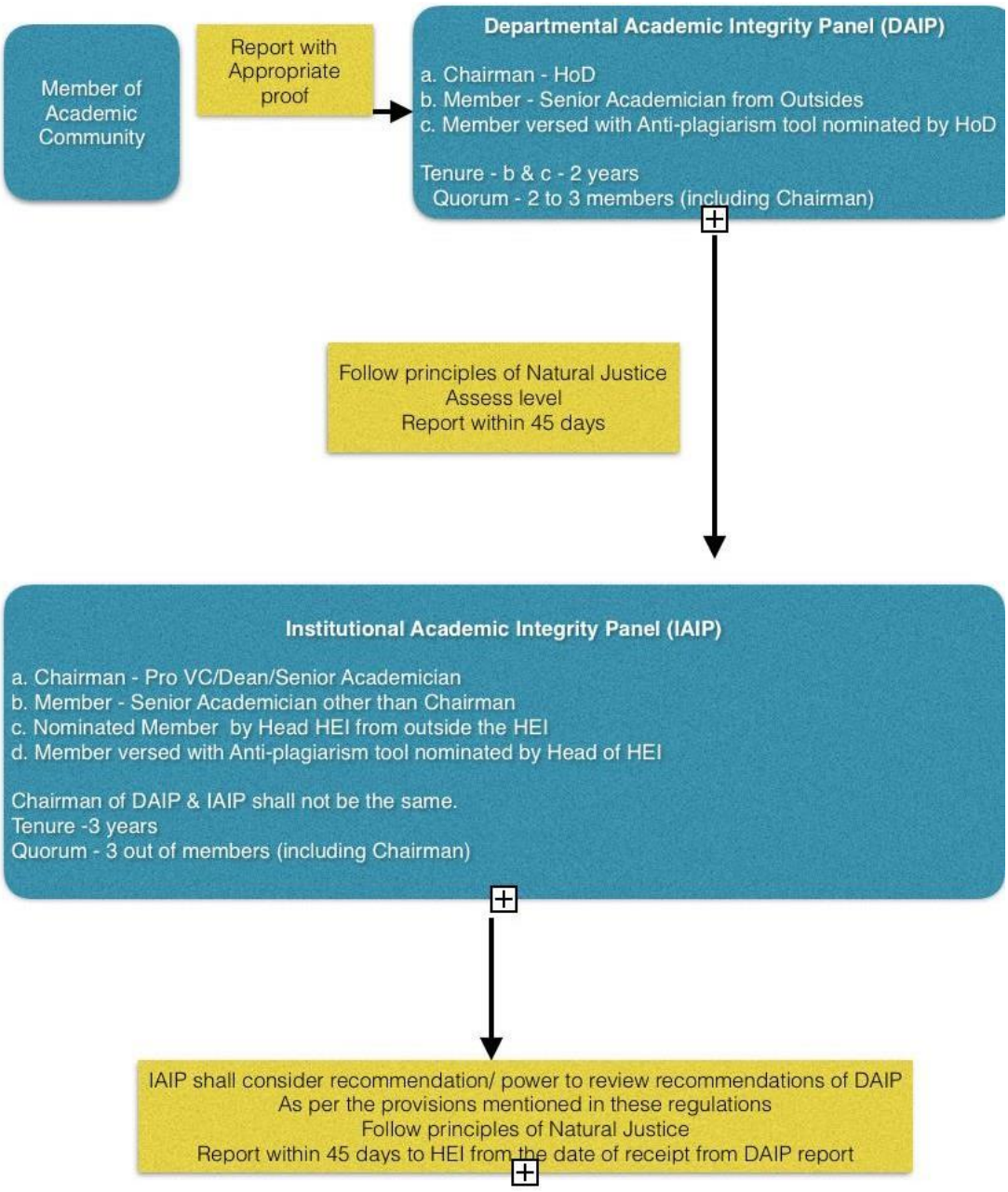
Note:

a. The Chairman of AIP & IAIP shall not be the same
b. The tenure of the committee members including the chairman shall be of three years.
c. The quorum for the meetings shall be 3 out of 4 members (Including the Chairman)

8.a) Tasks assigned to the IAIP

i. The IAIP shall consider the recommendations of the DAIP
ii. The IAIP shall also investigate the cases of Plagiarism as per the provisions in this notification.
iii. The IAIP shall follow the principles of natural justice while dealing with the complaints / allegations of plagiarism against the student, Faculty, researcher or staff.
iv. The IAIP shall have power to review the recommendations of the DAIP, including penalties with due justification.
v. The IAIP shall send its report including the recommendations on penalties to be imposed to the Head of the concerned head of the Constituent unit of the University within 45 days from the receipt of recommendation of the DAIP / complaint/ initiation of the proceedings.

   The process for reporting the suspected /alleged cases of plagiarism is summerized in the flow chart given below.



Flow chart depicting process of reporting the suspected/ alleged cases of plagiarism

9. Penalties for acts of Plagiarism

Depending on the level of the severity of acts of plagiarism committed by as student, faculty, researcher or the staff of the DMIMS(DU) or its constituents units, the IAIP shall recommend the penalty (ies) as under to the Head of the constituent unit for evoking disciplinary action. (Table 9.1)

	Level of Severity	**Thesis & Dissertation (Students)**	**Academic and Research Publication (Students, researcher, staff, faculty)**
Level 0	Similarity up to 10%	Minor Similarities, no penalty	Minor similarities, no penalty.
Level 1	Similarity 10% to 40%	Submit a revised script within stipulated time not exceeding 6 months	Shall be asked to withdraw manuscript.
Level 2	Similarity 40% to 60%	Debarred from submitting a revised script for a period of one year	1. Shall be asked to withdraw manuscript. 2. Shall be denied a right to one annual increment. 3. Shall not be allowed to be a supervisor to any new Master's, M.Phil., Ph.D. Student/scholar for a period of two years.
Level 3	Similarity above 60%	Registration for programme shall be cancelled	1. Shall be asked to withdraw manuscript. Shall be denied a right to two successive annual increments. 3. Shall not be allowed to be a supervisor to any new Master's, M.Phil., Ph.D. Student/scholar for a period of three years.
Penalty on repeated plagiarism Note 1		Such student shall be punished for the plagiarism of *one level higher* than the previous level committed by him/her. In case where plagiarism of highest level is committed then the punishment for the same shall be operative.	Shall be asked to *withdraw manuscript* and shall be punished for the plagiarism of *one level higher* than the lower level committed by him/her. In case where plagiarism of highest level is committed then the punishment for the same shall be operative. In case level 3 offence is repeated then the disciplinary action including suspension/termination as per service rules shall be taken by the University.

	Level of Severity	Thesis & Dissertation (Students)	Academic and Research Publication (Students, researcher, staff, faculty)
Penalty in case where the degree/credit has already been obtained **Note 2**		If plagiarism is proved on a date later than the date of award of degree or credit as the case may be then his/her degree or credit shall be put in abeyance for a period recommended by the IAIP and approved by the Head of the Institution.	If plagiarism is proved on a date later than the date of award of degree or credit as the case may be then his/her degree or credit shall be put in abeyance for a period recommended by the IAIP and approved by the Head of the constituent unit.
Note 3			HEIs shall create a *mechanism* so as to ensure that each of the paper publication/thesis/dissertation by the student, faculty, researcher or staff of the University is checked for plagiarism at the *time of forwarding/submission.*
Note 4			If there is any complaint of plagiarism against the Head of constituent unit , a suitable action, in line with these regulations, shall be taken by the Controlling Authority of the University.
Note 5			If there is any complaint of plagiarism against the Head of Department/Authorities at the institutional level, a suitable action, in line with these regulations, shall be recommended by the IAIP and approved by the Competent Authority.
Note 6			If there is any complaint of plagiarism against any member of DAIP or IAIP, then such member shall excuse himself / herself from the meeting(s) where his/her case is being discussed/investigated.

Table 9.1 – depicting the level of plagiarism and corresponding penalties

DATTA MEGHE INSTITUTE OF MEDICAL SCIENCES
[Deemed to be Univeristy]

Conferred 'A' Grade status by H.R.D. Ministry Govt. of India.
Re-accredited by NAAC (3rd Cycle) with 'A+' Grade
Placed under Category-I (Graded Autonomy) by UGC

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No. 57of 2019

Date:12th September, 2019

NOTIFICATION

As approved by the Hon'ble Vice Chancellor, DMIMS (DU), the **Policy for Adjunt Faculty** (Annexed) is hereby notified for the information of all the concernced.

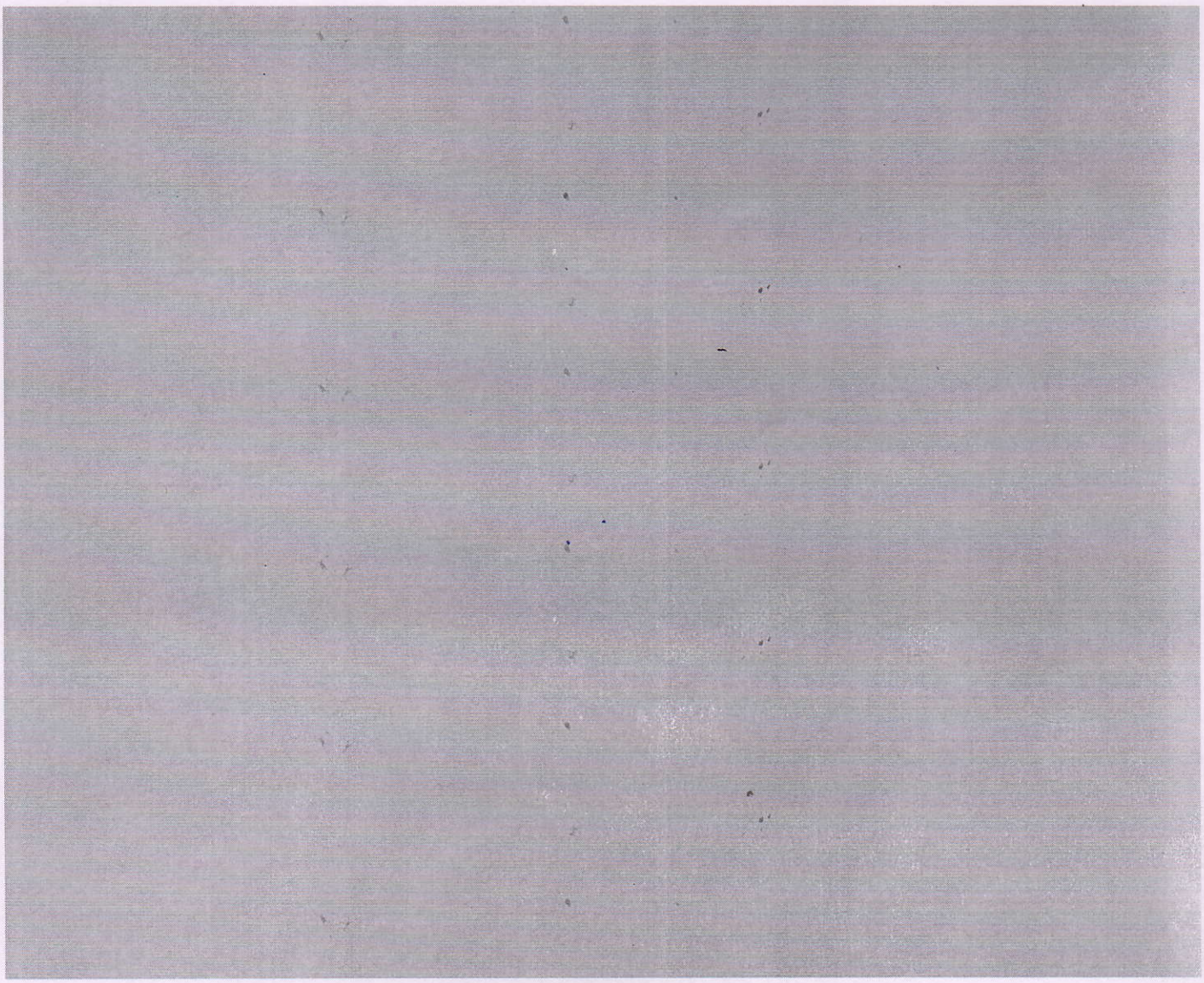
Registrar
DMIMS
(Deemed to be University)

Encl: Policy for Adjuct Faculty

Copy to:

1. Hon'ble Pro Chancellor, DMIMS (DU)
2. Hon'ble Vice Chancellor, DMIMS (DU)
3. Hon'ble Pro Vice Chancellor, DMIMS (DU)
4. The Chief Coordinator, DMIMS (DU)
5. All the Heads of Institutions, DMIMS (DU)
6. The Principal, FNTCN
7. All the Deans, Faculties, DMIMS (DU)
8. The Dean, Interdisciplinary Health Sciences, DMIMS (DU)
9. The Dean, Examinations, DMIMS(DU)
10. The Dean, Allied Health Science, DMIMS (DU)
11. The Dean, Allied Courses
12. The Principal, DMCP
13. The Director, School of Advanced Studies, DMIMS (DU)
14. The Director, SHPER, DMIMS (DU)
15. The Director, Personnel & Planning, DMIMS (DU)
16. The Director, (Intl. Initiatives & Strategic Planning), DMIMS (DU)
17. The Director, IQAC
18. Mrs. Manisha Meghe, Director, Ravi Nair Physiotherapy College, Sawangi (Meghe)
19. Sr. Tessy Sebastian, Director, Nursing
20. The Director, Examinations, Assessment and Evaluation, DMIMS (DU)
21. The OSD, DMIMS(DU)
22. The Finance Officer, DMIMS (DU)
23. The Asst. Registrar (Academics), DMIMS (DU)
24. CAOs/AOs/AAOs of all constituent colleges
25. Website Incharge

POLICY FOR ADJUNCT FACULTY



Preamble:

Datta Meghe Institute of Medical Sciences (Deemed to be University) has been improving the quality and quantum of research. Therefore, it becomes imperative to involve experts, professionals and researchers from various faculties to contribute to the emerging needs of higher education system. Taking an integrated initiative towards skill development and upgradation of the competencies, DMIMS(DU) offers courses from basic till research level degrees aimed at skill development and upgradation to meet the existing and emerging needs at the regional and national level. Acute shortage of quality faculty is widely felt in the system of higher education as a whole. However, it is felt more prominently in skill-based courses. It is well realized that there is lot of creative talent and intellectual resources available within the country that are not formally connected to the higher education system. It is imperative that the expertise and experience of such individuals, who are outside the main stream academic system, flows into our Institute. This would enhance, strengthen and improve the quality of teaching, training and research. It is also necessary to have uniformity and transparency in the process of hiring adjunct faculty in the institution.

Objectives for Adjunct Faculty

- Enhancing quality of skills by involvement of skilled professionals in Research/Academic/training/ specialised services on regular basis
- to foster trans-disciplinary approach and synergize the outside 'real world' experience with the inside intellectual pursuits in the university
- To promote the interaction of skilled professionals with the learners and facilitate the imparting of industry relevant standards
- To enable higher educational institutions to access the eminent teachers and researchers who have completed their formal association with the university/college, to enhance quality of teaching, to collaborate and to stimulate research activities for quality research; and to play mentoring and inspirational role
- To recognize the skills of professionals in their respective areas of excellence irrespective of their academic qualifications to impart training to the learners of skill based vocational courses in Universities and Colleges.
- Skilled professionals working in sectors known for their hands-on skilling techniques and expertise.

There are three areas of expertise of Adjunct faculty a) Research b) Academic/Training c) Specialist Services (Clinical etc).

Area of expertise of Adjunct faculty	Adjunct faculty in Research	Adjunct faculty in Academic/Training	Adjunct faculty in Specialist Services (Clinical etc)
Monitoring of activities of Adjunct faculty by	• HoD • Research Head Constituent College • HoI • Director R&D	• HoD • Vice Dean • Academic Dean • HoI	• HoD • CMS • HoI
Activities of Adjunct faculty	• Mentoring, nurturing and supporting the young talents to innovate pragmatic solutions • Research support with a thrust on research capacity building, trans-disciplinary research • Identify the motivated young talents with research and innovation aptitude • Collaborations between colleges, research institutes, universities • Promote grant writing for high impact research projects in the identified trust areas • Create networking of eminent scientist from leading institutions from National and International Universities and agencies. • Number of Visits - case to case basis with approval from Competent authority	• Teach students in specialized area of subjects. • Integrate subject knowledge and hands-on experience in development of learning processes. • New approaches to revitalizing teaching effectiveness include placing an emphasis on effective pedagogy and paying increased attention to the learning needs of the learners • Number of Visits - case to case basis with approval from Competent authority	• Providing Specialist Services • Training, Handholding capacity building of young clinicians and surgeons • Create networking with the specialist of prominence. • Providing linkages to hospitals of excellence for training opportunities to the young faculty • Number of Visits - case to case basis with approval from Competent authority
Expected Outcome	• Minimum 2 Publication • Networking with 2 research institutes of prominence • Assistance in One grant submission per year	• Integrate effective pedagogy • Outcomes will be measured as per the agreement with respect to indulgence and operation after approval from Competent authority	• Specialised Services (Clinical, etc.) provides will be measured as per the agreement after approval from Competent authority

Target Groups:

- Professionals, experts, officials from ICMR/DST/DBT/ICSSR etc
- Overseas researchers, Academicians
- Experts from Central and state Universities; business corporations, NGOs and professional associations.
- Officials from professional councils and statutory bodies like UGC and AICTE, both serving and retired

Selection Criteria:

- Accomplished scholar in the area of specialization and the association would add value to the research programmes of the University
- The competent authority based on the recommendation of a Committee will appoint adjunct Faculty. Period of empanelment will vary from 12 months to 03 years as decided by the Institution on mutually agreed terms and conditions. It is expected that any application for adjunct faculty be first discussed at the department level. The department may forward the application with comments specifying the suitability of such candidate(s) in the department / institution level academic activities. If the department recommends a case for adjunct faculty, a Committee should examine the same.
- The strength of Adjunct faculty may not exceed 25 % the sanctioned strength of faculty at any time.

Roles and Responsibilities:

- Adjunct faculty is expected to interact with and supervise the research students in the area of his specialization or professional proficiency.
- The adjunct faculty may participate by advising faculty on their research projects, serving as a liaison between the institutions and industry or government entities to identify research and/or funding opportunities or by working with faculty to identify research projects that would benefit private industry and/or government entities.

Costs and Honorarium:

- Adjunct faculty will be provided travel cost, as per entitlement, from his/her institution/place of stay and back, Duration and number of visits will be on Case-to-Case Basis with prior approval from Competent Authority.
- She/he will be provided accommodation by the university.
- She/he will be provided an honorarium of Rs. 4000/- (Rs. Four Thousand Only) per day of service.

Monitoring of performance:

At the end of assignment, every Adjunct Faculty will submit a 'performance report' to the host university / college with a copy to the University Grants Commission. The performance report may be considered for his continuation / renewal of next tenure.

Incentives for Research:

Research: (Eligibility for receiving incentives for publication is that the published manuscript should reflect Affiliation of Datta Meghe Institute of Medical Sciences in database of Scopus/Web of Science/ PubMed)

- Publication in any one of the following database Scopus/Web of Science/ PubMed: **INR 10000/-**
- Publication in any two of the following database Scopus/Web of Science/ PubMed: **INR 15000/-**
- Impact Factor more than 3 (Thomson Reuter / Clarivate analytics): **INR 20000/-**

Budget:

Total cost will be not more than INR. 12 Lakh per Year for the incentives and honorarium for Adjunct Faculty visit. It will be phase-wise

(A Cap ofINR 1.2 lakhs annually for visit honorariumwith re-appropriation of budget among the three heads, a) Adjunct faculty in Research, b) Adjunct faculty in Academic/Training c) Adjunct faculty in Specialist Services (Clinical etc).)

Faculty wise distribution of Budget (re-appropriation of budget among the faculties**):**

- Faculty of Medicine -30%
- Faculty of Dentistry-20%
- Faculty of Ayurveda-15%
- Faculty of Paramedical sciences -10%
- Faculty of Nursing -10%
- Others --15%
