क्षेत्रीय आयुर्विज्ञान संस्थान, इंफाल: मणिपुर

REGIONAL INSTITUTE OF MEDICAL SCIENCES, IMPHAL, MANIPUR

(स्वास्थ्य और परिवार कल्याण मंत्रालय,भारत सरकार के अंतर्गत एक स्वायत्त संस्थान)

(An Autonomous Institute under the Ministry of Health & Family Welfare, Govt. of India)

STANDARD OPERATING PROCEDURES

Version: 1.0

August, 2024

बहु-विषयक अनुसंधान इकाई, रिम्स

Multi-Disciplinary Research Unit

Implemented by: Regional Institute of Medical Sciences, Imphal

Supported by Department of Health Research, Ministry of Health & Family Welfare

Government of India

C E R T I F I C A T E

Imphal the 27th August, 2024

It is hereby certified that this 25 pages' document, which has been proposed by the Executive Committee, Multi-disciplinary Research Unit, Regional Institute of Medical Sciences, Imphal, and duly concurred by the Local Research Advisory Committee, MRU, RIMS, shall be the instrument of "Standard Operating Procedure of MRU, RIMS, Imphal". Further certified that, any issue(s) not explicitly mentioned herein, shall be operationalized as per the majority decision of the EC, MRU, RIMS.

This shall begin to apply, be valid and thus take effect immediately.

(Prof. Lisam Sanju kumar Singh)
Chairman,
Local Research Advisory Committee
Multi-disciplinary Research Unit
Regional Institute of Medical Sciences, Imphal

(Prof. G. Sunil kumar Sharma)
Director
Regional Institute of Medical Sciences, Imphal
and
Chairman, Executive Committee, MRU, RIMS

Executive Committee MRU, RIMS w.e.f. 10/06/2024

Sl.	**Name & Designation**	**Department & Institute**	**EC, MRU**
1	Prof. G. Sunil Kumar Sharma Director	Regional Institute of Medical Sciences, Imphal	Chairperson
2	Dr. Chongtham Rajlakshmi Professor	Department of Anatomy, RIMS, Lamphelpat	Member
3	Dr. Ng. Gunindro Singh Professor	Department of Pharmacology, RIMS, Lamphelpat	Member
4	Dr. Chetan Maibam Associate Professor	Department of Surgery, RIMS, Lamphelpat	Member
5	Prof. T. Jeetenkumar Sigh Professor	Department of Medicine, RIMS, Lamphelpat	(Nodal Officer-MRU)

Local Research Advisory Committee MRU, RIMS w.e.f. 10/06/2024

Sl.	**Name & Designation**	**Department & Institute**	**LRAC, MRU**
1	Prof. Lisam Sanju Kumar Singh Professor & Head	Department of Biotechnology, Manipur University	Chairperson
2	Prof. Bishwalata Rajkumari Professor	Department of Community Medicine, JNIMS, Porompat	Vice-Chairperson
3	Dr. H. K. Das, Deputy Director	RMRC, Dibrugarh RMRC, Dibrugarh (Representative of ICMR)	Member
4	Prof. Helen Kamei Professor	Department of Obs. & Gynae Medicine, JNIMS, Porompat	Member
5	Dr. Y. Premchandra Singh Jt. Director	SNO & NCD Health Services, Govt. of Manipur	Member
6	Prof. Ratan Konjengbam Professor	Department of Pathology Medicine, RIMS, Lamphelpat	Member
7	Dr. Salam Kenny Singh Associate Professor	Department of Medicine, RIMS, Lamphelpat	Member
8	Prof. T. Jeetenkumar Sigh Professor	Department of Medicine, RIMS, Lamphelpat	Member Secretary (Nodal Officer-MRU)

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Regional Institute of Medical Sciences
Standard Operating Procedures (SOP) for Multi-Disciplinary Research Unit for intramural & extramural research

1. Introduction

Multi-Disciplinary Research Units (MRUs) is a project under the Department of Health Research / Indian Council of Medical Research. The government of India, in June 2013, approved the scheme for the establishment of Multi-Disciplinary Research Units (MRUs) in the Government Medical Colleges/Research Institutes. It is a path-breaking initiative to develop/strengthen the health research infrastructure in the country to fulfil the newly allocated function of the Department related to "Promotion, Coordination, and Development of Basic, Applied and Clinical Research".

2. Objectives of the scheme:

- Undertaking of clinical trials by MRUs as per the Allocation of Business Rules of Government of India.
- Undertaking of multi-centric research projects by MRUs, medical colleges, a n d research institutes.
- Capacity building and human resource development in the field of health research.
- Encourage and strengthen an environment of research in medical colleges.
- Bridge the gap in the infrastructure which is inhibiting health research in the Medical Colleges by assisting them to establish multidisciplinary research facilities with a view to improving the health research and health services.
- To ensure the geographical spread of health research infrastructure, in order to cover un-served and under-served Medical Colleges and other institutions.
- To improve the overall health status of the population by creating evidence-based application of diagnostic procedures/processes/methods.

3. Major functions of the MRU

3.1. To undertake research in **non-communicable diseases and other need-based research** as recommended by the Local Research Advisory Committee (MRU, RIMS)/Expert Committee of the DHR.

3.2. To promote and encourage quality medical research in the Institution.

3.3. To constitute the local research committees for identifying the research priorities and projects with the participation of State health system officials.

4. Composition and functional mechanism of Executive Committee (EC) & Local Research Advisory Committee (LRAC)

Executive Committee MRU

1	Chairperson	Director/Principal/Dean (Research) of the Medical College/Institute
2	Three faculty members	one each from preclinical, para-clinical & one from clinical departments (preferably one either from medical or surgical departments)
3	Nodal Officer of MRU	Faculty nominated by head of Medical College/Research Institution

The functions of the executive committee (EC) vide R.11016/05/2024-HR dated 09.05.2024 of Department of Health Research, Government of India shall be as follows:

a. Establish the mechanism for receiving proposals from faculty
b. Encourage wide participation of different departments in proposals submission to MRU
c. Review proposals for presentation to LRAC for finalisation/selection or otherwise.
d. Oversee the distribution of contingency funds for activities of MRU and support LRAC approved projects.

The working mechanism of the Executive Committee shall be as:

a. The EC will meet every quarter. Minutes of quarterly meetings should be communicated to LRAC.
b. Participate in LRAC as observers (except for the Nodal Officer, who is also the member secretary of LRAC).
c. All decisions of EC shall be by majority.
d. The term of EC shall be four (4) years.

The Competent Authority has also approved that, in case of transfer of the Nodal Officer, one of the members of the Executive Committee shall be appointed as new Nodal Officer by the head of the Institution. Proper handing over of the charge must be ensured by the Institution head. It has also been decided that the Nodal Officer for DHR schemes of VRDL and MRU should not be the same.

Chairperson of the Executive Committee:

As per the DHR, MoHFW guidelines, Director of the Institute is the Chairperson of the EC, MRU RIMS. Chairperson shall nominate one of the faculty member preferably of the professor level, as Nodal officer for overseeing the function of the MRU, who will also be designated as the Member Secretary of LRAC. Chairperson of EC will also Constitute/reconstitute the Local Research Advisory Committee (LRAC) and Executive Committee (EC).

The working mechanism of the Executive Committee:

In case of anticipated absence of the chairperson in a planned EC meeting, a seniormost member will be elected by the members present. The quorum of the EC meeting would be 03/05. If a member is unable to attend a meeting his or her opinion/comment on the project or matter in the agenda may be submitted to the chairperson/Nodal officer before the date of meeting or decision. The decision of the committee/approval is more by consensus of the members present in the meeting. As the proposal is circulated 02 weeks before the meeting and if a member is absent following is considered: if no objection /comments are obtained from the member they are considered to be approved by that member. There shall be no post facto/retrospective approval of research proposal.

Composition and functions of Local Research Advisory Committee (MRU) RIMS

1	Chairperson	External Medical Expert, preferably Professor level from reputed Research Institution/University
2	Co-Chairperson	External Medical Expert, preferably Professor level from reputed Research Institution/University
3	Three Clinicians/Academicians	One external and two internal with expertise in non-communicable diseases – one expert specializing in the disease identified in research project.
4	One nominee of theState Health/ Medical Education Department.	
5	One nominee from the ICMR HQ of the nearest ICMR institute	
6	Member Secretary	Nodal Officer, MRU

The functions of the Local Research Advisory Committee (LRAC), vide R.11016/05/2024-HR dated 09.05.2024 of the Department Health Research, Government of India, shall be as follows:

- The local research advisory committees would identify the research priorities and projects at the medical college level. The committee would approve new proposals and monitor the ongoing projects already approved by LRAC, in terms of the progress against project specific outcomes and timelines proposed by the PI. The quality of research work would be monitored by the Evaluation Committee constituted by the DHR.

The working mechanism of the Local Research Advisory Committee shall be as:

- The LRAC will meet every 06 monthly. Quorum of the LRAC meeting shall be [05/08]
- EC members shall participate in LRAC meetingas observers (except for the Nodal Officer, who is also the member secretary of LRAC).
- All decisions of EC shall be by majority.
- The LRAC is reconstituted with half of the members changing every three years to ensure rotation of all members. The maximum tenure of any member should not exceed beyond 06 years.
- If a member is unable to attend a Meeting, his or her opinion/comment on the project or matter in the agenda may be submitted to the chairperson/Nodal officer before the date of meeting or decision. The decision of the committee/approval is more by consensus of the members present in the meeting. As the proposal/agenda is circulated 02 weeks before the meeting and if a member is absent, the following is considered: if no objection /comments are obtained from the member they are considered to be approved by that member. There shall be no post facto/retrospective approval of research proposal.

4.1. Chairperson of LRAC

4.1.1 The chairperson will chair all meetings of the LRAC, RIMS, Imphal. The chairperson is empowered to convene emergency meetings of the LRAC, RIMS or a sub-group/committee as per requirement. The chairperson will be responsible for conducting committee meetings, leading all discussions and deliberations pertinent to review of the research proposals.

4.1.2 In case (event) of anticipated absence of the chairperson at a planned LRAC meeting, the Co-chairperson will chair the session. For reasons beyond control, if both the chairperson and Vice-chairperson are not available, an acting chairperson will be elected from amongst the external members by the members present. The acting chairperson will have all the powers of the chairperson for that meeting.

4.1.3 The chairperson will appoint the SOP team to improve the existing SOP or formulate a new SOP, if necessary.

4.2. Member Secretary

4.2.1 The Member Secretary will conduct the business of the EC/LRAC RIMS, Imphal, in consultation with the Chairperson of EC or LRAC. He or She, assisted by the Secretariat staff, will maintain records and communicate with all concerned, including the Director, RIMS.

4.2.2 The Member Secretary is in charge of the Secretariat of the EC/LRAC, RIMS, Imphal.

4.2.3 The Member Secretary will prepare, maintain the meeting agenda and minutes, and EC/LRACdocumentation. He/she will sign documents and communications related to EC/LRACfunctioning.

4.2.4 The Member Secretary will receive research proposals submitted to the Secretariat. He/she shall prepare and distribute study files, organize an effective and efficient tracking procedure for each proposal.

4.2.5 The Member Secretary will report to the Chairperson on all matters related to the EC/LRAC, including monitoring of the research proposals reviewed by the EC/LRAC, RIMS, Imphal.

4.2.6 The Member Secretary will communicate with the Principal Investigator regarding EC/LRACdecisions related to the submitted research proposal.

4.2.7 The Member Secretary will arrange to provide updates on relevant and contemporary issues in health research to the committee members, and training of MRU members, if needed.

4.2.8 The Member Secretary will issue official receipts, prepare for audits, inspections, annual reports and financial statements of the MRU, RIMS, Imphal.

4.3. Members

4.3.1 Members should be aware of local, social and cultural norms, as this is the most important social control mechanism.

4.3.2 It is the responsibility of each LRAC member to review research proposals, attend LRACmeetings and participate in discussions and deliberations so that appropriate decisions can be arrived at.

4.3.3 Any LRACmember can put forth suggestions to the Chairperson/ Member Secretary/Nodal officer as mail/letter/verbal request.

4.3.4 LRACmembers should participate in capacity building activities in biomedical research.P*rovide information and documents related to training organised by MRU.*

LRAC members will assist the Chairperson and Nodal officer/Member Secretary in carrying out LRAC activities as per the SOP.

Declaration of Conflict of Interest (CoI) by EC & LRAC members:

All members will declare conflict of Interest. If there is CoI the member would voluntarily withdraw from the meeting while making a decision on the project/proposal which evokes COI. The member should Inform the chairperson/Nodal officer (member secretary) prior to review & recorded so in the minutes. All members shall sign Declaration of CoI

4.4 Multi-Disciplinary Research Unit Staff

The staff for the MRU will be engaged purely on contractual basis and on consolidated remuneration and would have no claim to a permanent employment with the DHR/ICMR. They would be subject to administrative control and other rules & regulations as applicable to them, of the Institute where the project is based Extension of engagement of a staff shall be subject to his/her APR.

The following categories of staff would be engaged under the MRU scheme:

i.	Research Scientists (RS-I, RS-II)	- 2
ii.	Lab. Technicians	- 2
iv.	DEO (Grade-A)	- 1

The qualifications, eligibility criteria for the appointment and rates of remuneration shall generally follow the ICMR pattern for similar categories of staff. However, medical college may make requisite adjustments to suit the requirements of research projects proposed to be taken up or to adopt the criteria followed by the State.

4.5 Up-gradation/down-gradation of approved staff

No alteration in the staff approved can be made by the institute/research Organisation without the permission of DHR/ICMR.

4.6 Equipment

Provision for equipment(s) for conduct of the study shall be provided based on the recommendations of the project by the Executive committee (EC) and final approval by the Local Research Advisory Committee (LRAC). This would vary on the nature, scope and need of the project.

All equipment should be purchased according to the rules and procedures of the RIMS Imphal , where the project is to be carried out.

Equipment procured through the grant should bear a label "DHR/MOHFW funded"

On completion of the study a list of all equipment procured from the project funds along with their cost, date of purchase, and suggestions for disposal should be sent to the **DHR**.

Equipment costing less than Rs 20,000 is generally allowed to be retained by the Institute, while for those costing more than Rs 20,000, the Department would take decisions on a **case by case** basis.

All expendable and non-expendable articles acquired for the project should be purchased in accordance with the procedure in vogue in the host institutions (RIMS, Imphal). For permanent and semi-permanent assets acquired solely or mainly out of the grant, a separate record in the form of a register in the prescribed Performa (Asset Register) shall be maintained by the Institute. The term "asset" means moveable property where the value exceeds Rs.1000/-. Separate assets registers for items costing more than Rs.20, 000/- and less than Rs.20,000 may be maintained.

4.7 Overhead expenses

Overhead expenses, if any, may be met from miscellaneous expenses as per ICMR/DHRnorms.

4.8 Re-appropriation of funds by MRU

Expenditure should on no account exceed the budget sanctioned for the project. Expenditure incurred over and above the sanctioned amounts against one or more, sub-heads of expenditure, such as pay and allowances, contingencies etc., shall not be met without the approval of the DHR, by re-appropriation of savings under the remaining sub-heads (except underthe sub-head 'equipment') by re-appropriation of money during the financial year, provided it is within overall sanctioned ceiling of the year. No expenditure shall be incurred on items not sanctioned under the scheme. Savings should also not be re-appropriated for meetings or incurring expenditure on staff that has not been sanctioned by the Department.

4.9 Number of projects with a Principal Investigator

Under normal conditions, a PI should not be implementing more than two research projects at a given point in time. While submitting an application for a research project, the PI should give in detail all the research projects completedand ongoing. Fresh research proposals can be considered only when the ongoing research proposals are about to conclude.

4.10 Annual progress report by MRU to DHR/by PI to MRU

The Host Institute would be required to submit an annual progress report and also give anaudited statement of expenditure by the Auditor of the research Organization/Institute etc. However, the first progress report should be submitted at least three months prior to the completion of the annual report so as to enable the evaluation and provide the grants within one year from the starting date. The subsequent annual report will be for **a** period of one year.

The financial and physical progress of the project would be evaluated by the DHR with technical support from ICMR.

The progress report and expenditure statement with respect to the project shall be reviewed at the time of therelease of subsequent grants.

The Principal Investigator (PI) may be asked to present the progress at the meeting of the Committee, if considered necessary. The consolidated report of the work done is to be provided to the department for evaluation and monitoring of progress and astatement of expenditure.

The suggestions and views of the Committee and mid-course corrections, if any, would be conveyed to the PI from time to time for effective conduct of the project. This would be binding on the PI.

4.11 Publication of results/presentation of papers:

The research papers and publications based on the results of the research project should acknowledge assistance from the MRU, RIMS, Imphal and DHR, MoHFW, GOI. Copies/reprints of papers published should be sent along with the progress/final report.

4.12 Intellectual property rights

All new intellectual property viz., patents, designs etc. generated as part of the research supported by the DHR under the scheme would belong to the department ***and*** other partners as per the Indian Council of Medical Research IPR policy, until any new policy is formulated by the Department of Health Research.

4.13 Conflict of interest declaration by investigators

In order to maintain objectivity in the conduct and reporting of research, it is imperative that the investigators should not have any financial or other interests that undermine scientific integrity while recording and reporting their data. Any research or other links of the investigators with industry are discouraged, as such a link would compromise or likely to compromise unbiased reporting of research data. In addition, such a financial conflict of interest could lead to loss of public faith on the credibility of data being reported, especially in the light of recent reports of financial conflict of interest of investigators in drug and other clinical trials. All investigators, desirous of DHR support should declare financial conflict of interest, if any, before submitting the project for support. They should also ensure that during the conduct of the project, they observe the same code of conduct. If the Department comes to know of any unethical conduct on the part of investigator including improper/incomplete declarations, the project is liable to be terminated immediately.

5. Terms of Reference

5.1. The Director, Regional Institute of Medical Sciences (RIMS), Imphal constitutes the Executive Committee (EC), MRU, RIMS. It would be preferable to appoint persons trained in bioethics or persons conversant with ethical guidelines and laws of the country.

5.2. The Director, RIMS, Imphal will appoint the Chairperson of the Local Research Advisory Committee, MRU, RIMS who will be from outside the Institute to maintain the independence of the committee. The chairperson should have preferably at least **minimum**1-3 years' experience of serving on committees.

5.3. The Director, RIMS, Imphal, will appoint the Nodal officer of the MRU,who will also be designated as the Member-Secretary of LRAC, from one of the medical faculty member of the Institution, preferably of the level of professor with domain specialty experience, preferably with knowledge of clinical research and ethics, with a personal interest in ethics and capacity for good communication skills.

5.4. The LRAC members will be appointed by the Director, RIMS, Imphal. Members will be selected in their capacities based on their qualifications, experience in domain field, interest, ethical and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the MRU. They should not have any known record of professional misconduct.

5.5. New members will be appointed under the following circumstances:

5.5.1 When a regular member completes his/ her tenure.

5.5.2 If a regular member resigns before the tenure is completed.

5.5.3 If a regular member ceases to be a member for any reason including death or disqualification (long term non availability, absence in 3 consecutive meetings).

5.5.4 To fulfil the membership requirements as stated in this SOP

5.6. The new members will be identified by the Chairperson according to the membership requirement i.e. as per the composition specified in this SOP, provided the potential member fulfils the conditions of appointment after discussion by the EC-MRU.

5.7. The names of new members to be appointed may be suggested by the LRAC members and the Chairperson to the Director, RIMS, Imphal for the final decision regarding the appointment.

5.8. The duration of appointment in the LRAC, RIMS, Imphal is initially for a period of 3 years. At the end of 3 years, the committee will be reconstituted and up to 50% of the members may be replaced by a procedure that includes nominations by the Chairperson of the EC, RIMS, Imphal and Head of the Institute. The maximum tenure should not exceed beyond 06 years.

6. How to Approach a Research Proposal under MRU, RIMS

6.1: Initial Submission (details are available on the website http://www.rims.edu.in)

6.1.1 Drafting the Proposal Letter & **Forwarding**: The forwarding letter should clearly state the research proposal title and the aims of the study through **the concern Head of Department/principal.**

6.1.2 Application for Support of Intramural Research Project under MRU Scheme: Include an application in the prescribed form for support under the intramural research project, available from Multi-Disciplinary Research Unit.

6.1.3 Concept Note: Submit a concept note of the research proposal. The prescribed format as per the Local Research Advisory Committee (LRAC) guidelines, is available from the Multi-Disciplinary Research Unit (MRU), RIMS.

6.2: Review Process

6.2.1 Receipt and Forwarding by MRU: The MRU will officially receive the research application and log it into their system. The application is then forwarded to the Executive Members for initial review.

6.2.2 Quarterly Review by Executive Members: The Executive Members shall review the applications quarterly, scheduled as per the Calendar of activities of the MRU. The EC will assess the feasibility, relevance, and potential impact of the proposed research. The Principal Investigator shall present the proposal to the EC on the date specified for the meeting, either onsite or by virtual mode. Recommendations or requests for additional information may be issued at this stage. The EC shall thus shortlist the proposals for onward presentation to LRAC for finalization, as per the schedule of the LRAC.

Decisions-

- Approval for presentation to LRAC
  - With/without minor modification
  - Nodal officer and Research scientist are authorized to take a decision after examining, if the investigator has addressed the comments /suggestions.
- Modification before approval for presentation to LRAC (resubmission)
  - A full EC meeting as scheduled in the calendar of the MRU shall re-examine the revised version and take a decision.
- Disapproval
- Discontinuation of the previously approved project.
  - If there is any major adverse effect/event(s) encountered/reported for an ongoing project approved by the MRU, It should be informed to the Nodal Officer MRU, Chairman, LRAC and Chairperson, EC (Director, RIMS, Imphal) within 24 hrs of getting the report, for a decision on continuance/discontinuance of the project. Any such decision should be ratified by the next LRAC meeting and minuted.

6.2.3 Biannual LRAC Review: Following the Executive Members' review, the application is forwarded to the LRAC. The LRAC conducts a thorough review of the proposal. LRAC meeting shall be held at-least every six monthly. The EC members shall attend the meeting as observer. They evaluate the scientific merit, ethical considerations, and alignment with institutional priorities. LRAC shall review the new proposals and monitor the progress of the ongoing proposals against the project specific outcomes and timelines proposed by the Principal Investigators of the projects. Principal Investigator shall be required to present the proposal to the LRAC Meeting, on the date specified for the meeting, either onsite or by virtual modeThe researcher will be notified of the decision, which could be:

Decisions-

- Approval for MRU support (with/without minor modification)
  - Nodal officer and EC member (i/c of research) are authorized to take a decision after examining, if the investigator has addressed the comments /suggestions. However, the decision so taken, shall be ratified in the following LRAC meeting and minuted.
  - Approval at this stage is only provisional and the final approval shall be accorded only after satisfaction of the administrative requirements(e.g Ethics clearance certificate and other documentations)
- Modification before consideration for approval (resubmission)
  - A full EC meeting as scheduled in the calendar of the MRU shall be authorized to examine the revised version and take a decision in reference to the comments made by the LRAC. However, the decision so taken, shall be ratified in the following LRAC meeting and minuted
- Disapproval
- Discontinuation of the previously approved project

Final approval status shall be granted only after Ethics clearance certificate submission.

6.3: Research Ethics Board (REB) Approval

6.3.1 Submission to REB: If the LRAC considers the proposal, the researcher has to submit the full proposal to the Research Ethics Board (REB), RIMS, Imphal. The REB will review the ethical aspects of the research, ensuring compliance with institutional and regulatory standards. Approval from the REB is mandatory before proceeding to the next steps.

6.4: Memorandum of Understanding (MoU)

6.4.1 Signing the MoU: Once the REB approves the proposal, an instrument of Memorandum of Understanding (MoU) will be appended between the Research proposers and the MRU. The MoU outlines the responsibilities and expectations of both the researcher and the MRU, RIMS. Both parties must sign the MoU to formalize the agreement.

6. 5: Sanction letter and Initiation of the study

6.5.1 Sanction Letter: The MRU, RIMS will issue a sanction letter detailing the approved budget for reagents and consumables required for the research. This letter serves as official authorization to begin the procurement of necessary materials.

6.5.2 Initiation of Study: The researcher can commence the study once the sanction letter is received and the necessary resources which include reagents, consumables and equipment are in MRU Lab facilities. Adherence to the approved research plan and timelines is crucial for the study's success and shall be strictly followed.

6. 6: Progress and Final Reporting

6.6.1 Progress Reports: The researcher is required to submit progress reports every six months to the Nodal Officer. These reports should detail the study's progress, any challenges encountered; including development of any adverse effects/outcome and interim findings. The progress of the ongoing study shall be presented in a quantifiable measure (as Percentage) against the project specific outcomes and timelines proposed by the PI of the study. Regular progress updates ensure ongoing support and oversight from MRU, RIMS.

6.6.2 Final Report and Publications: Upon completion of the project, the researcher must compile a final report summarizing the study's outcomes, conclusions, and potential implications. Any publications resulting from the research should acknowledge the support and resources provided by MRU, RIMS, and the Department of Health Research (DHR), MoHFW, GOI. The final report and publications are crucial for documenting the research's contributions and securing future support for similar initiatives.

 # In case of any doubt or conflict regarding interpretation and for any specific matter(s) not provided herein, the decision of the Director, RIMS, Imphal & Chairman, Executive Committee, MRU, RIMS, Imphal shall be final and binding.

Amendments

Subject to updating of the guidelines/provisions of Multi-Disciplinary Research Unit (MRU) scheme by the Department of Health Research, Ministry of Health & Family Welfare and necessity arising out of practical functioning of the MRU; any alterations, additions and omissions etc. in the SoP shall be amended by a majority decision of the Executive Committee (3/5 as quorum). Consequent upon concurrence of the proposal, by the Chairman, Local Research Advisory Committee and final approval by the Chairman, Executive Committee & Director, Regional Institute of Medical Sciences, Imphal, it shall be duly notified by the Nodal Officer, MRU.

Annexure-A

Annual calendar of MRU-RIMS, Imphal

Month	1st Week	2nd Week	3rd Week	4th Week
April	Progress Report submission to DHR		Capacity Building	
May			Capacity Building	
June	**Progress Report submission by researchers**	EC meeting		**LRAC Meeting**
July	Progress Report submission to DHR	Counselling of Investigator(s)	Capacity Building	
August			Capacity Building	
September		EC meeting		Equipment check-up
October	Progress Report submission to DHR		Capacity Building	
November			Capacity Building	
December	**Progress Report submission by researchers**	EC meeting		
January	Progress Report submission to DHR			**LRAC Meeting**
February		Counselling of Investigator(s)	Capacity Building	
March		EC meeting		Equipment review

Annexure-B

APPLICATION FOR SUPPORT OF INTRAMURAL RESEARCH PROJECT UNDER MRU SCHEME

1. First submission/re-submission after correction:
2. Title of the Research Project:

3. Name, Designation, Institute &contact details

A.

i) Principal Investigator:
Designation:
Permanent address:
Contact no.:
E-mail:

ii) Co-Principal Investigator:
Designation:
Permanent address:
Contact no.:
E-mail:

iii) Co-Investigator(s):
Designation:
Permanent address:
Contact no.:
Email:

iv) Co-Investigator(s) :
Designation :
Permanent address :
Contact no.:
Email :

B. For Sr. faculty, date of superannuation:

4. Research Ethics Board Application: Yes/No
5. Nature of study: Faculty/PGT/MCh/DM/PhD
6. Submission of the same proposal to any other funding agency: Yes/No
7. Number of research project(s) by the investigators at the time of application-
   a) Total: b) at MRU, RIMS:

8. Duration of Research Project (maximum 2 years):
i) Period required for preparation of instruments, measurements and standardization of protocols: ii) Period which may be needed for collecting the data: iii) Period that may be required for analyzing the data: iv) Period required for publication: *(Project completion report and publication(s) of the study should duly acknowledge support of MRU,RIMS & DHR)* 9. If multi-centric, ethical clearance of the coordinating centers: Yes/No

I/we hereby declare that the above mentioned information is true & correct. I/we will abide by all the regulations prescribed by the MRU, RIMS.

Signature of Co-Investigator (s) Signature of P.I. with Seal

1.

2. Signature of Co-P.I. with Seal

3.

Signature of HoD with Seal

* In case, Principal Investigator is not from Regional Institute of Medical Sciences (RIMS), the appended Co-Investigator/Investigator from RIMS shall automatically deem to have expressed commitment/intent to pursue the study as per the provisions of Multi-Disciplinary Research Unit.

Annexure-C

Multi-Disciplinary Research Unit
Regional Institute of Medical Sciences, Imphal

CONCEPT NOTE FORMAT FOR RESEARCH PROPOSAL

Title of the project :

Name of Principal Investigator :
Department/College :
Name of Co-Principal Investigator :
Department/College :
Name of Investigator :
Department/College :

Date of initiation of the study :
Probable date of end of the study :
Introduction/Rationale(300 words) **:**
Novelty/Innovation(250 words) **:**
Feasibility (250 words) :

Aims/Objectives :
Methods (800 words) :

i. Study Design
ii. Setting
iii. Duration of study
iv. Sampling: Study population, sample size, randomization, recruitment, inclusion/ exclusion
v. Operational guidelines for testing (if any)
vi. Data/sample collection procedure
vii. Data handling & Analysis
viii. Ethical issues and steps to minimize harms to participants

Outcome (150 words) :
(Major expected outcomes of the study)
Risk involved in the study :
Benefits of the study :
Tentative Budget*(with Justification)* **:**

A. **Staff** *(no funding for staff appointment)*:
B. **Non Recurring :**
C. **Recurring**
   1. Reagents :
   2. Stationery items/office supply :
D. **Contingency/Consumables** :
E. **Report writing and preparation :**
F. **Overhead charges (3%) :**

Tentative Time line (Gantt chart) **:**
References:

Signature of the PI

Annexure -D

Progress report format for intramural research under MRU

Section A
Title of the project
Name of the Investigator/Supervisor
Name of Supervisor, if any
Department
Objectives of study
Progress of study in Gantt Chart (expressed in percentage of the accomplishment against the project specific outcomes and timelines proposed by the PI)
Date of initiation of the study
End (probable) date of the study

Section B
Study design
Objectives of the study
How randomization (if any) is done?
Participants (write 'not applicable' wherever not relevant)
How many participants have been recruited?
How many refused to participate?
How many didn't consent?
How many have withdrawn consent?
How many are lost to follow up?

Section C
Is there any serious adverse event? If so, describe
Is there any other adverse event/incident? If so, describe
Has/have the event(s) been reported to REB, RIMS?

Section D
Is there any change/deviation from the original protocol?
If so, what and why?

Section E
Are there any other issues that need to be redressed on Equipment, consumables etc.?

Date:
Place:

Signature of the Investigator/Supervisor

Annexure -E

Memorandum of Understanding (MoU)

PREAMBLE

Whereas, the DHR, MoHFW, Government of India, formulated Multi-Disciplinary Research Unit (herein referred to as MRU) scheme, for promoting health research in Medical Institutes.

Whereas, MRU RIMS Imphal invites research proposals from the faculties of the institute for support as per the MRU scheme of DHR, GOI.

Whereas, upon review by the Executive Committee (EC) MRU RIMS and final approval by Local Research Advisory Committee (LRAC) MRU RIMS, for support from MRU RIMS Imphal and submission of Institutional Ethics Clearance Certificate.

Now therefore,

This agreement is made

BETWEEN

Multi-Disciplinary Research Unit, Regional Institute of Medical Sciences, Imphal, a scheme under DHR, for promotion of research, with its office at Regional Institute of Medical Sciences , Imphal, which expression shall include its successors and assigners unless context requires a different construction . Represented by Nodal officer (herein referred to as first party)

AND

Research proposer, an expression shall where the context so admits, include its Principal Investigators (PI), Co-PI, Investigators (in case of SR/PGT/MCh /DM students /Non-RIMS as PI, the concern Guide/Co-Investigator[RIMS] shall be an extended assignee), represented by the Principal Investigator (PI) with office in the department of ……working as, ……..
With permanent address,……..
contact number,…….. Email…… (herein referred to as second party)

Of the project proposal entitled
"……"

(both first party & the second party are hereinafter referred to as "the parties")

We the following, agree to the conditions as laid down hereunder for efficient utilization of the services of the MRU in pursuing the LRAC approved research proposal.

1. Parties shall utilize the resources of MRU judiciously and purely for the approved protocol.
2. The first party shall support the proposed study which is duly approved by the LRAC and having submitted the ethics clearance certificate, in the agreed terms.
3. Parties agreed that, the terms of the components of supports to be accorded and the period for support shall be
   ……
4. Parties are fully aware of and shall pursue in accordance with the prescribed rules of the government, in terms of purchase, procurement and such other services in regard to the approved proposal.
5. Second party shall inform MRU, if investigator decides to modify protocol or discontinue the study for necessary follow-up action and addressing the associated liabilities.
6. Second Party shall utilize the facility with utmost care and avoid any damage for which the PI shall be held responsible for the consequential liabilities.
7. Second party is liable for refunding the fund incurred & consumed if the approved project is not undertaken/discontinued without prior valid & documented permission of the MRU
8. Parties are fully aware that, any misconduct in any form or violation of ethics shall invite undesirable punitive actions as provided by the ICMR guidelines.
9. Second party shall submit progress report to the MRU ……. monthly in a quantifiable measure of progress (eg. Percentage and in reference to the Gantt chart of the proposal) till the completion of the study in the prescribed format.
10. Second party shall publish/disseminate the outcome of the study and duly acknowledge the support of DHR, MoHFW and MRU, RIMS Imphal. a copy of such publication/dissemination work document shall be submitted to the MRU, RIMS
11. Parties shall settle all outstanding dues/liabilities with MRU after the completion of the study and in agreement with the MRU guidelines. Such action shall be documented.
12. Parties agree that, any issues in question, interpretation and difference arising between parties and for matters not mentioned herein, the decision of the Chairman, Executive Committee, Multi-Disciplinary Unit ,Regional Institute of Medical Sciences, Imphal shall be final and binding.
13. The document shall be effective from the date of signing by both the parties. It shall be valid till the publication of the study and a discharge certificate is issued by MRU. It shall be in a mutually agreed term and signed.

In witness thereof, the two parties hereunto have signed on this …… day of …… 2024 in two originals, in English.

Further, certify that, we have read, understood, and agreed to the terms and conditions of this MOA set forth herein.

Signature	Signature
Name in full:	Name in full:
Principal Investigator	for and on behalf of the MRU, RIMS
Date……..	Date……..
Witness	Witness
1.	1.

……

Annexure-F

Ref. No. **Imphal, date**

Sanction letter of intramural project under MRU scheme

To,

The [Researcher's Name],
[Researcher's Department],
Regional Institute of Medical Sciences,
Imphal 795004

Subject: Approval of Support for Consumables and Reagents for Intramural Research Activities

Dear [**Researcher's Name**],

We are pleased to inform you that the Multi-Disciplinary Research Unit, RIMS, Imphal, has approved your request for support of consumables and reagents for the research entitled [**title name**] bearing **DHR/RIMS/MRU:...** This decision reflects our commitment to fostering innovative research within our institution.

The approved support includes the provision of the following items:

1. **Consumables:** [List specific consumables, e.g., pipette tips, culture plates, etc.]
2. **Reagents:** [List specific reagents, e.g., DNA extraction kits, antibodies, etc.]
3. **Other(s):** [List e.g., data management & analysis, etc.]

Please ensure that all procurement and usage of the provided consumables and reagents are in compliance with the MRU's guidelines and protocols. We trust that this support will significantly contribute to the successful advancement of your research project.

Kindly acknowledge receipt of this letter and provide a brief progress report on your research activities every six months in prescribe format available at MRU to help us monitor and evaluate the impact of the provided support.

We wish you the very best in your research endeavours and look forward to seeing the impactful outcomes of your work.

Sincerely,

[ ]
Nodal Officer& Member Secretary
Local Research Advisory Committee
Multi-Disciplinary Research Unit
Regional Institute of Medical Sciences,
Imphal, rims.mru@gmail.com

Annexure-G

Multi-Disciplinary Research Unit
Regional Institute of Medical Sciences, Imphal

Conflict of Interest Declaration

Name:

Position in LRAC/EC, MRU, RIMS:

I hereby declare to the best of my knowledge that I:

- Do not have any apparent interest whether real or personal, in the selection or awarding of grant to any of the applicants under the scheme
- Do not have any family members, who are applicants, with apparent interest whether real or personal
- Do not have any personal position that may be in conflict of interest with the applicants for grant under the scheme
- Do not have in any way personal or real interest that may affect my duty or responsibility in selecting grantees or awardees in the scheme

Other statements:

_____
_____
_____

#Declare additional statements that are not part of, or exceptions above.

I hereby declare that I fully understand that in case any information that may cause me to be in a position that shall be in conflict of interest with regard to my duties and responsibilities arises after this declaration, I shall thereafter inform the Committee.

I shall abide by the rules and regulations set forth by the Standard Operating Procedures of MRU, RIMS including if any relevant rules and regulations, with regard to conflict(s) of interest.

I hereby declare that I make this conflict of interest declaration with the above details being true and correct to the best of my knowledge and in good faith.

Date: Signature

- *This form requires LRAC/EC members to disclose details of any and all interests that are relevant that may be in conflict with their duties and responsibilities in a grant selection process.*
- *A conflict of interest may exist if a member in his or her official duties of having any role or responsibility that may involve in deciding or selecting could draw a connection or affiliation. This may be due to the possibility of influence in the performance of his or her duties that may be damaging to the trust and confidence of the public.*
- *Please fill out this form as a manifestation that no conflict of interest exists in your position in the selection and decision for the grant to the applicants.*

Acknowledgements

The Executive Committee, Multi-Disciplinary Research Unit, RIMS, Imphal expresses due acknowledgment of having referred to the updated guidelines published by Indian Council of Medical Research, Research Ethics Board (RIMS, Imphal), regulations of Manipur Societies Registration Act 1989 and guidelines of Department of Health Research, Ministry of Health & Family Welfare, Government of India and others not specifically mentioned herein. Valuable inputs, suggestions from the learned Chairpersons, members of the Executive Committee, Local Research Advisory Committee and overall guidance provided by Director, RIMS is highly solicited.