National Institute of Physical Medicine and Rehabilitation
Kalletumkara, Thrissur 680683, Kerala, India

Standard Operating Procedure (SOP) For National Institute of Physical Medicine and Rehabilitation- Institutional Ethics Committee (NIPMR-IEC)

Standard Operating Procedures (SOP)
for
National Institute of Physical Medicine and Rehabilitation
Institutional Ethics Committee
(NIPMR-IEC)

Version No: 1/2022

Prepared By:
Ms. Madhumita Rajendraprasad
(Member, NIPMR - IEC)

Reviewed and Approved by:
Dr. K. S. Vijayalekshmi Amma
(Member Secretary, NIPMR - IEC)
&
Dr. V. Raman Kutty
(Chairman, NIPMR - IEC)

Effective Date :
January 2023 - January 2026

CONTENTS

I. Standard Operating Procedures SOP:

The following may be called as “Standard Operating Procedures for NIPMR-IEC (NIPMR- Institutional Ethics Committee.

II. Adoption of SOP:

National Institute of Physical Medicine and Rehabilitation (NIPMR), Kalletumkara has adopted these written Standard Operating Procedures (SOP) to ensure the protection of the rights and welfare of human participants in biomedical, experimental and behavioral research conducted at NIPMR, Kalletumkara.

III. Purpose of the NIPMR-IEC:

To review proposed studies with human participants to ensure that they conform to internationally and nationally accepted ethical guidelines, monitor studies once they have begun and, where relevant, take part in follow-up action and surveillance after the end of the research.

IV. Scope of the NIPMR-IEC

- To advise and recommend on ethical matters arising in relation to research involving human participants.
- To ensure research is designed and conducted in accordance with the ICMR and CDSCO rules and regulations for the responsible conduct of research and the National Statement on Ethical Conduct in Human Research.
- To consider the ethical implications of all research proposals received by the Committee approve, request amendment of, or reject a research proposal on ethical grounds.
- To monitor and audit approved research to verify that the conduct of research conforms to the proposal that is approved by the Committee.
- To adopt measures to identify and manage any real, potential and/or perceived conflicts of interest of NIPMR-IEC members and or researchers.
- To handle any complaints about research or the conduct of research on humans.

V. Types of projects that will be reviewed by the NIPMR-IEC

- The committee shall review all studies carried out by NIPMR staff and students and ensure that they are in accordance with New Drugs and Clinical trials rules 2019 and ICMR National Ethical Guidelines
- It is expected that an independent scientific review/peer review of the research project is conducted prior to submission to the NIPMR-IEC by the NIPMR- Institutional Review Board (NIPMR-IRB).

- For multicentric biomedical and health research, all participating sites may agree upon mutually to utilize the services of one common Ethics Committee (EC) from a participating site identified as designated main EC for the purpose of primary review. This EC should be located in India and registered with the relevant authority. However, the local site requirements, such as informed consent process, research implementation and its monitoring, etc. may be performed by NIPMR-IEC.

VI. Objective:

The objectives of these Standard Operating Procedures of the Institutional ethics committee (IEC) of National Institute of Physical Medicine and Rehabilitation, Kalletumkara are:

1. To maintain effective functioning of the NIPMR - IEC
2. To ensure quality and technical excellence and consistent ethical review of all the submitted health and biomedical research proposals involving human participants in accordance with the ICMR ethical guidelines for biomedical research on human subjects.

VII. Authority under which NIPMR- IEC is constituted:

The Executive Director, NIPMR shall decide the Chairperson and the committee members will be selected based on their competence, experience and integrity by sending an official request letter (Annexure 1A & 1B). Members will confirm their acceptance to the Executive Director by providing all the required information for membership (Annexure 2). The Chairperson shall furnish any information or report to Executive Director, NIPMR.

VIII. Role and Responsibilities of NIPMR - IEC:

1. The NIPMR – IEC will review all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and well- being of all actual and potential research participants before approving the research proposals. The goals of research, however important, shall never be permitted to override the health and well- being of the research subjects.
2. The NIPMR – IEC will ascertain whether all the cardinal principles of research ethics viz., Autonomy, Beneficence, Non – maleficence, Respect for Free and Informed Consent, Respect for Human Dignity, Respect for Vulnerable Persons , Respect for Privacy and Confidentiality and Justice are taken care of in planning, conducting and reporting of the proposed research. For this purpose, it will look into the aspects of protocol review, selection of participants, voluntary participation of potential participants, informed consent process, risk benefit ratio, distribution of burden and benefit, maintenance of privacy and confidentiality and provisions for appropriate compensations.

3. It will review the proposals before the commencement of the study as well as review periodically until the completion of the study through appropriate well documented procedures. Such a review may be based on the periodic study progress reports furnished by the investigators and/or monitoring and internal audit reports furnished by the Sponsor and/or by visiting the study sites.
4. The mandate of the IEC shall be to review all research projects to be conducted at the Institution involving human beings directly or indirectly, irrespective of the funding agency.
5. NIPMR - IEC will provide advice to the researchers on all aspects of the welfare and safety of the research participants after ensuring the scientific soundness of the proposed research through appropriate Scientific Review Committee/ Research Committee. In case an ethics committee revokes its approval accorded to a trial protocol, it will record the reasons for doing so and at once communicate such a decision to the Investigator as well as to the Licensing Authority.
6. In case of serious adverse event, other than death occurring to the clinical trial subject, the ethics committee shall forward it's report on the serious adverse event after due analysis along with its opinion on the financial compensation, if any, to be paid by the sponsor of his representative, whosoever had obtained permission from the Licensing Authority for conducting the clinical trial, to the licensing authority within twenty one calendar days of the occurrence of the serious adverse event.

IX. Composition of NIPMR - IEC:

NIPMR -IEC will be a multidisciplinary and multi-sectorial body in composition and independent. The number of members of the Review Board may range from 7 to 15.

The chairperson of the IEC will be from outside the Institution to maintain the independence of the Committee. The Member Secretary will belong to the same Institution and will conduct the business of the Committee. Other members will be a mix of medical / non-medical, legal, scientific and non-scientific persons and may also include members of public to reflect the differed points of view.
There will be representation of age and gender in the Committee to safeguard the interest and welfare of all sections of the society. Member should be aware of local, social and cultural norms, as this is an important social control mechanism. IEC may invite subject experts to take their views, whenever it is needed.
The NIPMR-IEC will include

1. Chairperson
2. One clinician/ Doctor from various Institutes
3. One pharmacologist
4. One legal expert or retired judge
5. One social scientist/ representative of non-governmental voluntary agency
6. One lay person from the community

7. A theologian
8. Member Secretaries- two persons from NIPMR

A Sub-Board of the main IEC may review proposals submitted by undergraduate or post-graduate students or if necessary, an IEC may be separately constituted for the purpose, which will review proposals in the same manner as described above.

X. Membership requirements:

1. All members will serve for a period of 3 years on renewable basis. New members will be Included in the IEC in such a way that there will be a mix of recently included members and members with some years of experience.
2. During the term, Executive Director in consultation with the Chairman can disqualify any member if, the contribution is not adequate and/or there is long period of (member) non availability.
3. A member can tender resignation of his office of membership from the IEC to the Executive Director, NIPMR through the Chairperson after serving one month advance notice.
4. Executive Director can replace the member of IEC as and when required.
5. Each member is required to sign the declaration and confidentiality agreement regarding IEC activities (Annexure 2)
6. Conflict of interest should be declared by members of the NIPMR-IEC prior to review meeting.

XI. Responsibilities of the IEC members:

Member	Responsibilities
Chairperson	• Conduct EC meetings and ensure active participation of all members during meeting • Ratify minutes of the previous meetings •Seek COI declaration from members and ensure quorum and fair decision making. • Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data, etc.
Member Secretary	Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review • Schedule EC meetings, prepare the agenda and minute. • Organize EC documentation, communication and archiving • Ensure training of EC secretariat and EC members. • Ensure SOPs are updated as and when required and adherence of EC functioning to the SOPs. • Prepare for and respond to audits and inspections. • Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for EC review. • Assess the need for expedited review/ exemption from review or full review. Assess the need to obtain prior scientific review, invite independent consultant, patient or community representatives. • Ensure quorum during the meeting and record discussions and decisions.
Basic Scientist	Scientific and ethical review - emphasis on intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report, drug safety and pharmacodynamics in case of clinical trials

Clinician	Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report) Review medical care, facility and appropriateness of the principal investigator, provision for medical care, management and compensation. Thorough review of protocol, investigators brochure and all other protocol details
Legal Expert	Ethical review of the proposal, ICD along with translations, MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol specific other permissions (NAC-SCRT, HMSC etc.) compliance with guidelines etc.
Social scientist/ philosopher/ ethicist/ theologian	Ethical review of the proposal, ICD along with the translations. Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any Serve as a patient/participant/ societal / community representative and bring in ethical and societal concerns.
Lay person	Ethical review of the proposal, ICD along with translation(s). Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks. Serve as a patient/participant/ community representative and bring in ethical and societal concerns. Assess on societal aspects if any.

XII. Appointment of members

Appointment / relieving / acceptance of resignation of any member of the NIPMR-IEC would be the prerogative of the Executive Director, NIPMR on the recommendation of NIPMR-IEC. The appointment of the IEC member will be confirmed after receipt of their consent to abide by the Good Clinical Practice (GCP) guidelines and maintenance of confidentiality. The Executive Director, NIPMR will appoint coordinating staff for IEC. They will be supervised by the Member Secretary

Sitting fee for NIPMR-IEC Members:
The Chairman NIPMR-IEC shall be paid a sitting fee of Rs 2000/= for a meeting and other members a fee of Rs 1000/= each for a meeting

XIII. Tenure of membership

The appointment of the members would be for a period of three years, after which they may be either replaced or reappointed with a fresh appointment letter prior to the end of tenure of members by the IEC secretariat.

XIV. Resignation of members

A member can resign by submitting a letter of resignation addressed to the Chairman and delivered to the Member Secretary the same will be informed by the Secretary to the appointing authority for formal acceptance and to initiate necessary replacement/recruitment procedure for filling up the vacancy. The members if opts to step down due to any genuine cause may do so with prior notice and proper information to the appointing authority.

XV. Removal of members

Members may be removed if:

If Executive Director, NIPMR; Chairman or member secretary receives a communication in writing alleging misconduct by a member.

A member can be disqualified if fails to attend more than 3 regular consecutive IEC meetings without prior intimation.

A list of members of the NIPMR-IEC, their appointment letters, bio-data and consent forms would be maintained by Member Secretary of the NIPMR-IEC This list and the copy of the working procedures would be made available to any investigator, for the purpose of filing of research projects, upon written request for the same to the Chairman

XVI. Quorum requirements:

Minimum of 50% of committee strength + 1 member and not less than 5 members will be required to compose a quorum for the meeting of which at least one member will be from outside the institution, and one member will be a non-scientific member and one from opposite gender. All decisions will be taken in meetings and not by circulation of project proposals. Quorum will have 5 members with following representations:

1. Scientific Expert/ Independent Consultant (A person with expertise in the field of research being presented before the committee).
2. Clinicians/ Doctors
3. Legal expert
4. Social scientist / representative of non-governmental voluntary agency / philosopher / ethicist / theologian or a similar person
5. Lay person from the community.

XVII. Updating and training NIPMR - IEC members:

All relevant new guidelines will be brought to the attention of the members.

The EC members will be encouraged to keep abreast of all national and international developments in ethics through orientation courses on related topics by its own members or regular training organized by constituted body/ (IEC), so that they become aware of their role and responsibilities. IEC members will be required to be trained in GCP, NDCT and ICMR Ethical Guidelines. Any change in the regulatory requirements should be brought to their attention and they should be aware of local, social and cultural norms, as this is the most important social control mechanism. This is needed for maintaining quality in ethical review .

XVIII. Conduct of NIPMR- IEC meetings:

The Chairperson will conduct all meetings of the NIPMR - IEC. In the absence of the chairperson an alternate Chairperson will be elected from the members by the members present, who will conduct the meeting. The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/ She will prepare the minutes of the meetings and get it approved by the Chairperson and all the members. The meeting shall be hosted at the NIPMR premises and the Principal Investigator is required to be present for the meeting. The members of the IEC can attend the meeting virtually in case of inconvenience in coming physically.

XIX. Independent consultants:

The NIPMR - IEC may call upon subject experts as independent consultants who may provide special review of selected research protocols, if need be. These experts may be specialists in the subject of research being presented such as: physiotherapy, occupational therapy, audiology and speech language pathology, psychology, nutrition, social work, developmental therapy, pediatrics, physiatry, special education, specific diseases or methodologies, or represent specific communities, patient groups or special interest groups. Eg.Persons with Cerebral Palsy, Spinal Cord Injury, ethnic minorities etc. They will be required to give their specialized views but will not take part in the decision making process which will be made by the members of the NIPMR - IEC.

XX. Conflict of Interest

No member of the NIPMR-IEC should have direct involvement in the conduct of the study.

Furthermore, no member should have financial, proprietary, professional, or other interests that may affect impartial, independent decision-making by the NIPMR-IEC. At the beginning of every meeting, IEC Member Secretary or Chairman will reconfirm that no conflict of interest exists for NIPMR-IEC members. Interests that may create a potential conflict of interest should be disclosed to the NIPMR-IEC prior to any discussion. The NIPMR-IEC will determine how to handle any such potential conflict. The NIPMR-IEC can require that a member with a potential conflict abstain from voting or take other means deemed appropriate.

XXI. Application procedures:

1. All proposals should be submitted on any working day 2 weeks in advance of scheduled meeting in the prescribed application form, the details of which are given under “XII Documentation”. Soft copy of SOP of NIPMR - IEC will be given to Principal Investigator (PI) / Co-PI if he/she has applied for review for the 1st time.
2. All relevant documents should be enclosed with application form. (Documents will be available with Member - Secretary, NIPMR - IEC and Institutional Website www.nipmr.org.in in the Downloadable section).
3. Required number of copies of the proposal along with the application and documents in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators/ Collaborators / Research Scholars shall be guided to the Chairperson NIPMR - IEC, through member secretary. In his absence via any person nominated by chairperson. Receipt of the application will be acknowledged by the IEC office.

acknowledged by the IEC office.

4. Every application will be allotted an IEC registration number to be used for all future correspondence and reference. The date of NIPMR - IEC meeting will be intimated to the Principal Investigator to attend the meeting and to make a brief presentation of the proposal and to clarify the points raised by the members.

5. The decision of the committee on the proposal will be communicated in writing. If revision is to be made, the revised document in required number of copies should be submitted within a stipulated period of time as specified in the communication or before the next meeting.

6. All research proposals/clinical trials funded/sponsored by Pharmaceutical companies, Agencies, Multinationals etc. will be charged an administrative fee/ processing fee as specified by Office of IEC of NIPMR. Waiver of these fees is permissible for non-funded studies, departmental studies, and studies funded by organizations like ICMR, UGC, DST Government of India, State Science & Technology Department, UNICEF, WHO, USAID. Non Profitable Organizations etc. In general, waiver of administrative fee is possible at the discretion of Chairperson, NIPMR - IEC.

7. **Review fee:** Students and staff shall be charged a fee of Rs 500/= for review of proposals.

XXII. Documentation:

All Research proposals (5 copies along with 1 CD) shall be submitted along with the information and documents as specified in Annexure-3 A, 3 B.

XXIII. Review procedures:

1. The meeting of the NIPMR -IEC will be held as specified by the member secretary. Additional review meetings can also be held with short notice as and when required. Meetings will be planned in accordance with the need of the work load.
2. The proposals should be sent to the NIPMR - IEC at least 2 weeks in advance of schedule meeting.
3. The IEC's member-secretary or secretariat shall screen the proposals for their completeness and depending on the risk involved categorize them into three types, namely, exemption from review, expedited review and full review (explanation is given below).
4. For expedited and exemption from review; the Member Secretary shall in consultation with the Chairman of IEC choose two reviewers (from the panel of IEC members) and review the proposal. In case it is not recommended for exemption or expedited review, then a full review shall be done.
5. Decisions will be taken by consensus after discussion, and whenever needed voting will be done. Decision of chairman will be final.

6. Researchers will be invited to offer clarifications if need be. The Principal investigator (PI) / Research Scholar will then present the proposal in person in the meeting. When the PI is not available due to unavoidable reasons the Co PI will present the proposal.
7. Independent consultants/experts will be invited to offer their opinion on specific research proposals if needed.
8. The decisions will be minuted and Chairperson's approval taken in writing.

1. Exemption from review

For exemption from review, the investigator should submit a request with the research proposal/ protocol (5 copies along with 1 CD). The IEC shall decide whether exemption should be granted based on following norms:

Proposals which present less than minimal risk fall under this category as may be seen in following situations:

i. Research on educational practices such as instructional strategies or effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Exceptions:

i. When research on use of educational tests, survey or interview procedures, or observation of public behavior can identify the human participant directly or through identifiers, and the disclosure of information outside research could subject the participant to the risk of civil or criminal or financial liability or psychosocial harm.
ii. When interviews involve direct approach or access to private papers.

2. Expedited Review

For expedited review, the investigator should submit a request with the research proposal/ protocol (5 copies along with 1 CD). The IEC shall decide whether expedition should be granted based on following norms

The proposals presenting no more than minimal risk to research participants may be subjected to expedited review. The Member- Secretary and the Chairperson of the IEC or designated member of the Committee or Subcommittee of the IEC may do expedited review only if the protocols involve -

1. Minor deviations from originally approved research during the period of approval (usually of one year duration).
2. Revised proposal previously approved through full review by the IEC or continuing review of approved proposals where there is no additional risk or activity is limited to data analysis.
3. Research activities that involve only procedures listed in one or more of the following categories:
    a. studies of drugs and medical devices only when -
        i. research is on already approved drugs except when studying drug interaction or

conducting trial on vulnerable population or

ii. Adverse Event (AE) or unexpected Adverse Drug Reaction (ADR) of minor nature is reported.

4. Research involving clinical materials (data, documents, records, or specimens) that have been collected for non-research (clinical) purposes.

5. When in emergency situations like serious outbreaks or disasters a full review of the research is not possible, prior written permission of IEC may be taken before use of the test intervention. Such research can only be approved for pilot study or preliminary work to study the safety and efficacy of the intervention and the same participants should not be included in the study that may be initiated later based on the findings of the pilot study.

a. Research on interventions in emergency situation

When proven prophylactic, diagnostic, and therapeutic methods do not exist or have been ineffective, physicians may use new intervention as devices to provide emergency medical care to their patients in life threatening conditions. Research in such instance of medical care could be allowed in patients -

i. when consent of person/ patient/ responsible relative or custodian/ team of designated doctors for such an event is not possible. However, information about the intervention should be given to the relative/ legal guardian when available later.

ii. When the intervention has undergone testing for safety prior to its use.

iii. Only if the local IRB (Institutional Review Board) reviews the protocol since institutional responsibility is of paramount importance in such instances.

iv. If Data Safety Monitoring Board (DSMB) is constituted to review the data.

DSMB are specifically required for:

- If the trial is intended to provide definitive information about effectiveness and /or safety of a medical or bio-behavioral intervention
- If there are prior data to suggest that the intervention being studied has the potential to induce potential harm.
- If the trial is evaluating any major endpoint, such that inferiority of one treatment arm has safety as well as effectiveness implications.
- If it would ethically be important for the trial to stop early if the primary question addressed has been definitively answered, even if secondary questions or complete safety information were not yet fully addressed.
- A DSMB may be required if:
  - ✓ The study involves high risk intervention(s), or
  - ✓ The study includes vulnerable population(s)

Constitution of DSMB:

The membership of the DSMB should reflect the disciplines and medical specialties

necessary to interpret the data from the study and to fully evaluate participant safety. The number of DSMB members depends on the phase of the trial, range of medical issues, complexity in design and analysis, and potential level of risk but generally consists of three to seven members including, at a minimum:

Expert(s) in the clinical aspects of the disease/patient population being studied;

One or more biostatisticians; and, investigators with expertise in current clinical trials conduct and methodology. *Ad hoc* specialists may be invited to participate as non-voting members at any time if additional expertise is desired.

Representatives of the manufacturer (industry collaborator) of the test device(s) or any other individual with vested interests in the outcome of the study are not eligible to serve on the DSMB although they may attend open sessions of the DSMB meetings.

Selection and Invitation to Participate in DSMB:

The Member Secretary (NIPMR-IEC) holds primary responsibility for the formation of the Roles and Responsibilities and developing the roster of potential DSMB members. Recommendations for proposed members are solicited from many sources. Study investigators and the industry collaborators should have the opportunity to review the list of proposed members before the candidate's interest and availability are confirmed by the Member Secretary. The proposed roster of members must be submitted to the Chairman, NIPMR-IEC for review and approval before invitations are issued.

Member Secretary, NIPMR- IEC is responsible for identifying the DSMB Chair.

DSMB member participation is generally for the duration of the study. Participation for standing DSMBs convened to monitor multiple protocols or lengthy studies may be for fixed terms. As continuity of review is essential, the duration of fixed terms should be staggered so that no more than one third of the membership changes at any one time.

Conflict of Interest:

No member of the DSMB should have direct involvement in the conduct of the study.

Furthermore, no member should have financial, proprietary, professional, or other interests that may affect impartial, independent decision-making by the DSMB. In addition, all DSMB and ad hoc members will sign a Conflict of Interest certification to that effect at the time they are asked to participate. At the beginning of every DSMB meeting, IEC Member Secretary or the DSMB Chair will reconfirm that no conflict of interest exists for DSMB members. Interests that may create a potential conflict of interest should be disclosed to the DSMB prior to any discussion. The DSMB will determine how to handle any such potential conflict. The DSMB can require that a member with a potential conflict abstain from voting or take other

means deemed appropriate. NIPMR- IEC may dismiss a member of the DSMB in the event of unmanageable potential conflict or appearance of conflict.

Selection and Invitation to Participate in DSMB:

The Member Secretary (NIPMR-IEC) holds primary responsibility for the formation of the Roles and Responsibilities and developing the roster of potential DSMB members. Recommendations for proposed members are solicited from many sources. Study investigators and the industry collaborators should have the opportunity to review the list of proposed members before the candidate's interest and availability are confirmed by the Member Secretary. The proposed roster of members must be submitted to the Chairman, NIPMR-IEC for review and approval before invitations are issued.

Member Secretary, NIPMR- IEC is responsible for identifying the DSMB Chair.

DSMB member participation is generally for the duration of the study. Participation for standing DSMBs convened to monitor multiple protocols or lengthy studies may be for fixed terms. As continuity of review is essential, the duration of fixed terms should be staggered so that no more than one third of the membership changes at any one time.

Study reports for DSMB meetings and Reports from DSMB:

It is the responsibility of the PI to ensure that the DSMB is appraised of all new safety information relevant to the study product and the study. Summary safety and enrollment data should be forwarded periodically to the DSMB. The DSMB should receive all protocol revisions and may receive other documents relating to the study.

The DSMB will approve written minutes that identify topics discussed by the DSMB and describe its individual findings, overall safety assessment, and recommendations. The rationale for recommendations will be included when appropriate. The DSMB Chair is responsible for drafting, circulating, and obtaining approval from other DSMB members in a prompt manner. Additional reporting (e.g., NIPMR-IEC) is the responsibility of the study team. Meeting minutes are to be held in the custody of the Chair until such time when the study is closed or the DSMB recommends early termination or in the event the minutes are requested for participant safety reasons or for regulatory purposes. The DSMB Chair will notify the NIPMR-IEC of any findings of a serious and immediate nature or recommendations to discontinue all or part of the study. Appropriate NIPMR-IEC staff (member Secretary and chairman NIPMR-IEC) will be notified immediately. In addition to verbal communications, recommendations to discontinue or substantially modify the design or conduct of a study must be conveyed to NIPMR-IEC in writing by e-mail, on the day of the DSMB meeting. This written, confidential report may contain unmasked supporting data and include the DSMB member's

rationale for their recommendations. The report should be submitted to NIPMR-IEC.

b. Research on disaster management

A disaster is the sudden occurrence of a calamitous event at any time resulting in substantial material damage, affecting persons, society, community or state(s). It may be periodic, caused by both nature and humans and creates an imbalance between the capacity and resources of the society and the needs of the survivors or the people whose lives are threatened, over a given period of time. It may also be unethical sometimes not to do research in such circumstances. Disasters create vulnerable persons and groups in society, particularly so in disadvantaged communities, and therefore, the following points need to be considered when reviewing such research:

i. Research planned to be conducted after a disaster should be essential culturally sensitive and specific in nature with possible application in future disaster situations.

ii. Disaster-affected community participation before and during the research is essential and its representative or advocate must be identified.

iii. Extra care must be taken to protect the privacy and confidentiality of participants and communities.

iv. Protection must be ensured so that only minimal additional risk is imposed.

v. The research undertaken should provide direct or indirect benefits to the participants, the disaster-affected community or future disaster- affected population and a prior agreement should be reached on this, whenever possible, between the community and the researcher.

vi. All international collaborative research in the disaster-affected area should be done with a local partner on equal partnership basis.

vii. Transfer of biological material, if any, should be as per Government rules taking care of intellectual property rights issues.

6. Expedited review may also be taken up in cases of nationally relevant proposals requiring urgent review.

3. Full Review

All research presenting with more than minimal risk, proposals/ protocols which do not qualify for exempted or expedited review and projects that involve vulnerable population and special groups shall be subjected to full review by all the members.

While reviewing the proposals, the following situations may be carefully assessed against the existing facilities at the research site for risk/benefit analysis:

a. Collection of blood samples by finger prick, heel prick, ear prick, or venipuncture:

i. from healthy adults and non-pregnant women who weigh normal for their age and not more than 500 ml blood is drawn in an 8 week period and frequency of collection is not more than 2

times per week;

ii. from other adults and children, where the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected has been considered and not more than 50 ml or 3 ml per kg, whichever is lesser is drawn in an 8 week period and not more than 2 times per week; ii.from neonates depending on the hemodynamics, body weight of the baby and other purposes not more than 10% of blood is drawn within 48 – 72 hours. If more than this amount is to be drawn it becomes a risky condition requiring infusion/blood transfusion;

iv. Prospective collection of biological specimens for research purposes by noninvasive means. For instance:

1. Skin appendages like hair and nail clippings in a non-disfiguring manner;
2. Dental procedures - deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction of permanent teeth; supra and sub-gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth;
3. Excreta and external secretions (including sweat);
4. Uncannulated saliva collected either in an unstipulated fashion or stimulated by chewing gum or by applying a dilute citric solution to the tongue;
5. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
6. Sputum collected after saline mist nebulization and bronchial lavages.

b. Collection of data through noninvasive procedures routinely employed in clinical practice. Where medical devices are employed, they must be cleared/ approved for marketing, for instance

i. physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy;

ii. Weighing or testing sensory acuity; iii. Magnetic resonance imaging;

iv. Electrocardiography, echocardiography; electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow etc.

v. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

c. Research involving clinical materials (data, documents, records, or specimens) that will be collected solely for non-research (clinical) purposes.

d. Collection of data from voice, video, digital, or image recordings made for research purposes.

e. Research on individual or group characteristics or behavior not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies etc.

XXIV. Aspects considered during review of research proposal.

1. Scientific design and conduct of the study.
2. Approval by appropriate scientific review committees / Research committee.
3. Examination of predictable risks/harms
4. Examination of potential benefits.
5. Procedure for selection of subjects including inclusion / exclusion, withdrawal criteria and other issues like advertisement details.
6. Management of research related injuries, adverse events.
7. Compensation provisions.
8. Availability of products, benefits to subjects after the study is completed if applicable.
9. Patient information sheet, informed consent form in English and in local languages.
10. Protection of privacy and confidentiality.
11. Involvement of the community, wherever necessary
12. Plans for data analysis and reporting.
13. Adherence to all regulatory requirements and applicable guidelines.
14. Competence of investigators, research and supporting staff.
15. Facilities and infrastructure of study sites.
16. Criteria for withdrawal of patients, suspending or premature termination of the study in National Institute of Physical Medicine and Rehabilitation, Kalletumkara.

XXV. Decision-making:

1. Members will discuss the various issues before arriving at a consensus decision. When consensus is not arrived at, the decision will be made by voting procedure.
2. A member should withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises and this should be indicated to the chairperson prior to the review of the application and recorded in the minutes.
3. Decision will be made only in meetings where quorum is complete.
4. Only members can make the decision. The expert consultants will only offer their opinions.
5. Decision may be to approve, reject or revise the proposals. Specific suggestions for modifications and reasons for modifications and reasons for rejection will be given.
6. In cases of conditional decisions, clear suggestions for revision and the procedure for having the application revised will be specified.
7. Modified proposals will be reviewed by an expedited review through identified members.
8. Procedures for appeal by the researchers will be clearly defined.

XXVI. Communicating the decision

1. Decision of the meeting on the proposals will be communicated by the Member Secretary in writing to the PI / Research Scholar within 10 working days after the meeting at which the decision was taken in the specified format (Annexure-5). A certificate of approval will be sent to the applicant within 2 weeks (Annexure-6). All the approvals will be valid for one year or for the duration of the project whichever is less. Investigator has to get his or her project re- approved after one year if necessary.
2. The communication of the decision will include:
    a. Name and address of IEC.
    b. The date, place and time of decision.
    c. The name and designation of the applicant.
    d. Title of the research proposal reviewed.
    e. The clear identification of protocol no., version no., date, amendment no., date.
    f. Along with protocol, other documents reviewed- Clear description of these documents along with Version No. and Date.
    g. List of EC members who attended the meeting- clear description of their role, affiliation and gender.
    h. A clear statement of decision reached.
    i. Any advice by the IEC to the applicant including the schedule / plan of ongoing review by the NIPMR - IEC
    j. In case of conditional decision, any requirement by IEC, including suggestions for revision, and the procedure for having the application re-reviewed.
    k. In case of rejection of the proposal, reason(s) for the rejection will be clearly stated.
    l. Signature of the member secretary with date.

XXVII. Following up procedures for approved proposals by PI / Sponsor

1. IEC will review the progress of all the studies for which a positive decision has been reached from the time of decision till the termination of the research.
2. Progress of all the research proposals will be followed at a regular interval of at least once a year. But in special situations, IEC will conduct the follow up review at shorter intervals basing on the need, nature and events of research project.
3. Periodic status report of study should be submitted at prescribed intervals for review, along with information and documents as specified in Annexure-4A, 4B 4C & 7 based on the safety concerns and this prescribed interval should be specified in the Letter of Communication of Decision to the PI from the IEC.
4. Final report should be submitted at the end of study.
5. Following instances and events will require the follow-up review/ Renewed Approval:
    a. Any protocol amendment likely to affect rights, safety or well-being of research subject

of conduct of study.

b. Any event or information that may affect the benefit/risk ratio of the study.

6. Protocol deviation, if any, should be informed with adequate justifications.
7. Any new information related to the study should be communicated.
8. Premature termination of study shall be notified with reasons along with summary of the data obtained so far.
9. Change of investigators/sites must be informed to the office of IEC.
10. Monitoring: Oversight mechanism will be in place to monitor the approved studies. Actual site visits can be made especially in the event of reporting of adverse events or violations of human rights and appropriate action will be taken when required and communicated to the applicant indicating modification/suspension/termination /continuation of the project. In case the IEC desires so, reports of monitoring done by the sponsor and the recommendations of the DSMB may also be sought.
11. Applicant must inform the time of completion of study and must send the result summary to IEC. IEC must receive a copy of final summary of study completed from the applicant.

XXVIII. Responsibilities of Sponsor/Investigator.-

Responsibilities of Sponsor

1. The Sponsor is responsible for implementing and maintaining quality assurance systems to ensure that the study is conducted and data generated, documented and reported in compliance with the protocol and Good Clinical Practice (GCP) Guidelines issued by the Central Drugs Standard Control Organization, Directorate General of Health Services, Government of India as well as with all applicable statutory provisions. Standard operating procedures should be documented to ensure compliance with GCP and applicable regulations.

2. Sponsors are required to submit a status report on the study to the Licensing Authority at the prescribed periodicity. In case of studies prematurely discontinued for any reason including lack of commercial interest in pursuing the intervention, a summary report should be submitted within 3 months. The summary report should provide a brief description of the study, the number of patients exposed to the intervention and duration of exposure.

3. In case of injury occurring to the subject, the sponsor (whether a company or an Institution) or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the study, shall make payment for medical management of the subject and also provide financial compensation for the study related injury.
4. The sponsor (whether a company or an institution) or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the study, shall submit details of compensation provided or paid for study, to the Licensing Authority within thirty days of the receipt of the order of the Licensing Authority.

Responsibilities of the Investigator(s).-

1. The Investigator(s) shall be responsible for the conduct of the trial according to the protocol and the GCP Guidelines. Standard operating procedures are required to be documented by the investigators for the tasks performed by them. During and following a subject's participation in a trial, the investigator should ensure that adequate medical care is provided to the participant for any adverse events. Investigator(s) shall report all serious and unexpected adverse events to the sponsor or his representative, whosoever had obtained permission from the licensing authority for conduct of the clinical trial, and the ethics committee that accorded approval to the study protocol, within twenty four hours of their occurrence. The report of the serious adverse event, after due analysis shall be forwarded to Chairman of the ethics committee and the head of the institution where the trial has been conducted within ten calendar days of occurrence of the serious adverse event of death.
2. The investigator shall provide information to the clinical trial subject through informed consent about the essential elements of the clinical trial and the subject's right to claim compensation in case of trial related injury or death. He shall also inform the subject or His/ Her nominee(s) of their rights to contact the sponsor or his representative whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial for the purpose of making claims in the case of trial related injury or death.

XXIX. Record keeping and archiving at the office of NIPMR - IEC:

1. All the documents and communications of IEC will be dated, filed and archived in a secure place.
2. Only persons, who are authorized by the Chairman of IEC will have the access to the various documents.
3. All the documents related to research proposals will be archived for a minimum period of 3 years in the Institute, following the completion /termination of the study.
4. No document (except agenda) will be retained by any IEC member.
5. At the end of each meeting, every member must return the CD containing all the research proposals and documents to IEC office staff. They will archive one copy in IEC office and other copies will be destroyed after one year.
6. Following documents will be filed and archived with proper label on the top of file for easy identification
    a. Constitution and composition of NIPMR- IEC
    b. Curriculum Vitae (CV) of all members of NIPMR- IEC with records of training in Human ethics.
    c. Standard Operating Procedures of NIPMR- IEC.
    d. Annual reports
    e. A record of all income and expenses of the EC, including allowances and reimbursements

made to the secretariat and EC members;

f. The published guidelines for submission established by the EC.
g. Copy of all study protocols with enclosed documents, progress reports, and SAEs.
h. Agendas and Minutes of all IEC meetings duly signed by the Chairperson / Member secretary.
i. Copy of all existing relevant national and international guidelines on ethics and laws along with amendments.
j. Copy of all correspondence with members, Principal Investigators and other regulatory bodies.
k. Record of all notification issued for premature termination of a study with a summary of the reasons;
l. Final report of the approved projects, including microfilms, CDs and Video recordings.

XXX. Terms of reference

Terms of reference will be maintained in the office of NIPMR - IEC. This includes

1. Membership Requirements
2. Terms of Appointment with reference to the duration of the term,
3. The policy for removal, replacement, resignation procedure,
4. Frequency of meetings, and
5. Payment of processing fee to the IEC for review, honorarium/ consultancy to the members/ invited experts *etc.*

The SOPs will be updated periodically based on the changing requirements. The term of appointment of members could be extended for another term and a defined percentage of members could be changed on regular basis. Preferably, IEC would appoint persons trained in bioethics or persons conversant with ethical guidelines and laws of the country. Substitute member may be nominated if meetings have been continuously missed by a member due to illness or other unforeseen circumstances.

XXXI ADMINISTRATION AND MANAGEMENT

A full time secretariat and space for keeping records is required for a well-functioning IEC. The members could be given a reasonable compensation for the time spared for reviewing the proposals. Reasonable fees can be charged to cover the expenses related to review and administrative processes for any third party (protocols submitted by researchers not employed by NIPMR, KALLETUMKARA) submission as described in section XI Point No 6. There should be provision for allocating reasonable amount of funds for smooth functioning of the IEC.

XXXII SPECIAL CONSIDERATIONS / PROTECTION OF VULNERABLE POPULATION

While all the above requirements are applicable to biomedical research as a whole irrespective of the specialty of research, there are certain specific concerns pertaining to specialized areas of research which require additional safe guards / protection and specific considerations for the IEC to take note of. Examples of such instances are research involving children, pregnant and lactating women, vulnerable participants and those with diminished autonomy besides issues pertaining to commercialization of research and international collaboration. The observations and suggestions of IEC will be given in writing in unambiguous terms in such instances. ICMR guidelines as applicable will be followed for protection of vulnerable population.

- Only the full committee should do initial and continuing review of such proposals. It is desirable to have empowered representatives from the specific populations during deliberations.
- Researchers must justify the inclusion of a vulnerable population in the research. NIPMR-IEC must satisfy themselves with the justification provided and record the same in the proceedings of the IEC meeting. The NIPMR-IEC should examine whether inclusion/exclusion of the vulnerable population is justified.
- If vulnerable populations are to be included in research, the IEC must ensure that additional protections are in place to safeguard the dignity, rights, safety and wellbeing of these individuals, additional safeguards, such as more frequent review and monitoring, including site visits should be done. Additional safety measures should be strictly reviewed and approved by the NIPMR-IEC.
- In vulnerable populations, when potential participants lack the ability to consent, a Legally Authorized Representative (LAR) should be involved in decision making
- Special care must be taken to ensure participant’s privacy and confidentiality, especially because breach of confidentiality may lead to enhancement of vulnerability.
- The informed consent process should be well documented. Additional measures such as recording of assent and re-consent, when applicable, should be ensured.

NIPMR-IEC should also carefully determine the benefits and risks of the study and examine the risk minimization strategies. As potential participants are dependent on others, there should be no coercion, force, duress, undue influence, threat or misrepresentation or incentives for participation during the entire research period. Vulnerable persons may require repeated education/information about the research, benefits, risks and alternatives, if any.

Annexure No 1 A.

Letter Ref. No: Date:

From

Executive Director,
NIPMR
Kalletumkara

To

_____
_____
_____

Sub: Constitution of Institute Ethics Committee (Human studies) - Reg.

****

Dear Sir / Madam,

On behalf of National Institute of Physical Medicine and Rehabilitation, Kalletumkara, an Autonomous Institute under Government of Kerala, I request your concurrence for possible appointment as a member of Institute Ethics Committee of NIPMR Kalletumkara. Kindly send your written acceptance in the enclosed format and provide short curriculum vitae along with the acceptance letter.

On receipt of your acceptance, I shall send you the formal appointment letter.
Yours sincerely,

Signature:

Name

Annexure No 1 B.

APPOINTMENT ORDER

Dr/ Mr. / Mrs/ Ms.:_____Date: _____

I am pleased to appoint you as_____of the Institutional Ethics Committee (IEC) (Human research) at National Institute of Physical Medicine and Rehabilitation, Kalletumkara (NIPMR, KALLETUMKARA) w.e.f_____ for a term of _____ year / months provided following conditions of appointment are met.

1. You should be willing to publicize your full name, profession & affiliation.
2. You are willing to record all reimbursement for work & expenses, if any, within or related to an EC & make it available to the public upon request.
3. You consent to sign confidentiality agreement between you & the IEC regarding meeting deliberations, applications, information on research participants, & related matters.

The renewal of your appointment will be by consensus & 1 month notice on either side will be necessary prior to resignation/ termination of appointment. Terms & Conditions regarding the resignation procedure, disqualification procedures, replacement procedures etc. may be found in the Standard Operating Procedures (SOPs) of IEC, NIPMR, KALLETUMKARA.

You will be paid a sum of Rs_____ per sitting as Honorarium for your services rendered and as per the guidelines given in Terms of Reference-IEC, NIPMR, KALLETUMKARA.

We sincerely hope your association with IEC, NIPMR will be fruitful to the Institute & the Community we serve.

Chairperson
(Name/Seal)
IEC, NIPMR
Kalletumkara – 680683

Signature of Appointee
(Name & Date)

Annexure No: 2

From,

_____
_____
_____

To
The Executive Director
NIPMR
Kalletumkara -680683

Sub: Consent to be a member of Institute Ethics Committee (Human Studies) - Reg.
Ref: Your Letter No: dated:

****

Dear Sir,

In response to your letter stated above, I give my consent to become a member of IEC of NIPMR Kalletumkara . I shall regularly participate in the IEC meeting to review and give my unbiased opinion regarding the ethical issues.

I shall be willing for my name, profession and affiliation to be published.

I shall not keep any literature or study related document with me after the discussion and final review.

I shall maintain all the research project related information confidential and shall not reveal the same to anyone other than project related personnel.

I herewith enclose my CV.

Thanking you,

Yours sincerely,

Signature _____

Name of the Member_____Date:

Telephone No: (Off) (Res) email:

Annexure No. 3 A

National Institute of Physical Medicine and Rehabilitation, Kalletumkara

Institutional Ethics Committee

Initial Review Submission Form for Research Proposal

1. Title of the research proposal
2. Name of the Principal Investigator with qualification and designation
3. Name of the Co-Investigator(s) with qualifications and designation
4. Name of the Institute / Hospital / Field area where research will be conducted
5. Forwarding letter from the Head of the Department / Institution / Guide.
6. Protocol of the proposed research: (includes and not limited to) clear research objectives, rationale for undertaking the investigations in human participants in the light of existing knowledge, inclusion and exclusion criteria for entry of participants. Precise description of methodology of the proposed research, including sample size (with justification), type of study design (observational, experimental, pilot, randomized, blinded etc.), intended intervention, dosages of drugs, route of administration, duration of treatment and details of invasive procedures if any, Plan to withdraw or withhold standard therapies in the course of research. Plan for statistical analysis of the study. Ethical issues in the study and plans to address these issues.
7. Proposal should be submitted with all relevant enclosures like proforma, case report forms, questionnaires, follow-up cards, participant recruitment procedures and brochures, if any, Informed consent process, including patient information sheet and informed consent form in English and local language(s). Investigator's brochure for trial on drugs/ devices/ vaccines/ herbal remedies and statement of relevant regulatory clearances. Source of funding and financial requirements for the project.
8. For any drug / device trial, all relevant pre-clinical animal data and clinical trial data from other centres within the country / other countries, if available.
9. Usefulness of the project / trial
10. Expected ‘benefits’ to volunteers / community. ‘Benefits’ to other categories if any
11. Explain all anticipated ‘risks’ (adverse events, injury, discomfort) of the project. Efforts taken to minimize the ‘risks’. Proposed compensation and reimbursement of incidental expenses and management of research related and unrelated injury/ illness during and after research period. Description of the arrangements for indemnity, if applicable in study-related injuries and description of the arrangements for insurance coverage for research participants (which will be in accordance to ICMR guidelines), if applicable.

12. Agreement to report all Serious Adverse Events (SAE) to NIPMR- IEC, KALLETUMKARA.
13. Other financial issues including those related to insurance (which will be in accordance to ICMR guidelines).
14. An account of storage and maintenance of all data collected during the trial.
15. Research proposals approval by scientific advisory committee
16. For international collaborative study details about foreign collaborators and documents for review of Health Ministry's Screening Committee(HMSC) or appropriate Committees under other agencies/ authority like Drug Controller General of India (DCGI)
17. For exchange of biological material in international collaborative study a MoU/ Material Transfer Agreement between the collaborating partners.
18. Statement of conflicts of interest, if any.
19. Agreement to comply with the relevant national and applicable international guidelines, Good Clinical Practices (GCP) protocols for clinical trials.
20. All significant previous decisions (e.g., those leading to a negative decision or modified protocol) by other ECs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of the modification(s) to the protocol made on that account. The reasons for negative decisions should be provided
21. A statement on, probable ethical issues and steps taken to tackle the same like justification for washout of standard drug, or the use of placebo control.
22. Curriculum vitae of all the investigators with relevant publications in last five years.
23. Plans for publication of results / positive or negative / while maintaining the privacy and confidentiality of the study participants.
24. Any other information relevant to the study.
25. Signature of the Principal Investigator with date.

Note: The above information and enclosures should be furnished wherever necessary depending upon the nature of study proposal

Annexure 3B

FORMAT FOR SUBMISSION OF PROJECTS INVOLVING RESEARCH IN HUMAN SUBJECTS FOR CLEARANCE BY NIPMR-IEC(NIPMR-INSTITUTIONAL ETHICS COMMITTEE)

Submit five (5) copies of the Research Project along with Covering letter and 'soft copy' on email ***nipmrin@gmail.com*** along with a blank CD with the following information to the Member Secretary, Institution Ethics Committee at Room No., _____NIPMR, KALLETUMKARA, Tel No.__ . The Principle Investigator must submit protocol forwarded through the Head of Department.

No research project shall be / can be started unless ethics clearance/approval is obtained. Please bear in mind that no retrospective / post facto ethical clearance can be provided to research projects which were neither submitted nor wetted by the Institution Ethics Committee.

All submissions should be made in the prescribed Format of the **Institution Ethics Committee** with signatures of all the investigators. The submission must be accompanied with *Participant Informed Consent Form* (PICF) and *Participant Information Sheet* (PIS), both in English and Hindi/Concerned local Language, **in a simple layman's language, in a narrative form, directed to Participant covering all the points given on the website,** before it can be considered for placing before the Institution Ethics Committee. Also ensure that all the pages are numbered.

Project Submission Time: Submissions will be received on all working days. Proposals received will be processed in the coming Institution Ethics Committee meeting The frequency will change depending upon the Load and will be updated on the website: www.nipmr.org.in

While submitting replies raised by the Institution Ethics Committee, the candidates are advised to mention the Institution Ethics Committee reference number/s and also attach a copy of the comments of the Institution Ethic Committee. Moreover if the approval is required in a particular format, the same may be submitted in a CD.

Amendment Submission: While submitting amendments in protocols a covering letter should be provided clearly stating the changes and a certificate by the PI that the changes made in the protocol will not hamper the safety of the subject in anyway

Form to be filled by the Principal Investigator (PI) for submission to NIPMR- IEC(NIPMR-Institutional Ethics Committee), NIPMR, KALLETUMKARA

(For attachment to each copy of the proposal)

Serial No of IEC Management Office:

Proposal Title:

	Name, Designation, Department & Qualifications	**Address Tel & Fax Nos. Email ID**	**No of projects already with Investigator**	**Signature**
PI				
Co-PI / Collaborators 1.				
2.				
3.				
4.				
5.				
6.				
	Please attach detailed Curriculum Vitae of all Investigators (with subject specific publications limited to previous 5 years).			

Tick appropriately

Sponsor Information :							
1. Indian	a) Government ☐		Central ☐		State ☐		Institutional ☐
	b) Private ☐						
2. International	Government ☐		Private ☐		UN agencies ☐		
3. Industry	National ☐		Multinational ☐				
Contact Address of Sponsor:							
Total Budget:							
Who will bear the cost of investigation/implants Drugs/contrasts?	1. ☐ Patient 2. ☐ Project 3. ☐ Exempted 4. ☐ Other Agencies(Name)_____						

1.Type of Study: Cross Sectional ☐ Case control ☐ Cohort ☐ Review ☐ Participating Centre: Single center ☐ Multi-centric ☐ Others (Specify) ☐		
2. Status of Review: New ☐ Revised ☐		
3. Are you aware if this study/similar study is being done elsewhere? **If Yes,** attach details	Yes	No
4. Brief description of the proposal – Introduction, review of literature, aim(s) & objectives, justification for study, methodology describing the potential risks & benefits, outcome measures, statistical analysis and whether it is of national significance with rationale (Attach sheet with maximum 500 words):		
5**. Subject selection:** i. Number of Subjects :		
ii. Duration of study :		
iii. Will subjects from both sexes be recruited	Yes	No
iv. Inclusion / exclusion criteria given	Yes	No
v. Type of subjects Volunteers ☐ Patients ☐		
vi. Vulnerable subjects Yes ☐ No ☐ (Tick the appropriate boxes) pregnant women ☐ children ☐ elderly ☐ fetus ☐ illiterate ☐ physical disability ☐ terminally ill ☐ seriously ill ☐ intellectual disability ☐ economically & socially backward ☐ any other ☐		

vii. Special group subjects yes ☐ No ☐
(Tick the appropriate boxes)

captives	☐	institutionalized	☐	employees	☐
students	☐	nurses/dependent	☐	armed	☐
any other	☐	staff	☐	forces	

6. Privacy and confidentiality

i. Study involves - Direct Identifiers ☐
Indirect Identifiers/coded ☐
Completely anonymised/ delinked ☐

ii. Confidential handling of data by staff	Yes	No
7. Use of biological/ hazardous materials i. Use of fetal tissue or abortus	Yes	No
ii. Use of organs or body fluids	Yes	No
iii. Use of recombinant/gene therapy **If yes,** has Department of Biotechnology (DBT) approval for rDNA products been obtained?	Yes	No
iv. Use of pre-existing/stored/left over samples	Yes	No
v. Collection for banking/future research	Yes	No
vi. Use of infectious/bio hazardous specimens	Yes	No
vii. Proper disposal of material	Yes	No
viii. Will any sample collected from the patients be sent abroad? **If Yes, justify with details of collaborators**	Yes	No
a) Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration?	Yes	No

b) Sample will be sent abroad because (Tick appropriate box):

Facility not available in India ☐
Facility in India inaccessible ☐
Facility available but not being accessed ☐
If so, reasons…….

8. Consent : *Written ☐ Oral ☐ Audio-Visual ☐

i. Consent form : (tick the included elements)

Understandable language	☐	Alternatives to participation	☐
Statement that study involves research	☐	Confidentiality of records	☐
			☐

Sponsor of study ☐ Purpose and procedures ☐ Risks & Discomforts ☐ Benefits ☐ Compensation for participation ☐ Compensation for study related injury ☐		Contact information Statement that consent is voluntary ☐ Right to withdraw ☐ Consent for future use of biological material ☐ Benefits if any on future commercialization ☐ eg. genetic basis for drug development	
*If written consent is not obtained, give reasons:			
ii. Who will obtain consent? PI/Co-PI ☐ Research staff ☐		Nurse/Counsellor ☐ Any other ☐	
. Will any advertising be done for recruitment of Subjects? (posters,flyers,brochure,websites- if so kindly attach a copy)		Yes	No
10. Risks & Benefits: i. Is the risk reasonable compared to the anticipated benefits to subjects/community/country?		Yes	No
ii. Is there Physical/social/psychological risk/discomfort? **If Yes**, Minimal or no risk ☐ More than minimum risk ☐ High risk ☐		Yes	No
iii. Is there a benefit a) to the subject? Direct ☐ Indirect ☐ b) Benefit to socity ☐			
11. Data Monitoring **i.** Is there a data & safety monitoring committee/Board (DSMB)?		Yes	No
ii. Is there a plan for reporting of adverse events? If Yes, reporting a done to : Sponsor ☐ Ethics Committee ☐ DSMB ☐		Yes	No
iii. Is there a plan for interim analysis of data?		Yes	No
iv. Are there plans for storage and maintenance of all trial database? **If Yes**, for how long?		Yes	No
12. Is there compensation for participation? **If Yes,** Monetary ☐ In kind ☐ Specify amount and type:		Yes	No

13. Is there compensation for injury? **If Yes,** by Sponsor ☐ by investigator ☐ by insurance company ☐ by any other ☐	Yes	No
14. Do you have conflict of interest? **(financial/non financial)** If Yes, specify:		
Conflict of interest for any other investigator(s) (if yes, please explain in brief)	1_____Yes No 2_____Yes No 3_____Yes No 4_____Yes No	
15. Participant Information Sheet (mark √ if yes)	☐ Attached English Version ☐ Attached Hindi Version ☐ Certified that Hindi version is a true translation of English version	
16. Participant Informed Consent Form (mark √ if yes)	☐ Attached English Version ☐ Attached Hindi Version ☐ Certified that Hindi version is a true translation of English version	
17. Whether any work on this project has started or not?	(mark √ if yes, X if no) (Please enclose a separat certificate to this effect)	

Checklist for attached documents:

Covering letter, through proper channel.	☐
Project proposal-02 Copies	☐
Curriculum Vitae of Investigators	☐
Brief description of proposal	☐
Patient information sheet	☐
Informed Consent form	☐
Investigator's brochure for recruiting subjects	☐
Copy of advertisements/Information brochures	☐
Copy of clinical trial protocol and/or questionnaire	☐
Institutional Review Board clearance	☐
HMSC/DCGI/DBT/BARC clearance if obtained	☐
Undertaking that the study shall be done in accordance with ICMR and GCP guidelines	☐
In case of multi-centric study, IEC clearance of other centres must be provided	☐
Definite undertaking as to who will bear the expenditure of injury related to the project	☐
In case an insurance cover is intended, Insurance certificate must be provided (as per ICMR guidelines)	☐
Permission to use copyrighted Questionnaire/proforma	☐

Investigator should provide undertaking what they will do with the leftover sample tissue
Certificate/undertaking as mentioned in column 17
Others

Annexure-4 A

National Institute of Physical Medicine and Rehabilitation, Kalletumkara
Institutional Ethics Committee

Ongoing Approved Research Review Submission Form

1. Reference number
2. Month / Year of approval
3. Number of ongoing review
4. Title of the research proposal
5. Name of the Principal Investigator (PI) with qualification and designation
6. Name of the Co-investigator(s) (Co-PI) with qualification and designation
7. Duration of the Project
8. Source of funding & financial allocation for the project / trial
9. Has subject recruitment begun?
10. If subject recruitment has not begun, give reasons and proceed to No:20
11. How many subjects have been screened?
12. How many subjects have been recruited?
13. How many more to be recruited
14. Is subject recruitment continuing?
15. Are there any 'drop outs'?
16. Are subjects still receiving active intervention?
17. Have there been any adverse events? If yes, give details
18. Have there been any Serious Adverse Events? If yes, give details.
19. Have there been any unanticipated study-related problems?
20. Is there any new risk or benefit information? If yes, give details.
21. Are there any interim changes to the protocol or consent form? If yes, give details including submission of revised protocol and consent form for approval
22. Does the scientific literature indicate changes in knowledge relevant to the conduct of the study?
23. List of attachments for review, if any
24. Remarks, if any
25. Signature of the Principal Investigator with date.

Note: The above information and enclosures should be furnished wherever necessary depending upon the nature of study proposal.

Annexure-4 B

NIPMR-IEC (NIPMR-Institutional Ethics Committee), Kalletumkara

Format for submission of revised/additional documents, protocols and information regarding already approved projects to be submitted by the Principal Investigator (PI)
(Two copies of this form along with the revised documents to be submitted)

1. IEC Reference No :

2. Approval Date and Number :

3. Title :

4. Principal Investigator :

5. Purpose of this submission :

6. New documents being submitted: Please list the documents being submitted along with the differences from the previously approved documents in a tabular form as below:

Sl. No	List of Documents being submitted	List the modifications/revisions made from previously approved proposal, wherever applicable

Place:
Date:

Signature PI/Collaborator _____
Name:

Annexure 4C

Six monthly progress of Project

Institute Ethics Committee Reference No._____

Study title:_____

Name of the Principal Investigator _____

Designation / Department _____

Duration of Study _____

Date of Starting of the Study _____

Period of Six monthly progress report: from_____to _____

Progress:

Amendments if any:

Discontinuation reasons:

Progress:

Signature of Principal Investigator _____
Date:_____

Annexure 5

Communication of Decision of the NIPMR-IEC (NIPMR-Institutional Ethics Committee)

IEC No:

Protocol title:
Principal Investigator:
Name & Address of Institution:
☐ New review ☐ Revised review ☐ Expedited review
Date of review (D/M/Y): Date of previous review, if revised application:
Decision of the IEC/ IRB: ☐ Recommended ☐ Recommended with suggestions ☐ Revision ☐ Rejected
Suggestions/ Reasons/ Remarks:
Recommended for a period of :

Please note *

- **Inform IEC immediately in case of any adverse events and serious adverse events.**
- **Inform IEC in case of any change of study procedure, site and investigator**
- **This permission is only for period mentioned above. Annual report to be submitted to IEC**
- **Members of IEC have right to monitor the trial with prior intimation.**

Signature of Member Secretary
NIPMR-IEC,
KALLETUMKARA

Annexure 6

National Institute of Physical Medicine and Rehabilitation, Kalletumkara

NIPMR-IEC- (NIPMR- Institutional Ethics Committee)

No. IEC. ---------- **Date: ----------**

NIPMR-IEC APPROVAL NOTICE

To: [Name], Principal Investigator

Date:

Re: IEC Proposal No._____: [Title]

I am pleased to inform you that at the convened meeting of_____the IEC voted to approve/ approve an amendment, and to re-approve (renewal approval of the protocol and the consent form(s) is for 12 months) the above referenced protocol. As Principal Investigator, you are responsible for fulfilling the following requirements of approval:

1. All co-investigators must be kept informed of the status of the project.

2. Changes, amendments, and addenda to the protocol or the consent form must be submitted to the IEC for re-review and approval **prior** to the activation of the changes. The IEC number assigned to the project should be cited in any correspondence.

3. Adverse events should be reported to the IEC. New information that becomes available which could change the risk: benefit ratio must be submitted promptly for IEC review. The IEC and outside agencies must review the information to determine if the protocol should be modified, discontinued, or continued as originally approved.

4. Only approved consent forms are to be used in the enrollment of participants. All consent forms signed by subjects and/or witnesses should be retained on file. The IRB may conduct audits of all study records, and consent documentation may be part of such audits.

5. NIPMR - IEC Office require review of an approved study not less than once per 12-month period. **Therefore, a continuing review application must be submitted to the IEC in order to continue the study beyond the approved period.** Failure to submit a continuing review application in a timely fashion will result in termination of the study, at which point new participants may not be enrolled and currently enrolled participants must be taken off the study.

Sincerely,

Member Secretary, NIPMR- IEC Chairman, NIPMR-IEC