Dr. Rajendra Prasad Government Medical College (Dr. RPGMC)
Kangra at Tanda, Himachal Pradesh, India – 176 001
Institutional Ethics Committee (IEC)
DGCI Registration No. ECR/490/Inst/HP/2013
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Terms of Reference

- Head, Dr.RPGMC will appoint chairperson and members of IEC.
- Head, Dr.RPGMC will be an appellate authority for IEC matters.
- Committee members should refer to their responsibilities as stated by IEC, Dr. RPGMC. *(Refer tables below)*
- The appointment of IEC members is for three years (Duration might be extended in case of change in standard operating procedures)
- About one third of members will be changed once in every three years.
- Committee will be responsible for declaration of conflicts of interest to the Chairperson, if any, at each meeting.
- Committee will ensure protection of the dignity, rights, safety and well-being of the research participants.
- Committee will ensure adherence of ethical conduct of research by the investigator team.
- Committee will perform its function through competent initial and continuing review of all scientific, ethical, medical and social aspects of submitted research proposals.
- Committee will ensure that universal ethical values and international scientific standards are to be followed in terms of local community values and customs.
- Committee will ensure privacy of the individual and confidentiality of data including the documents related to meetings.
- Committee will review progress reports, final reports and any adverse events. It will also give needful suggestions regarding care of the participants and risk minimization procedures, if applicable.
- Committee will recommend appropriate compensation for research related injury, wherever required.
- Committee will carry out monitoring visits at study sites as and when needed.
- Committee may see that conduct of same/similar research by different investigators from same institution need not be done.

Membership Requirements

Position	Requirements
Chairperson	• Should not be currently affiliated to Dr. RPGMC. • Should possess at least a master's degree in health and non-health sector. • Should be honoured by international, national, and state government/non-government body. • Should have experience to work with ethics committee. • Should be able to spare time to conduct IEC meetings. • Should have good communication skills
Member secretary	• Should be regular employee (Faculty Member) of Dr. RPGMC. • Should possess master's degree in medical or non-medical field • Should possess research experience. • Should possess knowledge and experience in ethics. • Should have good communication skills. • Should be able to devote adequate time to manage IEC processes and procedures.
Basic Medical Scientists	• Should have basic degree/diploma in basic medical science. • One member should have a master degree/diploma in Pharmacology. • Should be able to spare time to attend committee meetings. • Affiliation to Dr. RPGMC is optional.
Clinician	• Should possess medical degree in clinical science. • Should possess clinical experience of not less than five years. • Should possess research experience of not less than five years. • Should be able to spare time to attend committee meetings. • Affiliation to Dr. RPGMC is optional.
Legal Expert	• Should have basic degree in law from a recognized institution/university. • Should possess legal experience of not less than five years. • Should be able to spare time to attend committee meetings. • Affiliation to Dr. RPGMC is optional.
Social Scientist	• Should possess master degree in social sciences/psychology/behavioural science, philosophy from a recognized institution/university. • Should have work experience of not less than five years. • Should be able to spare time to attend committee meetings. • Affiliation to Dr. RPGMC is optional.
Layperson	• Should be member of community. • Should be literate • Had not pursued a medical science/health related career. • Resident of district Kangra, Himachal Pradesh.

	• Should be aware of local dialect (*Kangri*), and *Hindi*. • Should be aware of moral values, norms, and culture of various areas of Himachal Pradesh. • Should be involved with community. • Should be able to spare time to attend committee meetings.

Member Responsibilities

Position	Responsibilities
Chairperson	• Conduct IEC meetings and be accountable for independent and efficient functioning of the committee • Conduct meetings and ensure active participation of all members of committee • Approve minutes of meetings • Seek any conflict-of-interest declaration from committee members • Handling of complaints against researchers, committee members, conflict of interest issues and requests for use of committee data, etc
Member Secretary	• Receiving, organizing, and circulating proposals for review. • Scheduling of IEC meetings. • Preparation of meeting agenda. • Documentation of IEC meetings. • Issuing IEC certificates and comments made by IEC to researchers submitting proposal for approval. • Facilitate training of committee members. • Ensure functioning of IEC as per SOPs. • Assess need of requested research proposals for expedited review/exemption from review/full review. • Assess need to call subject experts/community representative and obtain a prior scientific review. • Update SOPs in case of changes.
Basic Medical Scientists	• Conduct scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, adverse effects, protocol deviation, progress and completion report • Assess drug safety and pharmacodynamics in case of a drug trail (by Pharmacologist)
Clinicians	• Carry out 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 (adverse events, protocol deviation or violation, progress and completion report) • Review medical care, facility and appropriateness of the principal investigator, provision for medical car, management and compensation. • Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.
Legal Expert	• Ethical review of the proposal, participant information sheet, and informed consent form along with translations, any memorandum of understanding, agreements of clinical trails, regulatory approval, insurance document, other site approvals, researcher's undertaking,

	protocol specific other permissions, such as, stem cell committee for stem cell research, government approvals for international collaboration, compliance with guidelines etc. • Interpret and inform committee members about new regulations if any.
Social Scientist	• Ethical review of the proposal, participant information sheet, and informed consent form 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, participant information sheet, and informed consent form 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.

Standard Operating Procedures (SOPs) for Resignation/Removal/Replacement of Members

- Members may resign from their position by submitting a formal letter to Chairperson.
- Member may be disqualified from their position in a case of,
    - Routine absence with a unanimous agreement of all remaining members.
    - Chairperson will have autonomy about giving a chance or not to member.
    - Chairperson should write a letter to absentee for her/his position.
    - Decision to remove member lies with the Chairperson, if reason seems justifiable.
- Immediate expulsion will be done if member does not comply to the responsibilities set for the members (stubborn- sets up stage for argument/ non-punctual/ not thorough with the job assigned)
- Members that have resigned or have been disqualified may be replaced by Principal, Dr.RPGMC.

Training of Members

Purpose and Scope: All members are updated and trained for changes/updates of procedures, technology, information, and ethics. It will be applicable to all committee members. Ethics committee office, Dr.RPGMC will ensure periodic trainings.

Topics:

- Ethical Guidelines for Biomedical Research on Human Participants, ICMR-2017
- Good Clinical Practice: Consolidated Guidance
- World Health Organization (WHO) Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, 2011
- New Drugs and Clinical Trial rules, 2019
- Trainings will be formal to all members on recent amendments and guidelines.

Recoding:

- All records like training curriculum, attendance sheet, etc. will be kept at IEC, Dr. RPGMC office.
- Record will have following information
    - Name:
    - Position in IEC: Chairperson, Member Secretary, Basic Medical Scientist, Legal Expert, Lay Person, Clinician.
    - Name of meeting/workshop/Conference
    - Date of meeting/workshop/Conference
    - Venue of meeting/workshop/Conference
    - Financial support by

Standard Operating Procedure for Protocol Review

- Researchers (Faculty, residents, and students) should submit research proposals;
    - Soft copy: iecdrpgmc@gmail.com
    - Hard Copies (Three): Room No: 831, third floor, Community Medicine, Paraclinical Block, Dr. RPGMC, Kangra at Tanda, 176001, Himachal Pradesh.
- Committee members should be given enough time (at least 1 week) to review the proposal and related documents, except in the case of expedited review.
- Committee members will not consult submitted protocols except during the scheduled meeting.
- Member Secretary will ensure completeness of documents for;
    - Cover letter to the Chairperson/Member Secretary
    - Type of review requested
    - Study Protocol: It should include, as applicable;

• Title page carrying the title of the proposal with signatures of the investigators • Brief/lay summary • Background with rationale of why a human study is needed to answer the research question • Justification of inclusion/exclusion of vulnerable populations • Clear research objectives and end points • Eligibility criteria and participant recruitment procedures • Detailed description of the methodology of the proposed research, including sample size (with justification), type of study design (observational, experimental, pilot, randomized, blinded, etc.), types of data collection, intended intervention, dosages of drugs,	• Procedure for seeking and obtaining informed consent with a sample of the patient/participant information sheet and informed consent forms in English and local languages. AV recording if applicable; informed consent for stored samples • Plan for statistical analysis of the study • Plan to maintain the privacy and confidentiality of the study participants • Research involving more than minimal risk, an account of management of risk or injury • Proposed compensation, reimbursement of incidental expenses and management of research related injury/illness during and after research period

route of administration, duration of treatment and details of invasive procedures, if any; • Duration of the study • Justification for placebo, benefit–risk assessment, plans to withdraw. If standard therapies are to be withheld; justification for the same.	• Provision of ancillary care for unrelated illness during the duration of research • An account of storage and maintenance of all data collected during the trial • plans for publication of results – positive or negative – while maintaining confidentiality of personal information/ identity • ethical considerations and safeguards for protection of participants.

  - The correct version of the participant information sheet and informed consent form in English and Hindi.
  - Case record form/questionnaire.
  - Investigator's brochure (as applicable for drug/biologicals/device trials)
  - Details of funding agency/sponsor and fund allocation (if applicable)
  - Undertaking with signatures of investigators.
  - Undertaking that no financial liability will be incurred to participants during study.
  - Regulatory permissions (as applicable).
  - Memorandum of Understanding (MoU) in case of studies involving collaboration with other institutions (if applicable).
  - Clinical trial agreement between the sponsors, investigator and the head of the institution(s) (if applicable).
  - Documentation of clinical trial registration (preferable).
  - Any additional document(s), as required by IEC (such as other IEC clearances for multicentric studies)
- The Member Secretary/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 committee review.
  - Expedited review can be conducted by Chairperson, Member Secretary and one or two designated members.
- A researcher will not decide that her/his proposal falls in the exempted, expedited or full review category.
- Researcher can approach the EC with appropriate justification for the proposal to be considered as exempt, expedited or if waiver of consent is requested.
- Committee will review all the proposals as forwarded by Member Secretary.

- Requirement and procedure of additional review by an independent expert will be decided during meeting.
- Committee will meet regularly with adoption of best practices in order to reduce the turn around time.
- Committee mat give decision;
    - Approved – with or without suggestions or comments;
    - Revision with minor modifications/amendments – approval is given after examination by the Member Secretary or expedited review, as the case may be;
    - Revision with major modifications for resubmission – this will be placed before the full committee for reconsideration for approval;
    - Not approved (or termination/revoking of permission if applicable) – clearly defined reasons must be given for not approving/terminating/revoking of permission
- Granted approval may be for the entire duration of the proposed research or can be subject to annual review depending on the type of study.
- Depending on the risk involved, the progress of the proposal may be monitored annually or at shorter intervals (quarterly, half yearly) as per decision of committee. Approval may be continued if progress is satisfactory.
- Committee may decide to reverse its positive decision on a study if it receives information that may adversely affect the benefit-risk assessment.
- The researcher will have an opportunity to reply/clarify to IEC comments or to discuss or present her/his stand.
- The researcher can also approach the head of the institute who serves as an appellate for IEC matters.
- The head of the institute as appellate has the power to dissolve the IEC or reappoint an IEC.

Standard Operating Procedures (SOPs) for Vulnerable Population

Vulnerable persons are those individuals who are relatively or absolutely incapable of protecting their own interests because of personal disability; environmental burdens; social injustice; lack of power, understanding or ability to communicate or are in a situation that prevents them from doing so. They may have an increased likelihood of incurring additional harm as they may be relatively (or absolutely) incapable of protecting their own interests. In general, such participants should be included in research only when the research is directly answering the health needs or requirements of the group. On the other hand, vulnerable populations also have an equal right to be included in research so that benefits accruing from the research apply to them as well. There are certain characteristics as they are associated with vulnerability; (Refer table in end)

- Legal: Children and clinical conditions like cognitive impairment and unconsciousness. As they are incapable of making a voluntary informed decision for themselves and their autonomy is compromised temporarily or permanently.
- Situational: Economically or socially or politically disadvantaged, (for example, certain ethnic or religious groups, individuals/communities which have hierarchical relationships, institutionalized persons, humanitarian emergencies, language barriers and cultural differences). They are able to give consent, but their voluntariness or understanding is compromised due to their situational conditions. It may also be that they are unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate which may lead them to give consent.

- Principles of inclusion;
  - Equal right to be included in research so that benefits accruing from the research apply to them as well.
  - Research should answer the health needs of the group.

- Participants must be empowered, to the maximum extent possible, to enable them to decide by themselves whether or not to give assent/consent for participation.
- Special care must be taken to ensure participant's privacy and confidentiality, especially because breach of confidentiality may lead to enhancement of vulnerability.
- All stakeholders must ensure that additional protections are in place to safeguard the dignity, rights, safety and wellbeing of these individuals.

- Protocols involving research among vulnerable population will undergo complete review. There will not be an exemption or expedition.
- Committee will assess that researcher take additional precaution should be taken to avoid exploitation/retaliation/reward/credits, etc., as they may either feel intimidated and incapable of disagreeing with their caregivers, or feel a desire to please them.
- Committee will act to protect rights and reduce the vulnerability for research by careful determination of risks and benefits. Committee will identify the risk minimization strategies.
- Committee will ensure that there should be no coercion, force, duress, undue influence, threat or misrepresentation or incentives for participation during the entire research period.
- Committee will assess the need for repeated education/information about the research, benefits, risks and alternatives, if any.
- Committee will assess for any form of stigmatization and discrimination to participants.
- Committee will assess the need to set-up support system to deal with medical and social problems.
- Committee will ensure their privacy, confidentiality and rights is required at all times during conduct of research and even after its completion.

Table: Examples of vulnerable population:

- Economically and socially disadvantaged (unemployed individuals, orphans, abandoned individuals, persons below the poverty line, ethnic minorities, sexual minorities – lesbian/ gay/bisexual and transgender (LGBT), etc.)
- Unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate which may lead them to give consent.
- Children (up to 18 years).
- Women in special situations (pregnant or lactating women, or those who have poor decision-making powers/poor access to healthcare)
- Tribals and marginalized communities
- Refugees, migrants, homeless, persons or populations in conflict zones,riot areas or disaster situations
- Afflicted with mental illness and cognitively impaired individuals, differently abled – mentally and physically disabled
- Terminally ill or are in search of new interventions having exhausted all therapies
- Suffering from stigmatizing or rare diseases or have diminished autonomy due to dependency or being under a hierarchical system (students, employees, subordinates, defence services personnel, healthcare workers, institutionalized individuals, under trials and prisoners

Quorum Requirements for Committee

- A minimum of five members or one third of the total members must be present at a meeting besides Member Secretary and Chairperson in order to issue a valid advice and/or decision, provided quorum is met.
- Professional qualifications of the quorum requirements should consist of:
    - One legal expert/social scientist as non-affiliated to Dr. RPGMC.
    - One Clinician
    - Two basic medical scientists
    - One pharmacologist
- As per revised Schedule Y of Drugs & Cosmetics Act, 1940, amended in 2005, the ethics committee approving drug trials should have in the quorum at least one representative from the following groups:
    - One pharmacologist
    - One clinician
    - One legal expert
    - One social scientist
    - One lay person

Management of Conflict of Interest (COI)

- Researchers:
  - Committee will review any declaration of COI by a researcher and suggest ways to manage these.
  - Academic or research institutions require a review to probe possible COI between scientific responsibilities of researchers and business interests (for example ownership or part-ownership of the researcher in the company developing a new product).
  - Committee will determine if the COI could damage the scientific integrity of a proposal or cause harm to research participants and should advise accordingly.
  - Committee will decide that whether the protocol should be rejected based on COI?
- Committee Members:
  - If any committee member has any COI with to be reviewed proposal, She/He is asked to declare and leave the room at time of said protocol and decision making.
  - The COI is to be declared in writing to the Chairperson and that will be kept as a record.
  - Committee will ensure that there will be no harm or lessen the benefits to participants.

Source: Indian Council of Medical Research. National Ethical Guidelines for Biomedical and Health Research involving Human Participants. 2017, New Delhi. India. Available at: https://naitik.gov.in/DHR/resources/app_srv/DHR/global/pdf/ICMR_National_Ethical_Guidelines2017.pdf