Standard Operating Procedures for Institutional Ethics Committee, Rajendra Institute of Medical Sciences, Ranchi

I. Standard Operating Procedure (SOP)
IEC, RIMS, RANCHI Version: 5.0 Date: 21.02.2022
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Name and Designation	Signature with date
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PREAMBLE

In response to the query raised at the Naitik portal of DHR, Govt of India, there is a need of amendment in Standard Operating Procedure (SOP) of the Institutional Ethics Committee, RIMS, Ranchi. As per the need, we have added role wise membership requirements and responsibilities and the guiding principle for academic, sponsored, and outside proposals in the new version of the SOP 01. Keeping in view the research in the field of genetics and genomics, we have also added two new headings in the new version of the SOP 'Human genetics testing and research' and 'Biobanking and data-sets'. We present the SOP 01, version 5.0 of IEC for the aforesaid purpose.

Members, SOP team.

22/02/22

Prof Dr Satish Chandra

22/02/2022

Dr S B Singh

Anupa Prasad. 22.02.22.

Dr Anupa Prasad

22/02/22

Serial No.	Current Version Number	Effective Date	Description (Changes from the previous)
1	1.0	22nd January 2016	Not Applicable
2	2.0	20th September 2018	Change in SOP Sl. No. 13 Recordkeeping and archival, page No. 14, point No. 3 is changed from 3 years to 5 years
3	3.0	25th December 2020	i. Introduction of "Preparing SOPs" page No. 4-8 ii. Introduction of "General Principles for functioning" Page No.9-10 iii. Introduction of "Informed Consent" Page No. 11-12 iv. Introduction of "Special considerations/Protection of Vulnerable Population" Page No. 13-16 v. Change in Composition of IEC, RIMS, Ranchi Page 18 vi. Introduction of "Office bearers' and Member Specific Roles and Responsibilities" Page No. 19-23 vii. Change in EC Review Fees, Amendment Fees and Archival Fee, Revised Initial review fee. Page No.23-25 viii. Introduction of "Review of Serious Adverse Event Reports and Compensation issues" Page No. 27-29 ix. Introduction of "Review of the Study Completion Report" Page No. 29 x. Introduction of "Waiver of the Informed Consent" Page No. 31 xi. Accountability of researchers for the protection of the environment and resources. Point 6; Page No. 32 xii. Introduction of "Annexures 1 to 14" Page No 35-53
4.	4.0	15th September, 2021	i. References of Schedule Y replaced with New Drugs and Clinical trial rules, 2019. ii. Informed Consent (at number 5) and "Special considerations/ Protection of Vulnerable Population" brought down (to page number 33-36) near waiver of consent;

			Proforma for the Subject Information Sheet attached as Annexure 14 [Participant Informed Consent Form for participants more than 18 years of age (FORM 3A)] and Parents/Legally accepted representative (LAR) Consent *Form* (FORM 3B) , Assent Form (FORM 3C) attached as annexure 15, 16 and annexure 17. iii. Office bearers' and Member Specific Roles and Responsibilities. iv. Record Keeping and Archiving name changed to Maintenance of records by the IEC for clinical trials and points added. v. IEC approval notice for the studies in annexure 07 changed to the Format to accord approval to clinical trial protocol by the IEC, RIMS, Ranchi. vi. Recommendations of payments of compensation and determination The Quantum of Compensation in Cases of Clinical Trial related Injury or Death added in section 1 vii. In section 13, Recommendations of payments of compensation in case of serious adverse event (SAE) criteria for assessment of trial relatedness of a serious adverse event, and determination the quantum of compensation in cases of Clinical Trial related Injury or death are added. viii. Form 2 (Form to be filled up by PI for submission to the IEC) added as annexure 10. ix. Checklist for verification of proposals submitted to IEC attached as annexure-19 (FORM 4). x. Record Keeping and Archiving at the office of IEC, RIMS, Ranchi named as Maintenance of records by Institutional Ethics Committee, RIMS, Ranchi for clinical trial (Section 20, page no. 40).

5.	5.0	18th February, 2022	Appointment of IEC members modified; point no. 1 removed in page 16. Qualifications and membership requirements added in page 19-21 Special requirements while doing research on tribal population added as point 18.5 in page 45 New header added- 'Human genetics testing and research' in page 48-53 New header added- 'Biobanking and data sets' in page no. 53-57

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IEC, RIMS, RANCHI

1. PREPARING STANDARD OPERATING PROCEDURES (SOPs): WRITING, REVIEWING, DISTRIBUTING & AMENDING SOPS FOR THE INSTITUTIONAL ETHICS COMMITTEE (IEC), RIMS, RANCHI.

Purpose: This SOP defines the process for writing, reviewing, distributing, and amending SOPs within the IEC, RIMS, Ranchi.

The SOPs will provide clear, unambiguous instructions to conduct activities of the IEC in accordance with the ICMR guidelines 2006, WHO Operating Guidelines for Ethical Review Committee that Review Biomedical Research, and ICH (International Conference on Harmonization) Good Clinical Practice (GCP), Code Federal Regulations Title 21.

Scope: This SOP covers the procedures of writing, reviewing, distributing, and amending SOPs within the IEC, RIMS, Ranchi.

Roles and Responsibilities of the Members and the Secretariat: It is the responsibility of the chairperson of the IEC to appoint the SOP Team to formulate the SOPs. SOP team will prepare the draft SOPs. The draft SOPs will be reviewed and approved by the IEC members. The SOPs will then be signed by Director, RIMS, Ranchi. The SOP team will be responsible to amend the SOPs as and when required.

The SOP team will consist of Member Secretaries of IEC, administrative staff, and one or two other IEC members. The team will-

- Assess the request(s) for SOP revision in consultation with the Secretariat and Chairperson
- Propose a new, or modification in existing SOPs as needed
- Select the format and coding system for the SOPs
- Draft the SOP • Review the draft SOP
- Submit the draft for approval to Chairperson.

Chairperson of the IEC:
Will appoint SOP Team
Will review and approve the SOPs
Will sign the approved SOP

IEC members:
Will review and sign the SOPs
Will return all out of date SOPs to IEC office

Secretariat of IEC:

- Will co-ordinate activities of writing, reviewing, distributing, and amending SOPs.
- Maintain on file all current SOPs and the list of SOPs.
- Maintain a file of all SOP amendment requests
- Maintain an up-to-date distribution list of each SOP circulated to IEC members
- Maintain a record of the investigators to whom SOPs are distributed against a requisition if any
- Ensure that all IEC members and involved administrative staff have access to the SOPs
- Ensure that the IEC members and involved staff are working according to the current version of SOPs
- Maintain a file of all previous SOPs of the IEC
- Assist in the formulation of SOP procedure
- Ensure SOP revisions as and when required to comply with national regulations.

Detailed instructions

Identify the need for new or amendment to the SOP

Any member of the IEC, or administrative staff or investigators or administration can make a revision request or notices an inconsistency/ discrepancy / has any suggestions on how to improve the existing SOPs or requests to design an entirely new SOP, can put forth his / her request by using the Request Form for Formulation of new SOP/ Revision of an SOP Form. This Formulation of the new SOP/ Revision of an SOP Form is submitted to the Chairperson, IEC.

The Chairperson will inform all IEC members about this request in a regular full board meeting. If IEC members agree to the request, the Chairperson will appoint an appropriate SOP team comprising of Member Secretaries of both committees. The Chairperson may also appoint one or two committee members as members of the SOP team, if necessary. This designated team will proceed with the task of revision/formulation process of the SOP. If IEC members do not agree to the request, no further action will be taken. The Chairperson will inform the person/ IEC member who requested modification of the SOP in writing about the decision.

Appointment of the SOP team

The Chairperson will constitute an SOP team consisting of the Member-Secretaries administrative staff and one or two other IEC members who have a thorough understanding of the scientific and ethical review process. The SOP writing team will carry out the subsequent steps.

List of relevant SOPs

- Write down step by step all the procedures of the IEC
- Organize, devise and name each process

Design a format and layout

Each SOP should be given a number and a title that is self-explanatory and is easily understood A unique code number with the format SOP xx / Vy will be assigned to each SOP. xx is a two-digit number assigned to a specific SOP. "V" refers to the version of the SOP and "y" is a number identifying the version e.g.-SOP01/V4 is SOP number 01 with V=version no.04

The first page of each SOP document will be signed and dated by the authors, the IEC members who have reviewed the SOPs, IEC Chairperson and Director, RIMS, Ranchi.

Preparation and submission of the final draft

- All the members of IEC may review the draft / revised SOP
- During respective IEC meetings, members can put forth their suggestions/comments on the draft / revised SOP
- The suggestions agreed upon unanimously by all IEC members will be incorporated and the final draft SOP will be formulated.
- The SOP team would stand automatically dissolved once the IEC takes the final decision regarding the SOP.

Final Approval of new/revised SOP

- The final version will be presented to the Chairperson of committee for review and approval. The Chairpersons will sign and date the SOP on the first page of the SOP document.
- This approved document will then be submitted to the Director, RIMS, Ranchi for acceptance. This date of approval is declared as the effective date for implementing the SOP.

Implementation, distribution, and filing of SOPs

- Approved SOPs will be implemented from the effective date.
- The Member Secretary will discuss the approved SOPs with the administrative staff and instruct them to implement the SOP accordingly.
- Approved SOPs will be distributed to IEC members and IEC staff according to the distribution list.
- When a revised version is distributed, the old version will no longer be effective. A copy of the old version will be archived in a master file.
- One complete original set of current SOPs will be archived in the SOP master file, by the IEC Secretariat and maintained in the IEC Office.
- A copy of the SOP master file will be maintained in the individual offices of IEC and DSMSC.
- Photocopies made from the paper versions of the SOP will be considered official only if stamped and signed by Member Secretary or authorized individual. A distribution log would be maintained.

Review and request for revision of an existing SOP

- Any member of the IEC or administrative staff or investigators or administration who notices that current SOPs have some lacunae or have any suggestions to improve a procedure should make a written request
- If IEC agrees with the request, the Chairperson will appoint an appropriate team for the revision process. If the committee does not agree, the Chairperson will inform the concerned individual who requested revision.
- The Member Secretary initializing the review and the Secretariat assists the Member Secretary of the SOP at least once every 2 years and records the dates of review in the SOP master file.

Manage and archive old SOPs

Old SOPs should be retained and marked "superseded" and archived in a file by the secretariat. The process of evolution of previous SOPs of the IEC will be documented in a defined format.

References

1. ICMR Ethical Guidelines for Biomedical Research on Human Participants, ICMR (2017)
2. WHO Operational Guidelines for Ethical Review Committee that Review Biomedical Research (Geneva 2000)
3. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) (1996)
4. Code Federal Regulation Title 21
5. TMC IEC SOP 2016
6. AIIMS Raipur IEC SOP, 2021.
7. New Drugs and Clinical Trial Rules, 2019, CDSCO.

Standard Operating Procedures for the Institutional ethics committee (IEC) of RIMS, Ranchi

[Rajendra Institute of Medical Sciences, Ranchi hereinafter referred to as "RIMS, Ranchi" 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 RIMS, Ranchi].

2. OBJECTIVE

The objective of SOP is to ensure quality and consistency in ethical review of Biomedical Research Proposal in accordance with ICMR Ethical guidelines for biomedical research on human subjects and drugs and cosmetics act rules, Govt. of India.

3. GENERAL PRINCIPLES FOR FUNCTIONING OF IEC, RIMS, RANCHI:

Principle of essentiality: IEC, RIMS, Ranchi will consider the necessity of the use of human participants for the research.

Principle of voluntariness: IEC will ensure that the rights of the participants are safeguarded, informed consent is taken from all the participants in local language and that respect is given to participants' willingness or non-willingness to participate in the study.

Principle of non-exploitation: IEC will ensure that there is an equitable selection of the participants and the benefits and burdens of the research are distributed fairly. Sufficient safeguards to protect the **vulnerable groups** would be ensured. The vulnerable populations include children, pregnant and lactating women, people with racial inequalities, economically or socially disadvantaged people, mentally challenged and mentally differently-abled persons, and persons with reduced autonomy (prisoners, students, subordinates, employees, defense service personnel).

Principle of social responsibility: The IEC will ensure that the research is being conducted in such a way that in any way social harmony in community relationships is not disturbed.

Principle of ensuring privacy and confidentiality: IEC will ensure the privacy of the potential participants. Their identity and records would be kept confidential by the researcher and access will be limited to only those authorized. In some special circumstances for a valid scientific or legal reason, IEC will have the right to breach the privacy of the information.

Principle of risk minimization: Due care will be taken by all stakeholders (including researchers, ECs, sponsors, and regulators) of RIMS, Ranchi at all stages of the research to ensure that the risks are minimal and appropriate care and compensation is given if any harm occurs.

Principle of professional competence: IEC will ensure that the research is planned, conducted, evaluated, and monitored throughout by competent persons with appropriate and relevant qualifications, experience, and/or training.

Principle of maximization of benefit: IEC will ensure that the research is designed and conducted in such a way that the benefits to the research participants and the society are maximized.

Principle of transparency and accountability: The research plans and outcomes emanating from the research being carried out at RIMS, Ranchi would be brought into the public domain through registries, reports, and scientific and other publications while safeguarding the right to privacy of the participants. Stakeholders involved in research would disclose any existing conflict of interest and manage it appropriately. The research would be conducted in a fair, honest, impartial, and transparent manner to guarantee accountability. Related records, data, and notes would be retained for the required period for possible external scrutiny/ audit.

Principle of environmental protection: IEC will monitor (it may appoint a sub-committee to) monitor the researchers who will be accountable for ensuring the protection of the environment and resources at all stages of the research, in compliance with existing guidelines and regulations.

4. ROLES AND RESPONSIBILITIES OF IEC, RIMS, RANCHI

A. The **IEC, RIMS, Ranchi** will review all types of research proposals involving human participants to s**afeguard the dignity, rights, safety, and wellbeing of all actual and potential research participants** before approving the research proposals. The goals of research, however important, will never be permitted to override the health and wellbeing of the human participants.

B. The **IEC, RIMS, Ranchi** 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** as well as justice are taken care of in planning, conducting and reporting of the research.

C. The **IEC, RIMS, Ranchi** 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 compensation. It will review the proposals before the commencement of the study as well as during the study period through appropriate, well-documented procedures. The review will 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.

D. 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.

E. 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 whether the research project is funded or non-funded, and if funded, then irrespective of the funding agency.

F. **IEC, RIMS, RANCHI** 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.

G. In case of **IEC, RIMS, RANCHI** revokes its approval according 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

H. In case of a **serious adverse event** or death occurring to the clinical trial participant, **IEC, RIMS, RANCHI** shall forward it's reporting on the serious adverse event or death, after due analysis, along with its opinion on the financial compensation, if any, to be paid by the sponsor or his representative, whosoever had obtained permission from the licensing authority as defined under rule 21(b) for conducting the clinical trial, to the chairman of the expert committee constituted by the licensing authority under appendix xii (gazette notification 30th January 2013) with a copy of the report to the licensing authority within twenty-one calendar days of the occurrence of the serious adverse event of death.

5. AUTHORITY FOR CONSTITUTING THE IEC, RIMS, RANCHI

The Director, RIMS, Ranchi will appoint the Chairperson and all the committee members based on their competence, experience and integrity. Members will confirm their acceptance to the Dean by providing all the required information for membership. The Chairperson will furnish any information or report to the Dean of Faculty, RIMS, Ranchi when required.

6. COMPOSITION OF IEC RIMS, RANCHI

The EC shall be multidisciplinary and multi-sectorial in composition. The **Institution Rajendra Institute of Medical Sciences, Ranchi** shall constitute the EC. Independence and competence shall be the characteristics of EC. The minimum number of members in the committee shall be seven and maximum number will be 15. It shall be constituted keeping in mind the representation of gender, scientific and non-scientific disciplines, clinical and non-clinical disciplines, the lay community, legal expertise, social science and others to represent different points of view, and to safeguard the interests and welfare of all sections of the community / society. The Committee shall comprise of a Chairperson, a vice chairperson, a Member Secretary, a joint member secretary, and other members from the critical categories, complying with the provisions of New Drugs and Clinical Trials Rules, 2019, and/or the National Ethical Guidelines for Biomedical and Health Research involving Human Participants of ICMR, 2017.

The composition shall be as follows:

1. Chairperson (not affiliated to the Institute)
2. Vice chairperson (not affiliated to the Institute)
3. Member secretary (from the Institute)
4. Joint Member secretary (from the Institute)
5. Basic Medical Scientist
6. Clinician
7. Legal expert
8. Lay person from the community
9. Social Scientists / NGO Representatives / Philosophers / Ethicist / Theologians

Expert Member/ Independent Consultants- Subject experts shall be invited to offer their views on review of research protocols and causality assessment for SAE. Their inputs shall be maintained on record and considered when reaching a decision. An expert member means a member who is a 'health care professional' (as mentioned below and registered by their respective council) and has professional qualifications or experience relating to the conduct of, or use of statistics in clinical research, unless those professional qualifications or experience relate only to the ethics of clinical research or medical treatment.

7. APPOINTMENTS

Director, RIMS, Ranchi will be responsible for making the appointment of committee members. Rule of appointments will be as following:

a. The member secretary shall be appointed from the institute.
b. All the members will serve for a period of 3 years. The membership will be renewed after the stated term of three years.
c. Members must accept the appointment in writing.
d. Members will be selected in their personal capacities, based on their interest, ethical and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the EC's work.
e. Members must disclose in writing any **conflict of interest**. The EC shall decide the extent to which members that might have a conflict of interest may participate in bringing out an advice/decision; refer to SOP- Confidentiality and Conflict of Interest Agreement. Members shall be required to sign a confidentiality agreement at the start of their term. [**Annexure 4, 5**]

7.1 Condition of appointment

a. A member should be willing to reveal his / her full name, profession and affiliation; all reimbursement for work and expenses, if any, within or related to the Committee as these details will be made available to the appropriate authority upon request.
b. A member should sign a confidentiality agreement regarding meeting deliberations, applications, information on research participants and related matters; in addition, all of the Committee administrative staff should sign a similar confidentiality agreement.

7.2 Appointment of new members

New members will be appointed under the following circumstances:

a. When a regular member completes his / her tenure.
b. If a regular member resigns or drops out before the tenure is completed.
c. If volume of proposals and frequency of review demands appointment of new members.
d. When a new member shall be appointed, he/she will be inducted in the same category to fulfill the norms the same category.

7.3 Conflict of interest

Conflict of interest (COI) is a set of conditions where professional judgement concerning a primary interest such as participants welfare or the validity of research tends to be unduly influenced by a secondary interest, financial or non-financial which may be personal, academic or political.

a. COI can be at the level of researchers, EC members, institutions or sponsors. If COI is inherent in the research, it is important to declare this at the outset and establish appropriate mechanisms to manage it.
b. IEC, RIMS, Ranchi has implemented policies and procedures to identify and mitigate conflicts of interest. It also educates the staffs about such conflicts.
c. Researchers have to ensure that the documents submitted to the EC include a disclosure of interests that may affect the research. IEC, RIMS, Ranchi will evaluate each study for any disclosed interests and ensure that appropriate means of mitigation are taken.
d. COI within the IEC would be declared and managed in accordance with standard operating procedure.

7.3.1 Policy to monitor or prevent COI

COI may also be defined as a set of conditions where professional judgement concerning a primary interest such as participant's welfare or the validity of research tends to be unduly influenced by a secondary interest, financial or non-financial (personal, academic or political). COI can be at the level of researchers, EC members, institutions or sponsors.
Situations where Conflict of Interest may arise when an IEC member, Investigator, research staff, or member of his/her immediate family:

a. has or will receive from the sponsor of the research financial or other form(s) of compensation; or
b. has a significant financial interest in the company/agency/firm that is sponsoring the research; or
c. discloses a conflict of interest to the governmental agency, or to the Institution or

[Immediate Family**:** Spouse or domestic partner, children and anyone who resides with the IEC member, Investigator, or research staff].

Significant Financial Interest: Anything of major monetary value, including but not limited to salary or other payment for services (e.g. consulting fees or honoraria); and intellectual property (e.g. patents, copyrights, and royalties from such rights).

7.3.2 Disclosure and Documentation of Financial Interest and COI

- The IEC will maintain a documented record of membership lists, lists of occupations/affiliations of members will be maintained.
- The IEC Chairperson or designee will ask IEC members for COI disclosure prior to each IEC Meeting.
- No IEC member may participate in the review of any project in which he or she has a conflicting interest, except to provide information requested by the IEC.
- Any disclosure of IEC member COI will be discussed prior to the deliberation of studies at each IEC Meeting. The IEC member may be asked to leave the meeting room during the formal discussion and voting on a research proposal where there is COI.
- If an investigator is a member of an IEC, the investigator has to submit a disclosure of interest document that may affect the research, if any to the IEC. However, the investigator cannot participate in the review or approval of any research in which he or she has a current or potential conflict of interest. The investigator should be absent from the meeting room while the committee discusses and votes on the research in which he or she has an interest.
- The Member Secretary will record any identified COI in the IEC meeting minutes.
- If COI disclosed prior to IEC Review, the investigator will be required to provide description of the relationship between investigator and/or immediate family with the sponsor of the research, statement in the informed consent form that addresses the conflict of interest, if required, and justification for exclusion of conflict of interest in the informed consent.
- COI developing after the IEC approval, the investigator will be required to inform the IEC chairperson or designee of the COI disclosure, submit the COI disclosure as an amendment

(revision) to the approved research protocol, and include a revised informed consent form that includes a statement addressing any potential conflict of interest, if appropriate. The IEC may require that COI be disclosed in the informed consent, that the Investigator or research staff member recuse him/herself as the principal Investigator (or part of the research staff, respectively), or from the study entirely.

7.4 Renewal of membership

a. The membership will be renewed after the stated term of three years.
b. Selection of members shall be done at least one month in advance.
c. There will be limit to the number of times that membership can be extended. To avoid Conflict of Interest (COI) and to bring new ideas and dimensions in the review, limitation the extension should be up to 1 or 2 times.
d. Extension of membership will be decided by Head of Institute.
e. Designated members of the EC who wish to attend EC meetings as observers shall read, understand, accept and sign the agreement contained in the Confidentiality / Conflict of Interest form (Annexure) at the beginning of the EC meeting and/or before scientific and ethical review tasks of the EC commence.

7.5 Resignation

a. If any member wishes to discontinue from the EC, he/she would be required to inform the Chairperson, in writing.
b. Members may voluntarily resign from the committee at a month's notice citing appropriate reasons and incase of internal members their membership would be considered withdrawn, if they resign from the Institute.

7.6 Termination procedure

During the tenure, Chairperson shall have the authority to terminate/ disqualify any of the members who has not complied with the conditions of appointment, is absent without prior information for three consecutive meetings or on an occurrence of any event that casts a serious doubt on the integrity or ethics of the member.

In all such situations/ circumstances, the Head of Institute shall be informed of such termination to the member prior or within 15 calendar days of termination. Documentation of the termination shall be recorded in the minutes of the next duly constituted EC meeting and the EC membership roster and circulars shall be revised.

8. QUALIFICATIONS AND MEMBERSHIP REQUIREMENTS

8.1 Educational requirements for the members

a. IEC members have a need for initial and continued education regarding the ethics and science of biomedical research. All IEC members must be conversant with ICMR Guidelines for Research involving Human Subjects 2006, and ICH-GCP guidelines.
b. IEC members will receive introductory training material in research bioethics and functioning of IEC and will be exposed to ongoing opportunities for enhancing their capacity for ethical review.
c. The IEC members will be encouraged to receive ongoing training by attending workshops at least once every year.
d. The IEC will conduct workshops from time to time to impart training to the IEC members and Institutional faculty members. The training programs would be scheduled and spread over the year.

Educational requirements of the members will be as follows in the table given below:

Serial No.	Member	Qualifications and Membership requirements
1.	Chairperson/ Vice-chairperson	Non-affiliated to RIMS, Ranchi. A well-respected person from any background with prior experience of having served/ serving in an EC
2.	Member Secretary	Affiliated to RIMS, Ranchi Should have knowledge and experience in clinical research and ethics, be motivated and have good communication skills. Should be able to devote adequate time to this activity which should be protected by the institution
3.	Basic Medical Scientist	Affiliated/ non-affiliated to RIMS, Ranchi Non-medical or medical person with qualifications in basic medical sciences In case of EC reviewing clinical trials with drugs, the basic medical scientist should preferably be a pharmacologist
4.	Clinicians	Affiliated/ non-affiliated to RIMS, Ranchi Should be individual/s with recognized medical qualification, expertise and training.

5.	Legal Experts	Affiliated/ non-affiliated to RIMS, Ranchi • Should have a basic degree in Law from a recognized university, with experience • Desirable: Training in medical law.
6.	Social scientist/ philosopher/ ethicist/theologian	Affiliated/ non-affiliated to RIMS, Ranchi Should be an individual with social/ behavioral science/ philosophy/ religious qualification and training and/or expertise and be sensitive to local cultural and moral values. Can be from an NGO involved in health-related activities
7.	Lay person	Non-affiliated to RIMS, Ranchi • Literate person from the public or community • Has not pursued a medical science/ health related career in the last 5 years • May be a representative of the community from which the participants are to be drawn • Is aware of the local language, cultural and moral values of the community • Desirable: involved in social and community welfare activities

9. MEMBER SPECIFIC ROLES AND RESPONSIBILITIES

9.1 IEC Members

The IEC will have the following office bearers who have the expertise and professional qualifications to review the proposals submitted.

Serial No.	Member	Member specific roles and responsibilities
1.	Chairperson/ Vice-chairperson	• Conduct IEC meetings and be accountable for independent and efficient functioning of the committee • Ensure active participation of all members (particularly non-affiliated, non-medical/ non-technical) in all discussions and deliberations • Ratify minutes of the previous meetings • In case of anticipated absence of both Chairperson and Vice Chairperson at a planned meeting, the Chairperson should nominate a committee member as Acting Chairperson or the members present may elect an Acting Chairperson on the day of the meeting. The Acting Chairperson should be a non-affiliated person

		and will have all the powers of the Chairperson for that meeting. • Seek COI declaration from members and ensure quorum and fair decision making. • Handle complaints against researchers, IEC members, conflict of interest issues and requests for use of IEC data
2.	Member Secretary	• Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review • Schedule IEC meetings, prepare the agenda and minutes • Organize IEC documentation, communication and archiving • Ensure training of IEC secretariat and IEC members • Ensure SOPs are updated as and when required and ensure 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.
3.	Basic Medical Scientist	• Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report • For clinical trials, pharmacologist to review the drug safety and pharmacodynamics.
4.	Clinicians	• 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 car, management and compensation. • Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.
5.	Legal Experts	• 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, such as, stem cell committee for stem cell research, HMSC for international collaboration, compliance with guidelines etc. • Interpret and inform EC members about new regulations if any.

6.	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.
7.	Lay persons	• 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.

9.2 The Secretariat

The Secretariat will be composed of the Member Secretary, IEC, and the administrative supporting staffs. The supporting staff consists of staff members of RIMS, appointed by the Director, RIMS. The secretariat shall have the following functions:

1. Organization of an effective and efficient tracking procedure for each proposal received.
2. Preparation, maintenance and distribution of study files.
3. Organization of regular IEC meetings.
4. Preparation of the agenda and the minutes of the meetings,
5. Maintenance of the IEC records and archives.
6. Communication with IEC members and PIs.
7. Arrangement of training for personnel and IEC members.
8. Provision of the necessary administrative support for IEC related activities to the Member Secretary, IEC.
9. Receipt of IEC processing fees for pharma-funded projects and the issue of official receipts for the same.

9.3 IEC administrative supporting staffs

1. There will be administrative attendant/s /helper/s who will help the IEC Chairperson and Member Secretary in executing functions of the IEC. Additional staffs may be appointed and duties assigned as and when deemed necessary by the IEC. The eligibility criteria for new staff to be appointed will be laid down depending on the required job profile. The need for appointment of administrative staff, job profile and qualifications may be recommended by IEC members during regular IEC meeting and will be recorded in minutes. These will be forwarded to the Director, RIMS.
2. The administrative staff will be appointed by conducting formal interviews as per RIMS policy.

Duties of the administrative staffs:

1. Organizing an effective and efficient tracking procedure for each proposal received.
2. Preparing, maintaining and distributing study files
3. Organizing IEC meetings regularly
4. Preparing the agenda and minutes of the meetings
5. Constitution of Institutional Ethics Committee,
6. Maintaining IEC records and archives.
7. Communicating with IEC members and PIs.
8. Arranging training for personnel and IEC members
9. Providing necessary administrative support for IEC related activities to the Member Secretary, IEC.
10. Receiving IEC processing fees and issuing official receipts for the same.
11. Corresponding with the IEC members, external experts and investigators.
12. Making the pre and post-arrangements of IEC meetings.
13. Preparing the agenda and minutes of the IEC meetings.
14. Answering queries of the investigators.
15. Filing study related documents.
16. Archiving and maintaining the study files.
17. Preparation for accreditation, audits
18. Training for investigators, key study personnel, IEC members, and IEC staff.
19. Participate in the development and subsequent implementation of SOPs
20. Developing an effective and efficient tracking procedure

Duties of the Attendant/s /Helper/s:

1. Assisting the secretariat in arranging the IEC meetings.
2. Dispatching sets of study documents to IEC members and external experts.
3. Receiving the study related documents from and dispatching the IEC letters to the investigators.

4. Filing study related documents.
5. Archiving and maintaining the study files
6. Corresponding with the IEC members and external experts. The IEC staff will report to the Member Secretary and/or Chairperson.
7. The office timings for the IEC staff will be as per RIMS rules and regulations. The staff will avail leave as per RIMS norms.

Directors, Head of Institution, Superintendents, Administrative officers who are responsible for business development will not be involved in the review process. In the absence of the Chairperson, Vice Chairperson will chair the meeting. In the absence of both, a member who is independent of the institution will chair the meeting as the Acting Chairperson.

10. QUORUM REQUIREMENTS

Minimum of 50% of committee strength and not less than 7 members are required to constitute the quorum for the meeting of which at least one member has to be from outside the institution, and one member will be a non-scientific member & one from opposite gender. All decisions will be taken in meetings and not by circulation of project proposals.

Quorum will have besides the Chairperson and the Member secretary, 6 members with following representations:

a. Basic medical scientists (preferably one pharmacologist).
b. Two clinicians
c. Legal expert
d. Social scientist / representative of non-governmental voluntary agency / philosopher / ethicist / theologian or a similar person
e. Lay person from the community

11. HONORARIUM, FEE AND IEC OFFICE EXPENSES

The members of the IEC, Rajendra Institute of Medical Sciences, Ranchi shall be paid Rs 1000/- as honorarium for attending the IEC meetings and reviewing the proposals.

11.1 Compensation and reimbursements to external members

All external members, and experts invited (if any) will be paid an honorarium of Rs. 1000/- for each meeting attended and transport facilities would be either provided by the institution or reimbursement will be done for travel costs incurred towards contributing to the workings of the IEC according to the Institution ‘s norms. Appropriate bills shall have to be submitted together to the Member Secretary.

11.2 EC Review and archival fee

The Ethics Committee (EC) shall charge an application fee for sponsored research projects. All research proposals/clinical trials funded/sponsored by Pharmaceutical companies, Agencies, Multinationals etc. will be charged an administrative fee/ processing fee.

Waiver of these fees is permissible for non-funded studies, departmental studies, and studies funded by organizations like ICMR, UGC, DBT, DST Government of India, State Science & Technology Department, UNICEF, WHO, USAID, Non profitable organizations etc.

All applications need to be mandatorily accompanied by application fee before it can be processed. The fee shall be paid by cheque or by demand draft drawn in favor of EC and accounts thus maintained.

11.2.1 Initial Review Fee

The EC shall charge a non-refundable, initial one-time review fee as administrative charges given below:

Pharmaceutical Industry and Contract Research Organisation (CRO) Funded Clinical Trials … ……. Rs. 50,000/- or 10% of the budget whichever is more.
Investigator Initiated Projects (Funded by Non-Govt. Funding Agency) ……... Rs. 20,000/-
Investigator Initiated Projects (From outside RIMS) ……... Rs. 25,000/-
Investigator Initiated Projects (Funded by Govt. Funding Agency) …… Rs. 5,000/-
Student research (thesis) …….. Rs. 500/-

11.2.2 Study renewal fee

The EC shall charge a yearly fee (Rs. 5000/) for ongoing review of the study from the second year. The study renewal review fee funds the costs of the Committee renewal review of the ongoing review of adverse events, protocol variances and site visits. The committee examines each Investigator's progress reports and activities for the previous year.

11.2.3 Amendment fee

The EC will charge an amendment fee of Rs 2000 for any amendment(s) in the ongoing study.

11.2.4 Archival fee

The EC will charge an amount of Rs 75,000 as archival fee for a tenure of 5 years.

All applications need to be mandatorily accompanied by the application fee before it can be processed. The fees shall be deposited by Demand Draft in favour of IEC, RIMS, payable at SBI, RMCC Branch, Ranchi or by NEFT in IEC current Account in SBI Account No. 39636660706 RMCC Branch, IFSC code no. SBIN000001672.

11.2.5 Office expenses

For the maintenance of the office, a sum of Rs 3000/- per month will be given to the secretariat.

12. APPLICATION PROCEDURE

1. All proposals should be submitted on any working day 1 month in advance of scheduled meeting in the prescribed Guidelines for submission of projects [**Annexure No. 12**]. The SOP is available on the RIMS website.
2. All relevant documents should be enclosed with the application form as provided in the check list [**Annexure no. 14**].
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, RIMS, Ranchi, through member secretary. In his absence via any person nominated by Chairperson, receipt of the application will be acknowledged by the IEC office. The investigators submitting the projects to the IEC for the approval will submit the project according to the prescribed guidelines, summary proforma and the checklist for submission. [**Annexure 12, 13 & 14**] along with the subject information sheet and consent form **[Annexure 9**].

Every application will be allotted an IEC registration number to be used for all future correspondence and reference. The date of IEC meeting will be intimated to the PI to attend the meeting and to make a brief presentation of the proposal and to clarify the points raised by the members. 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 time as specified in the communication or before the next meeting.

13. REVIEW PROCEDURES

1. The meetings of the IEC, RIMS, Ranchi will be held on periodic intervals, 2nd week of every month unless otherwise specified by the member secretary. Additional review meetings can also be held with short notice as and when required.

2. Additional meetings will be planned in accordance with the need for the **Expedited IEC Approval**. An expedited review (which may involve less waiting time for IEC approval) may be carried out by the IEC chairperson or by one or more experienced IEC members designated by the chairperson. The reviewers may exercise all of the authorities of the IEC except that of disapproving the research. A proposal submitted for expedited review may be disapproved only by the full IEC.

3. The proposals should be sent to the IEC at least 1 month in advance of scheduled meeting.

4. 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, RIMS, Ranchi, through member secretary. Receipt of the application will be acknowledged by the IEC office.
5. The notice of each IEC meeting along with the agenda shall be sent to all the members at least one week before the meeting.
6. The IEC'S member-secretary 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.
7. Decisions will be taken by consensus after discussion, and whenever needed voting will be done. Decision of chairperson will be final.
8. Every application will be allotted an IEC registration number to be used for all future correspondence and reference. The date of IEC meeting will be intimated to the PI to be available and to clarify the points raised by the members if any.
9. 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.
10. Researchers will be invited to offer clarifications if need be. The 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.

11. Independent consultants/experts will be invited to offer their opinion on specific research proposals if needed.
12. Minutes of the meeting will be written down and chairperson's approval will be taken in writing.

The IECs Member Secretary or the Secretariat shall screen all the proposals for their completeness and depending on the risk involved, categorize them into three types: Exemption from Review, Expedited Review and Full Review.

13.1 Types of Review

There are three types of review. Proposals will be eligible for a particular type of review as per the following table:

Serial Number	Type of review	
1.	**Exemption from review**	Proposals with less than minimal risk where there are no linked identifiers. These include: • Research conducted on data available in the public domain for systematic reviews or meta-analysis; • Observation of public behaviour when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person; • Quality control and quality assurance audits in the institution; • Comparison of instructional techniques, curricula, or classroom management methods; • Consumer acceptance studies related to taste and food quality; and • Public health programmes by Govt agencies such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers)
2.	**Expedited Review**	Proposals that pose no more than minimal risk may undergo expedited review. These include: • Research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples; • Research involving clinical documentation materials that are non-identifiable (data, documents, records); Modification or amendment to an approved protocol including administrative changes or correction of typographical errors and change in researcher(s); • Revised proposals previously approved through expedited review, full review or continuing review of approved proposals; • Minor deviations from originally approved research causing no risk or minimal risk; • Progress/annual reports where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee; and • For multicentre research where a designated main EC among the participating sites has reviewed and approved the study, a local EC may conduct only an expedited review for site specific requirements in addition to the full committee common review. • Research during emergencies and disasters

3.	**Full Review**	All research proposals presenting more than minimal risk that are not covered under exempt or expedited review should be subjected to full committee review. These include: • Research involving vulnerable populations, even if the risk is minimal; • Research with minor increase over minimal risk; • Studies involving deception of participants; • Research proposals that have received exemption from review, or have undergone expedited review/undergone subcommittee review should be ratified by the full committee, which has the right to reverse/or modify any decision taken by the subcommittee or expedited committee; • Amendments of proposals/related documents (including but not limited to informed consent documents, investigator's brochure, advertisements, recruitment methods, etc.) involving an altered risk; • Major deviations and violations in the protocol; • Any new information that emerges during the course of the research for deciding whether or not to terminate the study in view of the altered benefit–risk assessment; • Research during emergencies and disasters either through an expedited review/ scheduled or unscheduled full committee meetings. This may be decided by Member Secretary depending on the urgency and need; • Prior approval of research on predictable emergencies or disasters before the actual crisis occurs for implementation later when the actual emergency or disaster occurs.

13.2 Terms of Reference

IEC, RIMS, Ranchi will function as per the latest version of its Standard Operating Procedure (SOP) manual to approve the academic, funded or sponsored proposals. A copy of the latest version of SOPs will be made available to each of the members and they would be trained on the SOPs. The SOPs will be available in the secretariat of the EC as both hard and soft copies. Updated SOP will also be floated at RIMS website (rimsranchi.org).

13.2.1 For the proposals from outside the RIMS, Ranchi

The two institutions, RIMS, Ranchi, and the user institution will have an MoU for utilizing the services of IEC, RIMS, Ranchi.
The user institution will provide a 'No Objection Certificate' and agree to be overseen by the IEC, RIMS, Ranchi.
The IEC RIMS, Ranchi would have access to all research records including the source documents and research participants for continuing review of the implemented project, including site visits.
The IEC, RIMS, Ranchi may undertake site monitoring and will have all the rights and responsibilities related to ethical review of the projects submitted by the user institutions.

13.2.2 For Multicentric Biomedical and Health Research

For multicentric biomedical and health research, including academic and funded/ sponsored research, all participating sites may decide 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. All sites would be required to obtain approval from their respective ECs, which would consider the local needs and requirements of the populations being researched and safeguard the dignity, rights, safety and well-being of the participants. This would require good communication and coordination between the researchers and EC secretariats of participating sites. For clinical trials under the Drugs and Cosmetics Act, the requirements as stated by CDSCO will be followed.

If IEC, RIMS, Ranchi does not grant approval for a multicentric study at its site, the reasons will be shared with other ECs and deliberated upon.

IEC may suggest site-specific protocols and informed consent modifications as per local needs. Separate review will be arranged for studies with a higher degree of risk, clinical trials or intervention studies where conduct may vary depending on the site or any other reason which requires closer review and attention.

Sponsor/funding agencies need be informed about any site-specific changes being made, and the modified version would only be used by the concerned site.

Plans for manuscript publication and a common final report with contributors from the participating sites would be decided upon before initiation of the study.

Site-specific data may be published only after the appropriate authorities accept the combined report and appropriate permissions are obtained.

13.3 Points to Stress upon while reviewing Research Protocols

The protocol would be reviewed keeping in mind the following points:

i. Measures to protect autonomy,
ii. Risk/benefit determinations with respect to the vulnerability
iii. Whether vulnerable subjects are bearing unequal burden in research.
iv. Member of the IEC who would be reviewing such protocols should be well versed
v. With the potential harm or risk of such population participating in the study. Special justification is required for inviting vulnerable individuals to serve as research subjects and, if they are selected, the means of protecting their rights and welfare must be strictly adhered to.
vi. The extent of protection afforded should depend upon the risk of harm and the likelihood of benefit. The judgment that any individual lacks autonomy should be periodically re-evaluated and will vary in different situations. The central issue for the

IEC to consider is whether the potential subject's ability to exercise free choice is limited in some way.

14. REVIEW OF THE SERIOUS ADVERSE EVENTS (SAE) REPORTS AND COMPENSATION ISSUES

14.1 Review of the SAE

- The primary responsibility of the IEC is to review and address SAE and unexpected events involving risks to research participants. In addition, the committee is authorized to offer mediation under appropriate circumstances.
- The IEC should also make sure that researchers/investigators are made aware of the policies and procedures concerning reporting and continuing review requirements.

The complete SAE / unexpected events report for detailed review shall be submitted to IEC as per the **data elements for reporting SAE occurring in a Clinical trial/ Bioavailability study/ Bioequivalence study**. [**Annexure 8]**

- Notifying the IEC does not relieve the PI from his/her responsibility to notify the sponsor and regulatory authorities.

14.2 For on-site SAE

14.2.1 Instructions for PI
All SAEs including Deaths should be reported within 24 hours of their occurrence to IEC, Sponsor or its representative and the Licensing authority.
After due analysis of the serious adverse event including Death, shall be forwarded by the Investigator to the Sponsor, the Chairperson of the IEC, Licensing authority and the Head of the Institution where the trial has been conducted.
The Chairperson of the Expert Committee constituted by the CDSCO (in case of death SAE) within fourteen calendar days of the occurrence of the serious adverse event of death.

14.2.2 SAE related activities before IEC meeting
After SAEs is received the IEC, member secretary will verify that the reports are complete, signed and dated by the PI/Co-PI and are checked for dates and typographical errors in the SAE event description, SAE event term etc.

14.2.3 Actions to be taken by IEC
The Member Secretary will review the SAE Report, and an expedited meeting will be called to review and opine on the SAE. Any queries raised shall be communicated to the PI for action.
After analysis, SAE (other than death) report and opinion on financial compensation would be sent to the Licensing Authority within 30 calendar days.
In case of death SAEs, the analyzed report and opinion on financial compensation would be sent to the Chairperson of Expert Committee and Licensing Authority with 30 calendar days.

14.3 For off-site SAEs

It is the PI's responsibility to submit the offsite SAEs to IEC and one copy is acknowledged and returned back.
If any queries are raised by the IEC, Member Secretary will communicate to PI by email or letters as applicable; else the Offsite SAEs are filed in the respective project files.

Depending on the trend observed by the committee, if appropriate, specific action or combination of actions will be taken. Some of those are listed below:

1) Note the SAE report in the IEC records if information submitted is found to be adequate.
2) Direct the PI to inform participants already enrolled in the study about the SAE and request them to undertake additional visits, additional procedures, additional investigations, etc. as prescribed in the amendment.
3) Request further follow up information or Request additional details Recommend an amendment to the protocol, the ICD, Participant information sheet, investigator brochure and/ or any other document.
4) Suspend certain activities under the protocol (while going on with activities intended to protect the safety, well-being of participants who have already been enrolled);
5) Suspend enrolment of new research participants;
6) Suspend the study till amendments requested for by the IEC are accepted
7) Suspend the study for a fixed duration of time;
8) Suspend the study till additional information is obtained; or suspend the study till review is completed.
9) Terminate the study.

14.4 Criteria for assessment of trial relatedness of injury or death or permanent disability to be related to clinical trial or bioavailability and bioequivalence study —

Any injury or death or permanent disability of a trial subject occurring during clinical trial or bioavailability or bioequivalence study due to any of the following reasons shall be considered as clinical trial or bioavailability or bioequivalence study related injury or death or permanent disability:-

(a) adverse effect of the investigational product;

(b) violation of the approved protocol, scientific misconduct or negligence by the sponsor or his representative or the investigator leading to serious adverse event;

(c) failure of investigational product to provide intended therapeutic effect where, the required standard care or rescue medication, though available, was not provided to the subject as per clinical trial protocol;

(d) not providing the required standard care, though available to the subject as per clinical trial protocol in the placebo controlled trial;

(e) adverse effects due to concomitant medication excluding standard care, necessitated as part of the approved protocol;

(f) adverse effect on a child in-utero because of the participation of the parent in the clinical trial.

(g) any clinical trial procedures involved in the study leading to serious adverse event.

14.5 Recommendations of payments of compensation in case of serious adverse event (SAE)

IEC, RIMS, Ranchi will instruct the sponsors or its representatives to provide payments of financial compensation in case of injury or death in clinical trial or bioavailability or bioequivalence study of new drug or investigational new drug-

(1) Where any death of a trial subject occurs during a clinical trial or bioavailability or bioequivalence study, the legal heir of the trial subject shall be provided financial compensation by the sponsor or its representative, who has obtained permission to conduct the clinical trial or bioavailability or bioequivalence study, in accordance with the procedure specified in rule 42.
(2) Where permanent disability or any other injury occurs to a trial subject during a clinical trial or bioavailability or bioequivalence study, the trial subject shall be provided financial compensation by the sponsor or its representative, who has obtained permission to conduct the clinical trial or bioavailability or bioequivalence study, in accordance with the procedure specified in rule 42.
(3) The financial compensation referred to in sub-rule (1) or sub-rule (2) shall be in addition to any expenses incurred on medical management of the trial subject.
(4) In the event of an injury, not being permanent in nature, the quantum of compensation shall be commensurate with the loss of wages of the subject as provided in the Seventh Schedule.
(5) The sponsor or its representative shall give an undertaking along with the application for clinical trial permission to the Central Licencing Authority to provide compensation in the case of clinical trial related injury or death for which subjects are entitled to compensation.
(6) Where the sponsor or its representative, who has obtained permission to conduct clinical trial or bioavailability or bioequivalence study, fails to provide financial compensation, as referred to in sub-rule (1) or sub-rule (2), the Central Licencing Authority shall, after affording an opportunity of being heard, by an order in writing, suspend or cancel the clinical trial or bioavailability or bioequivalence study or restrict the sponsor including its representative, who has obtained permission to conduct clinical trial or bioavailability or bioequivalence study, to conduct any further clinical trial or bioavailability or bioequivalence study or take any other action for such period as considered appropriate in the light of the facts and circumstances of the case.

14.7 Determination of the quantum of compensation in cases of regulatory clinical trial related injury or death

1. Formula in case of clinical trial related death:

Compensation = (B x F x R) / 99.37

Where,

B = Base amount (i.e. 8 lacs)

F = Factor depending on the age of the trial subject as per Annexure 1 (based on Workmen Compensation Act)

R = Risk Factor depending on the seriousness and severity of the disease, presence of co-morbidity and duration of disease of the trial subject at the time of enrolment in the clinical trial between a scale of 0.5 to 4 as under:
(1) 0.5 terminally ill patient (expected survival not more than (NMT) 6 months)

(2) 1.0 Patient with high risk (expected survival between 6 to 24months)

(3) 2.0 Patient with moderate ris

(4) 3.0 Patient with mild risk

(5) 4.0 Healthy Volunteers or trial subject of no risk. However, in case of patients whose expected mortality is 90% or more within 30 days, a fixed amount of Rs. 2 lacs should be given.

2. Formula in case of clinical trial related injury (other than death):

For calculation of quantum of compensation related to injury (other than death), the compensation shall be linked to the criteria considered for calculation of compensation in cases of death of the trial subject as referred to in section of this Schedule. The quantum of compensation in case of Clinical Trial related SAE should not exceed the quantum of compensation which would have been due for payment in Case of death of the trial subject since the loss of life is the maximum injury possible.

As per the definition of SAE, the following sequelae other than death are possible in a clinical trial subject, in which the trial subject shall be entitled for compensation in case the SAE is related to clinical trial.

(i) A permanent disability: In case of SAE causing permanent disability to the trial subject, the quantum of compensation in case of 100% disability shall be 90% of the compensation which would have been due for payment to the nominee (s) in case of death of the trial subject. The quantum for less than 100% disability will be proportional to the actual percentage disability the trial subject has suffered.
Accordingly, following formula shall be applicable for determination of compensation:

Compensation = (C x D x 90) / (100 x 100)
Where:
D = Percentage disability the trial subject has suffered.

C = Quantum of Compensation which would have been due for payment to the trial subject's nominees)
in case of death of the trial subject.

(ii) Congenital anomaly or birth defect:

The congenital anomaly or birth defect in a baby may occur due to participation of anyone or both the parent in clinical trial. Following situations may arise due to congenital anomaly or birth defect.

(a) Still birth;

(b) Early death due to anomaly;

(c) No death but deformity which can be fully corrected through appropriate intervention;

(d) Permanent disability (mental or physical). The compensation in such cases would be a lump sum amount such that if that amount is kept by way of fixed deposit or alike, it shall bring a monthly interest amount which is approximately equivalent to half of minimum wage of the unskilled worker (in Delhi). The quantum of compensation in such cases of SAE shall be half of the base amount as per formula for determining the compensation for SAE resulting into death. In case of birth defect leading to sub-clause (c) and (d) of this clause to any child, the medical management as long as required shall be provided by the Sponsor or his representative which will be over and above the financial compensation.

(iii) Chronic life-threatening disease; and

(iv) Reversible SAE in case it is resolved.

In case of clinical trial related SAE causing life-threatening disease and reversible SAE in case it is resolved, the quantum of compensation would be linked to the number of days of hospitalisation of the trial subject. The compensation per day of hospitalization shall be equal to the wage loss. The wage loss per day shall be calculated based upon the minimum wage of the unskilled worker (in Delhi). Since, in case of hospitalisation of any patient not only the patient loses his/her wage, there will be direct or indirect losses of various kind including inconvenience, wage loss of attendant, etc. The compensation per day of hospitalisation in such case shall be double the minimum wage. Accordingly, following formula shall be applicable for determination of compensation:

Compensation = 2 X W X N.

Factor (F) for calculating the amount of compensation

Age	Factor
Not more than…	
16	228
17	227
18	226
19	225
20	224
21	222
22	221
23	219
24	218
25	216
26	215
27	213
28	211
29	209
30	207
31	205
32	203
33	201
34	199
35	197
36	194
37, and so on …as given in - New Drugs and Clinical Trial Rules_2019	192

Where, W = Minimum wage per day of the unskilled worker
N = Number of days of hospitalization

Query on Serious Adverse Events:

In potentially contentious issues, Member Secretary, IEC will inform Chairperson and Chairperson may use his/her discretion to bring it to the full board IEC meeting. The reply will be sent to DCGI with a copy of the same to Principal Investigator.

15. REVIEW OF THE STUDY COMPLETION REPORT

Before Each Board Meeting:

The Secretariat will receive 1 copy (soft and hard) of Study Completion Report from the Principal Investigator. The study completion report is expected from the investigator within 1 month of completion of the study at the site. A brief study report containing data analysis from all the centers can be submitted by the investigator once available from the sponsor. The Secretariat shall review the report for completeness before submission for the Board meeting. If necessary, the IEC secretariat will retrieve the master file from the archiving with permission of the Member Secretary. The Secretariat shall verify the submitted Study Completion Report along with Study Completion Report to the Chairperson. Prior to sending the Study Completion Report to the Chairperson, the Secretariat will prepare the Study Completion statement and attach this also to the packet sent to the Chairperson.

The Chairperson and the Member Secretary will review the report, Study Completion Report Form and Study Completion statement and notify it to the other IEC members at the forthcoming full board meeting or the Chairperson can designate two other IEC members to review the Study report and related documents. If deemed necessary, the Chairperson may keep the report for discussion at the forthcoming IEC meeting.

The Secretariat will send the Study Completion Report Form and Study Completion statement to the designated IEC members if required. The Secretariat shall include the Study Completion Report Form in the agenda for IEC members for discussion at the full board meeting.

During the Board meeting

The Secretariat shall request the IEC member(s) designated the task to review a copy of the Final Report to present his/her comments. The Member Secretary entertains any discussion of the study. If appropriate to the discussions, the Chairperson may call for voting for final decision or whether to request further information or to take other action with the investigator.

After the Board meeting

The Secretariat will note the decision in the meeting minutes and the study shall be considered as closed if decision by IEC is “Noted”. The IEC decision is notified to the investigator as
a) noted in the IEC records
b) request for additional information / clarification

The Secretariat will accept and file the Final Report and get the Study Completion Report Form signed by the Chairperson and file it. With the permission of the Member Secretary, the secretariat will retrieve the file from the archiving. The final report will be placed in the master file and kept in the archival area. The Administrative Officer will archive the entire study protocol for a period of 5 years from the date of completion of the project if the decision is noted and closed.

16. DECISION-MAKING AND THE FORMAT TO ACCORD APPROVAL TO CLINICAL TRIAL PROTOCOL BY THE IEC, RIMS, RANCHI

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 in case of a conflict of interest and it should be intimated to the chairperson prior to the review of the application and recorded in the minutes of the meeting.
3. Decision will be made only in meetings where quorum is complete.
4. Only the members can make the decisions. the expert consultants will only offer their opinions.
5. The PI will be intimated about the decision of the committee with IEC approval notice [**Annexure 11**]
6. Decision about the proposals will be communicated as **Approved, Approved with Modifications or Rejected**. Specific suggestions for modifications and reasons for modifications and reasons for rejection will be given. 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.

17. INFORMED CONSENT:

- The IEC will ensure that the participants have been given sufficient, accurate information about the study.
- The Informed Consent document should contain all of the information that the participant needs to make an informed decision about taking part in the study **[Please refer to annexures 15, 16. 17. 18].**
- The participant must sign and date the informed consent document before taking part in any study procedures.
- The consent form should be written in non-technical language that participants would understand. Also, it should be written in language consistent with the participants' educational level, cultural views, and familiarity with research.
- The participant may withdraw consent and decline to participate in the study at any time before or after signing the consent document until their participation in the study is completed.
- The informed consent should state those aspects of the study/trial that are experimental, the risk and the benefits of the study/trial, the number of participants involved as well as the expected duration of the participant’s involvement in the study/ trial.
- IEC will ensure that adequate provision is made to protect subjects’ privacy and maintain the confidentiality of data.
- It should state the compensation and/or treatment available to the participant in the event of trial-related injury.
- It should state the anticipated expenses, if any, to the participant for participating in the study and the anticipated prorated payment, if any, to the participant for participating in the study.

18. SPECIAL CONSIDERATIONS / PROTECTION OF VULNERABLE POPULATION:

Vulnerable Population will be taken care of by the IEC as there are specific concerns about specialized areas of research that require additional safeguards and protection. Vulnerable persons are those who are relatively (or absolutely) incapable of protecting their interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests.

Efforts will be made to ensure that individuals or communities invited for research be selected in such a way that the burdens and benefits of the research are equally distributed.

1. Research on genetics should not lead to racial discriminate.
2. Persons who are economically or socially disadvantaged should not be used to benefit others who are better off.
3. Rights and welfare of mentally challenged and mentally differently able persons who are incapable of giving informed consent or those with behavioral disorders must be protected. Appropriate proxy consent from the legal guardian should be taken after the person is well informed about the study, needs for participation, risks, and benefits involved, and the privacy and confidentiality procedures.
4. Adequate justification is required for the involvement of participants such as prisoners, students, subordinates, and employees, service personnel, etc. who have reduced autonomy as research participants, since the consent provided may be under duress or various other compelling reasons.

Individuals whose willingness to volunteer in a research study may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation or of a retaliatory response from senior members of a hierarchy in case of refusal to participate may also be considered vulnerable. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention.

"Vulnerable" or "special" participants include as listed below:

- pregnant women, human fetuses and neonates,
- prisoners,
- children,
- cognitively impaired persons
- Students and employees, sub-ordinates
- Minorities (as defined by national constitution and/or socio-economically backward, refugees, and such others.
- Economically and/or educationally disadvantaged AIDS/HIV positive subjects.
- Terminally ill Subjects
- Geriatric population

18.1 Role of various stakeholders on vulnerable population

Role of researchers, ethics committee and sponsors on vulnerable population will be as follows:

Stakeholders	Obligations
Researcher	Should recognize the vulnerability of the participant and ensure additional safeguards are in place for their protection. Justify inclusion/exclusion of vulnerable populations in the study. COI issues must be addressed. Have well defined procedures (SOPs) to ensure a balanced benefit-risk ratio. Ensure that prospective participants are competent to give informed consent. Take consent of the LAR when a prospective participant lacks the capacity to consent. Respect dissent from the participant. Seek permission of the appropriate authorities where relevant, such as for institutionalized individuals, tribal communities, etc. Research should be conducted within the purview of existing relevant guidelines/regulations.
Ethics Committee	• During review, determine whether the prospective participants for a particular research are vulnerable. • Examine whether inclusion/exclusion of the vulnerable population is justified. • Ensure that COI do not increase harm or lessen benefits to the participants. Carefully determine the benefits and risks to the participants and advise risk minimization strategies wherever possible. • Suggest additional safeguards, such as more frequent review and monitoring, including site visits. • 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. • ECs have special responsibilities when research is conducted on participants who are suffering from mental illness and/or cognitive impairment. They should exercise caution and require researchers to justify cases for exceptions to the usual requirements of participation or essentiality of departure from the guidelines governing research. ECs should ensure that these exceptions are as minimal as possible and are clearly spelt out in the ICD. • IEC, RIMS, Ranchi follows its SOP for the handling proposals involving vulnerable populations.
Sponsors	• The sponsors including government, institution or pharmaceutical company, will have to justify the inclusion of vulnerable groups in the protocol and make provisions for protecting their safety. • The sponsor will enable monitoring and ensure that procedures are in place for quality assurance (QA) and quality control (QC). • The sponsors will also ensure protection of the participants and research team if the research is on sensitive topics.

18.2 Special Requirements when Children are part of the Research

The following is required when children are enrolled in research:

- Children will not be involved in research that can be carried out equally well with adults.
- The purpose of the research is to obtain knowledge relevant to the health needs of children. For clinical evaluation of a new, drug the study in children should always be carried out after the phase III clinical trials in adults.
- For studies prior to phase III the drug has a therapeutic value in a primary disease of the children.
- The settings of the research should provide the child and the parents adequate medical and psychological support.
- Interventions intended to provide direct diagnostic, therapeutic, or preventive benefit for the individual child participants must be justified in relation to potential risks involved in the study and potential benefits to society.
- The risk presented by interventions not intended to benefit the individual child participant is low when compared to the importance of the knowledge that is to be gained.
- Interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual child participant as any available alternative interventions.
- A parent or legal guardian of each child has given a proxy consent.
- The assent of the child should be obtained to the extent of the child's capabilities such as in the case of mature minors or adolescents, unless there is no medically acceptable alternative to the therapy provided or tested, and consent has been obtained from at least one parent or guardian.
- Such trials, unless an exception is justified, should be conducted in patients having a disease or condition for which the investigational product is intended. Participants in these trials should be particularly closely monitored and should be withdrawn if they appear to be unduly distressed.

18.3 Special Requirements when Adults can’t give consent

A non-therapeutic clinical trial (i.e. a trial in which there is no anticipated direct clinical benefit to the participant) should be conducted in participants who personally give consent and who sign and date the written consent document.

Non-therapeutic clinical trials may be conducted in participants with consent of a legally acceptable representative (LAR) provided the following conditions are fulfilled:

- The objectives of the clinical trial cannot be met by means of a trial in participants who can give consent personally.
- The foreseeable risks to the participants are low.
- The negative impact on the participant’s wellbeing is minimized and low.
- The clinical trial is not prohibited by law.
- The opinion of the CREC is expressly sought on the inclusion of such participants, and the
- written opinion covers this aspect.

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

18.4 Special Requirements when the research participants are Pregnant women or Nursing Mothers

The following is required when Pregnant or nursing women are enrolled in research:

- Pregnant or nursing women should under no circumstances be the participant of any research unless the research carries no more than minimal risk to the fetus or nursing infant and the object of the research is to obtain new knowledge about the fetus, pregnancy and lactation.
- As a general rule, pregnant or nursing women should not be participants of any clinical trial except such trials are designed to protect or advance the health of pregnant or nursing women or fetuses or nursing infants, and for which non-pregnant women or non-nursing mothers would not be suitable participants.
- The justification for participation of these women in clinical trials would be that they should not be deprived arbitrarily of the opportunity to benefit from investigations, drugs, vaccines, or other agents that promise therapeutic or preventive benefits. Example of such trials are to test the efficacy and safety of a drug for reducing perinatal transmission of HIV infection from mother to child, trials for detecting fetal abnormalities and for conditions associated with or aggravated by pregnancy etc.
- Women should not be encouraged to discontinue nursing for the sake of participation in research and in case she decides to do so, harm of cessation of breast- feeding to the nursing child should be properly assessed except in those studies where breast feeding is harmful to the infant. Compensation in terms of supplying supplementary food such as milk formula should be considered in such instances.
- Research related to termination of pregnancy: Pregnant women who desire to undergo Medical Termination of Pregnancy (MTP) could be made participant for such research as per The Medical Termination of Pregnancy Act, GOI, 1971.
- Research related to pre-natal diagnostic techniques: In pregnant women such research should be limited to detect the fetal abnormalities or genetic disorders as per the Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, GOI, 1994 and not for sex determination of the fetus.

18.5 Special requirements while doing research on Tribal population

- Research on tribal populations should be conducted only if it is of a specific therapeutic, diagnostic and preventive nature with appropriate benefits to the tribal population.
- Due approval from competent administrative authorities, like the tribal welfare commissioner or district collector, should be taken before entering tribal areas.
- Whenever possible, it is desirable to seek help of government functionaries/local bodies or registered NGOs who work closely with the tribal groups and have their confidence.
- Where a panchayat system does not exist, the tribal leader, other culturally appropriate authority or the person socially acceptable to the community may serve as the gatekeeper from whom permission to enter and interact should be sought.
- Informed consent should be taken in consultation with community elders and persons who know the local language/dialect of the tribal population and in the presence of appropriate witnesses.
- Even with permission of the gatekeeper, consent from the individual participant must be sought.
- Additional precautions should be taken to avoid inclusion of children, pregnant women and elderly people belonging to particularly vulnerable tribal groups (PVTG).
- Benefit sharing with the tribal group should be ensured for any research done using tribal knowledge that may have potential for commercialization.

18.6 Special Requirements Concerning the Consent of Prisoners

- In case of prisoners as the research participants, the IEC, RIMS, Ranchi will approve the study as prisoner research.
- It will also include a prisoner advocate in its membership.
- The IEC members (exclusive of prisoner members) must have no association with the prisoner(s) involved in the research, apart from their membership with IEC.

19. WAIVER OF INFORMED CONSENT

It is the responsibility of the IEC to review and approve a request for verbal/written consent waiver. The Member Secretary will record the decision in the minutes and in the Application Form. The Chairperson will sign and date letter conveying the decision.
When a request for waiver of consent is received from the Principal Investigator (PI) to the IEC, the following steps are taken:

- The IEC Secretariat will check if the concerned documents are filled completely and the required list of documents is enclosed.
- The IEC members will review the request taking into consideration the types of studies for which waiver of consent may be granted.
- The IEC will ensure that there are adequate mechanisms described in the protocol for protection of the identity of the research participants and maintaining confidentiality of the study data.
- The final decision whether to grant the waiver is taken at a full board meeting unless the project is considered under expedited review

  The decision regarding approval / disapproval of waiver is informed to the Principal Investigator in writing. If the waiver is not granted, the IEC will provide reasons for the same.

20. RESPONSIBILITIES OF THE SPONSORS AND THE INVESTIGATORS TO THE IEC, RIMS, RANCHI

20.1 Responsibilities of the Sponsor(s)

- The clinical trial Sponsor is responsible for implementing and maintaining quality assurance systems to ensure that the clinical trial is being 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.
- Sponsors are required to submit a status report on the clinical trial to the licensing authority at prescribed intervals.
- In case of studies prematurely discontinued for any reason including lack of commercial interest in pursuing the new drug application, 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 drug, dose and duration of exposure, details of adverse drug reactions, if any, and the reason for discontinuation of the study or non-pursuit of the new drug application.

- Any report of serious adverse event of death occurring in clinical trial, after due analysis shall be forwarded by the sponsor to chairman of the ethics committee and chairman of the expert committee constituted by the licensing authority as defined in New Drugs and Clinical Trials, 2019 with a copy of the report to the Licensing authority and the head of the Institution where the trial has been conducted within ten calendar days of occurrence of serious adverse event of death. The report of the serious adverse event other than death, after due analysis, shall be forwarded by the sponsor to the Licensing authority, 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.
- In case of injury or death occurring to the clinical trial subject, the sponsor (whether a pharmaceutical company or an Institution) or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial, shall make payment for medical management of the subject and also provide financial compensation for the clinical trial related injury or death in the manner as prescribed in Appendix XII of gazette notification dated 30th January 2013.
- The sponsor (whether a pharmaceutical company or an institution) or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial, shall submit details of compensation provided or paid for clinical trial related injury or death, to the Licensing Authority within thirty days of the receipt of the order of the Licensing Authority.

20.2 Responsibilities of the Investigator(s):

Investigators will ensure that the IRB receives all the documents it requires to review the proposed research.

- They will admit no participant to a study before the IRB has issued its written approval of the study.
- The Investigator(s) shall be responsible for the conduct of the trial according to the protocol, New drugs and Clinical Trial, 2019 and the GCP Guidelines.
- The investigator will report promptly to the IRB:
- In case of changes to or deviations from the protocol, including changes made to eliminate immediate hazards to study participants.
- Changes that increase the risk to participants or significantly affect the conduct of the study.
- All adverse drug reactions that are both serious and unexpected.
- New information that may adversely affect the safety of participants or the conduct of the study.
- Standard operating procedures are required to be documented by the investigators for the tasks performed by them.

- The researchers will be accountable for ensuring the protection of the environment and resources at all the stages of the research, in compliance with existing guidelines and regulations.
- 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 Licensing Authority as per the recommended guidelines, 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 of death, after due analysis shall be forwarded by the investigator to Chairman of the ethics committee and Chairman of the Expert Committee constituted by the Licensing authority under Appendix XII with a copy of the report to the Licensing Authority 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.
- The report of the serious adverse event other than death, after due analysis shall be forwarded to the Licensing Authority, 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.

The investigator shall provide information to the clinical trial subject through informed consent process 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.

21. MAINTENANCE OF RECORDS FOR CLINICAL TRIALS BY THE OFFICE OF IEC, RIMS, RANCHI FOR THE CLINICAL TRIALS

The Ethics Committee shall maintain data, record, register and other documents related to the functioning and review of clinical trial or bioavailability study or bioequivalence study, as the case may be, for a period of five years after completion of such clinical trials, namely:

(i) The constitution and composition of the Institutional Ethics Committee,
(ii) The curriculum vitae of all members of the Institutional Ethics Committee, RIMS, Ranchi,
(iii) The standard operating procedures followed by the Institutional Ethics Committee, RIMS, Ranchi,
(iv) National and international guidelines followed by the Institutional Ethics Committee, RIMS, Ranchi,
(v) Copies of the protocol, data collection formats, case report forms, investigators brochures, etc., submitted for review,
(vi) All correspondence with committee members and investigators regarding application, decision and follow up,
(vii) Agenda of all Ethics Committee meetings and minutes of all Ethics Committee meetings with signature of the Chairperson,
(viii) Copies of decisions communicated to applicants,
(ix) Records relating to any order issued for premature termination of study with a summary of the reasons thereof,
(x) Recommendation given by Ethics Committee for determination of compensation,
(xi) Records relating to the serious adverse event, medical management of trial subjects and compensation paid.
(xii) One soft of copy of research proposals will be archived and rest of the copies will be destroyed after one year.
(xiii) Only authorized person will have the access to data related to IEC, RIMS Ranchi.

The Ethics Committee shall furnish the information maintained as and when required by the Central Licencing Authority or any other officer authorised on its behalf.

22. HUMAN GENETICS TESTING AND RESEARCH

There is a great concern for ethical issues than in the field of human genetics. There is a very narrow gap between routine genetic testing and research raising several ethical, legal and social issues (ELSI), which warrant continuous and prompt monitoring and judicious response to the emerging ethical issues.

22.1 General issues

- ◊ The harm/risks associated with genetic testing may be psychosocial rather than physical in the form of anxiety, depression or disrupted family relationships.
- ◊ Potential benefits and risks should be discussed thoroughly with prospective participants. Appropriate communication skills are required for genetic counselling which is akin to therapy.

- ◊ There is a likelihood of social stigmatization and discrimination in schooling, employment, health and general insurance, which requires greater care in recruiting participants in research. IEC, RIMS, Ranchi is committed to maintain confidentiality in genetic testing keeping in view its social implications.
- ◊ There is often an overlap between genetic research and services for the physician as well as the patient and therefore, adequate safeguards against therapeutic misconceptions are needed.
- ◊ Genetic and genomic technologies cause emergence of newer ethical concerns and issues. Therefore, IEC members need to keep abreast of such advancements and understand their implications. The IEC reviewing genetic research will have necessary expertise to understand the ethical implications and provide safeguards for research participants.
- ◊ There is a need to have a team of clinicians, geneticists, genetic counsellors, and laboratory personnel to work together.
- ◊ Genetic testing and research often require dealing with persons who are unable to protect their rights and safety and may be vulnerable, such as children, individuals with mental illness, cognitively impaired individuals, people with rare diseases and others. Therefore, IEC, RIMS, Ranchi is committed to look into the vulnerability of study participants.

22.2 Genetic Counselling

- ◊ Pre- and post-test non-directive counselling will be given by persons who are qualified and experienced in communicating the meaning of genetic information as some conditions may require termination of pregnancy or selection of embryos to avert birth of a genetically abnormal child/foetus. While disclosing the result, appropriate options should be provided to the family to enable them to come to a decision.
- ◊ While general principles of counselling require the presence of both spouses, necessary care and caution must be taken so as not to break families. Truthful counselling with extreme caution and patience is essential to explain the situation in a proper perspective to minimize psychosocial harm.

22.3 Privacy and confidentiality

The researcher will explain the specific nature of the confidentiality of data generated through genetic testing/research to the patient/participant. Disclosure may cause psychosocial harm and needs careful handling.

Participants should be told of the limits of the researcher's ability to safeguard confidentiality in certain circumstances and the anticipated consequences of breach of confidentiality.

The researcher will delink data to maintain confidentiality and safeguard the information for basic research. However, If the result of the research is of benefit to the health of the participants then, with approval of the EC, data would be re-linked for communication of the result.

Genetic research requires collection of family history and details about other members of the family, thus involving them as secondary participants. If identifiable information is being collected about the secondary participants, their informed consent will be required.

An individual has the right to keep information generated by screening/testing confidential and not share it with family members to avoid the possibility of domestic disputes if the genetic information is damaging, such as results revealing non-paternity, disease carrier status or others.

The researcher will not reveal the genetic information to family members without the participant's permission.

If family members are recruited/tested then their information will be kept confidential from each other by the physician/researcher.

If disclosure is absolutely warranted to provide treatment or counselling, the physician will obtain informed consent from the family member concerned. If that family member does not consent, then the physician will balance the risks of non-disclosure against breach of confidentiality and take an appropriate decision.

Storage of samples collected as part of routine care with potential for future genetic research will be done with appropriate consent from individuals.

Transfer to or sharing of biological material and/or data with other laboratories within the country should be done as per relevant guidelines.

22.4 Informed consent

- ◊ Stringent norms and caution will be followed in the consent process when done for research purposes. For routine genetic diagnostic testing, written consent may not be needed, however, for any research it is required.
- ◊ Informed written consent will be obtained for procedures such as pre-symptomatic testing, next generation sequencing (NGS), prenatal testing, genomic studies, carrier status etc.
- ◊ The consent for screening or a subsequent confirmatory test does not imply consent to any specific treatment or termination of the pregnancy or for research.
- ◊ If the research or testing involves a child, appropriate age-specific assent will be obtained along with parental consent.
- ◊ The consent form for genetic testing for research will have explanations/details on the elements and how the data/samples will be stored, for how long, and procedures involved in anonymization, sharing, etc.
- ◊ Choice to opt out of testing/withdraw from research at any time will be mentioned; whether the proband would like to share her/his genetic information with family members who may benefit from it; and issues related to ownership rights, IPR concerns, commercialization aspects, and benefit sharing.
- ◊ Group consent/community consent will be taken from Community Head (Mukhiya) or culturally appropriate authority for the population or community-based studies.
- ◊ Transmission of a genetic abnormality from parents, especially the mother to the fetus, could be a very sensitive cultural issue. If information is revealed to the husband or other members of the family, it may cause marital discord. Appropriate counselling should be part of the testing process.
- ◊ Consanguineous marriages are common in some communities. If there are inherited diseases detected in the family, it is the responsibility of the health professionals/ researchers to inform participants regarding the possible implications that may arise due to consanguinity. Appropriate pedigrees need to be prepared and stored, as these can reveal a lot regarding disease inheritance in affected families.

22.5 Publication aspects

Publication of pictures, pedigrees or other identifying information about individuals, families or secondary participant(s) will be done with fresh or re-consent. Features on the face will be masked to prevent identification. If these features have to be revealed for scientific reasons, this fact will be stated clearly in the informed consent form and fresh consent will be obtained, if not taken earlier.

22.6 Misuse of genetic technology

- ◊ Genetic information has potential for misuse as well as long-term implications.
- ◊ Prenatal sex selection is not allowed at RIMS, Ranchi. To prevent misuse of genetic tests, particularly pre-selection of sex, GOI has enacted the Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994, amended in 2003.
- ◊ All researchers in this area shall follow the provisions of this Act. Prenatal sex determination is prohibited by law for sex selection of the foetus.

22.7 Genetic Diagnosis/Testing and Screening

- ◊ History and pedigree involve obtaining history of other members of the family of the proband under investigation. It may reveal information about the likelihood of individual members of the family being either carriers of genetic defects or being affected by the disease.
- ◊ The results of genetic tests in diseases that are multifactorial in origin and have a polygenic basis involving multiple genes or gene–environment interaction or those that are late onset, must be communicated carefully to prevent unnecessary worry or fear in the minds of individuals.
- ◊ Genetic screening implies searching a population for those individuals who have or are susceptible to a serious genetic disease; or who, though not at risk themselves, are carriers and thus at risk for having children with a particular genetic disease.
- ◊ It is essential for screening to be purposive. Besides validation of screening tests, it should also be ensured that a suitable intervention and counselling are available.
- ◊ Those being screened are entitled to receive sufficient information about what is proposed to be done, reliability of the screening test, and what will be done with the collected samples.
- ◊ Although screening may be permissible to allay anxiety, the response of different individuals might vary, which should be borne in mind by the health-care provider.
- ◊ Confidentiality should be maintained in handling of results with emphasis on responsibility of individuals with an abnormal result to inform partners and family members. In case of refusal, the duty of confidentiality shall weigh higher than the duty for beneficence to family members unless sharing of information is vital to prevent serious harm to the beneficiary in the family. In such case, appropriate precautions may be taken to ensure that only the genetic information needed for diagnosis/treatment is shared.
- ◊ Screening tests should be sensitive enough to identify a significant proportion of affected persons (the detection rate) with minimal misidentification of unaffected persons (the false positive rate). Screening tests do not aim to make a diagnosis, but rather rationalize the use of more accurate confirmatory tests.

- ◊ Population screening: Genetic disorders can be population specific (for example, thalassemia and sickle cell disease in Jharkhand).
- ◊ Population screening should not be undertaken without prior education of the population to be screened and counselling should be integrated with the programme. Wherever applicable, community permission/group consent should be taken for screening in addition to individual informed consent.
- ◊ Researchers will conduct coded or reversible anonymized testing on general population to establish prevalence of genetic traits/diseases. Blood spots collected for screening newborns for treatable disorders could also be used for this purpose. In case information derived from stored specimens might be useful to an individual, the code may be broken with the approval of the IEC.

22.8 Invasive testing for prenatal diagnosis

Preliminary genetic counselling of women for invasive prenatal diagnosis should include the following:

- ◊ risk of the fetus being affected
- ◊ natural course and prognosis of the specific disorder
- ◊ risks and limitations of the invasive procedures to be used
- ◊ time required before a report can be issued; m possible need for a repeat procedure in the event of a failed att attempt; and
- ◊ limitation of a test due to laboratory error.

22.9 Non-invasive prenatal screening/testing (NIPS/NIPT):

Recent advances in genomic technologies have resulted in the shift of antenatal aneuploidy screening towards the development of NIPS methods by using cell-free foetal (CFF) DNA sequences isolated from a maternal blood sample.

Utmost caution will be taken while reporting the foetal status after prenatal testing.

HLA testing on embryos and fetuses will not be done.

22.10 Pre-implantation genetic screening and diagnosis (PGS and PGD):

In this technique, in vitro screening is done on early embryos for a panel of common genetic disorders, such as aneuploides, and specific disorders with family history or proven carrier status in parent(s) to implant unaffected embryos.

Advanced techniques like chromosomal microarray (CMA) might theoretically raise ethical issues regarding eugenics and designer babies based on selection of embryos.

The ethical concerns regarding selection of sex and therefore adequate safeguards will be taken to prevent misuse.

22.11 Newborn screening (NBS):

Newborn screening is a robust measure for secondary prevention of genetic diseases through early diagnosis with timely intervention and should ideally be in a programme mode and providing not only diagnosis, but also management and treatment along with counseling.

- ◊ NBS should not be generally done when there are no existing therapeutic modalities available (such as special diets) or treatment may not be affordable or no known intervention available for management.

- ◊ The family should have a choice to decide if they would like to be part of newborn screening program with appropriate consent explaining the requirements and implications of the screening with provision to "optout".
- ◊ Community education and advocacy regarding NBS should precede the initiation of the program.
- ◊ Availability of facilities for confirmatory diagnosis and experts for management of the disorders be in place before initiating the program.

22.12 Chromosomal microarray

Interpretations and reporting of CMA results at RIMS, Ranchi will be done cautiously and CNV and VUS will be identified and correlated with the phenotypes.

22.13 Whole exome sequencing (WES) and whole genome sequencing (WGS)

These high throughput next generation sequencing techniques, especially WES, are increasingly being used in clinical practice have raised a new challenge for counsellors as well as patients.

- ◊ These genomic techniques identify pathogenic mutations or variations of unknown significance in many other genes, hidden genetic disorders or cancers which may manifest later.
- ◊ The individual will be informed and asked whether she/he would like to know about unrelated genetic mutations. The results should always be interpreted keeping in mind the coverage of genes of interest. Families/individuals opting for the test will be counselled regarding grey areas in these upcoming technologies prior to testing. They would be made aware that WES/WGS may not give conclusive results.

22.14 Genome-wide association study (GWAS)

Genetic epidemiology, also known as genome-wide association study, involves an examination of many common genetic variants in different individuals to see if any variant is associated with a trait. A GWAS typically focuses on associations between single-nucleotide polymorphisms (SNPs) and traits like major diseases, particularly multifactorial disorders.

23. BIOBANKING AND DATA SETS

A biobank is an organized collection of human biological materials with usually associated dataset stored for years in appropriate facilities for research and potential commercial purposes with inbuilt policies for transparency. The space occupied by organized collection of these materials and data is termed biorepository.

Ethical issues pertaining to consent requirements for the collection and banking and further uses of tissue and DNA samples and/or data are the same but with greater responsibilities concerning their ownership, access and benefit sharing to the individual or community. Therefore, to prevent any exploitation and protect the rights of donors, individual informed consent, clarity on custodianship, and approval of the IEC will be sought for each of the project.

The key aspects related to maintaining confidentiality and privacy of donors of biological materials and/or data that will be inspected by IEC are:

- ◊ The sample will be anonymized by delinking the person from her/his biological material.
- ◊ Confidentiality of data will be maintained, and ethnic identity will be respected especially in population based genetic studies.
- ◊ More precautions will be taken in cases of stigmatizing diseases.

23.1 Storage of biospecimens and data with personal identifiers:

- ◊ Informed consent, confidentiality, privacy, and re-consent are largely influenced by the degree of identifiability, whether the biospecimens and data are anonymized or not. As a general principle, research will be conducted in our institution on least identifiable data.
- ◊ If some degree of identifiability has to be retained for reasons related to the research, for example, anonymized data or specimens will not allow later withdrawal of consent by an individual, while in the coded category, this will be possible.
- ◊ In the latter scenario, the custodians of the respective biorepository or biobank will have a greater responsibility to take adequate measures to safeguard the codes and the data to respect the privacy and confidentiality of individual research participants.
- ◊ Permissibility of a certain research design, acceptability of benefits versus risks, and adequacy of the informed consent, will thus have to be assessed by the IEC, RIMS on a case by-case basis, taking into account specific contextual and potential vulnerability factors of the participants and the sensitive nature of the proposed research.

23.2 Ethical issues related to donors

Informed consent for biobanking poses specific ethical issues as the aims of scientific study based on which biospecimens are collected and stored in a biorepository are not defined clearly at the time of collection when there are no specific end points and there is a time lag between the collection of the sample and its use in research.
The issues involve multiple stages at which consent needs to be administered – storage, analysis of the biospecimens/samples, use of data linked to the sample, incidental findings, return of results to the participant, sharing of the sample/data with other researchers/national or international institutions, multicentre and multinational collaborations and potential commercialization. These raise issues of access and benefit sharing.

23.3 Use of stored material or data for research

Biobanks can use the stored material/data for doing research themselves or they can outsource or supply such material/data to other researchers or institutions on a nonprofit basis.

23.4 Ownership of the biological samples and data:

- ◊ The participant owns the biological sample and data collected from her/him and therefore, could withdraw both the biological material donated to the biobank and the related data unless the latter is required for outcome measurement and is so mentioned in the initial informed consent document.
- ◊ Complete anonymization would practically make the original donor lose the right of ownership. Biobanks/institutes are the custodians or trustees of the samples and data through their ECs as their present and future use would be done under of the respective ECs. Researchers have no claim for either ownership or custodianship.

23.5 Transfer of biospecimens:

A Material Transfer Agreements (MTA) should be executed if the biospecimens are likely to be shipped from the host institution to collaborating institutions within the country or abroad. The EC should oversee the process of the in-country and international material transfer. Mandatory regulatory clearances with appropriate MoU are required if biospecimens are to be sent overseas as per the notification related to transfer of human biological material for commercial purposes released by the Directorate General of Foreign Trade (DGFT).

23.6 Secondary or extended uses of stored samples/re-consent:

The EC will examine circumstances under which the biological material or the data were originally collected, and informed consent obtained. The decision about anonymization/informed consent waiver or re-consent will be made on a case-by-case basis.
The following will be considered while using stored samples:
1. whether the proposed use is aligned with the original consent given for the earlier research and scrutinize the validity of the objectives of the new research;
2. whether provisions for ensuring anonymity of the samples for secondary use are stated;
3. whether the permission of LAR is obtained for post-mortem uses of samples;
4. whether the consent form mentions retention and various possible future uses of tissues in the form of a tiered consent; and
5. Whether provisions have been made for allowance of waiver of consent if the donor is not traceable or the sample/data is anonymized or it is impractical to conduct the research.

23.7 Benefit sharing:

Biological materials and/or data have potential commercial value but the participants' contribution and their share in this benefit is very often not known to them. The informed consent document should emphasize this aspect with necessary clauses for clarity about benefit sharing.

23.8 Role of the EC in Biobanking:

ECs play a key role in oversight and use of the bio- and data repositories for research, scientific and public health program. Research proposals, which require biorepository services including material transfer and available data sets, should be reviewed by the EC, either an institutional one or that of the biorepository.

Biological material/data in forensic departments of laboratories Specimens collected for forensic purposes and related or unrelated data (DNA profiling) offer a good source for academic research after the initial purpose has been served. Data sharing with researchers across the globe is a common practice for refining techniques to develop biomarkers, which could identify missing persons in most difficult circumstances (for example, highly decomposed bodies, disaster situations). In academic institutions, there is a demand for organs and tissues for education, training, and research purposes.

23.9 Informed consent:

If there is no written consent by the deceased person permitting use of organs or tissues, the family can be approached for consent for use of left-over organs or tissues.

- ◊ No consent would be required if sample or data is anonymized.
- ◊ If the deceased has no claimant, then forensic officials will be authorized to give permission for use of material/data from its sources and be responsible for use of unclaimed cadavers.
- ◊ The quantity of tissue taken would be minimal, particularly if it is seen externally on the body to preserve the dignity of the dead and be culturally acceptable by the next of kin or closest relative or friend.
- ◊ The information in the informed consent document should state what tissue/organ will be retained, who will be the custodian, duration of storage of sample, what type of research would be conducted and method for disposal of the remains.
- ◊ Genetic research or revelation of any other stigmatizing factors like HIV, etc. in the deceased may have implications for family members. In such instances, all ethical requirements as in the case of live participants will be followed.
- ◊ The role of the IEC, RIMS, Ranchi is to review and approve the type of consent – broad, tiered with or without option to opt-out or specific and to assess from whom it would be taken – the family, closest relative or friend – or whether sample anonymization should be done.

23.10 Governance of biobank/biorepository:

- ◊ Each biorepository will have its own technical authorization committee with representation of both science and ethics and external members. The committee will function in tandem with the EC.
- ◊ The technical authorization committee, indigenous to the biorepository, will govern collection of specimens, disbursement of biospecimens and data to researchers. The same committee would also oversee regulatory aspects like execution of MTA or data transfer agreement (DTA) for transfer of biospecimens and/or data to other institutions.
- ◊ Stand-alone huge repositories should have separate technical authorization committees and ECs to undertake the above-mentioned tasks.
- ◊ The IEC will look into whether the biobank has well-structured SOPs and clear guidelines for collection, coding, anonymization, storage, access, retrieval and sharing of biospecimens and data.
- ◊ The technical authorization committee/governance committee comprises members as clinicians, geneticists, lawyers, basic scientists, sociologists, epidemiologists, statisticians and ethicists.

23.11 Special issues related to datasets

With increasing ease of establishing and maintaining large repositories the primary objective of data collection and storage in some of these databases may not be research but with advances in information technology (IT) and decreasing costs, they offer a huge potential for subsequent research as well as commercialization. Whenever such repositories will be used for purposes of research or for subsequent commercialization, it will follow the expected requirements of other health-related research with due diligence, including review by the IEC.

There is also a proliferation of data mining and other data science tools that can be employed on existing databases for research purposes to reduce costs and health related processes. IEC approval is required to establish legitimacy of the purpose for data mining, access control and about the usefulness of information for particular groups (such as rare disease group). Data privacy, data accuracy, data security, and possibility of legal liability would be ensured when the data is outsourced or sold. Auditing will be done to detect misuse.

Health data is increasingly being collected outside of traditional healthcare settings. Data is shared with third parties not only for research, but also for commercial gain. Big data in health research raises a wide spectrum of ethical issues, ranging from risks to individual rights, such as privacy and concerns about autonomy to individuals. There are unique aspects, such as its data sources, scale, and open access provisions. Ethical issues related to data security, sharing, rights, benefit sharing and others surrounding big data need to be closely examined.

Databases maintained in electronic/digital formats, linked by internet or other networks, using cloud computing technologies and those associated with big data initiatives, may pose additional risks to privacy and confidentiality than what is described under biobanks or traditional paper-based data repositories. Hence, in such situations all reasonable measures must be adopted to respect and protect privacy and confidentiality of individuals.

23.12 Measures to ensure privacy and confidentiality of individuals

- ◊ Physical safety and security of the involved devices and computer servers will be ensured.
- ◊ Data security measures such as password protection will be done.
- ◊ Provision of differential and role-based controlled access to data elements for members of the research team will be made.
- ◊ Data encryption when data is transferred from one location/device to another will be ensured
- ◊ Benefit sharing with owners and related legal issues will be ensured.

23.13 Contingency plan:

One of the important but often neglected ethical issues related to biorepository is the legacy or contingency plan. RIMS, Ranchi will develop the contingent plans for sustainability of the biobanks.

24. REFERENCES

1. ICMR Ethical Guidelines for Biomedical Research in Humans
2. CDSCO-GCP
3. WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants.
4. AIIMS-P SOP 2013-2014
5. TMC IEC SOP 2016
6. AIIMS Bhuvneshwar IEC SOP 2012-13
7. Office of the Human Research Protection, US Department of Health and Human Services (HHS).
8. CREC-STM SOP Version 3
9. New Drugs and Clinical Trials Rules, 2019 - CDSCO

ANNEXURES

Memo No…… Dated……

APPOINTMENT ORDER OF MEMBER OF IEC

To,

Dr./ Mr. / Mrs.: _____

Subject- Appointment as Member of Ethics Committee

I understand that you were approached by my office for exploring your interest to join the Institutional Ethics Committee (IEC), RIMS, Ranchi and I am happy to know about your willingness to join.

It is my privilege to appoint you as a member in the category ……. of the Institutional Ethics Committee (IEC), (Human research) at Rajendra Institute of Medical Sciences, Ranchi (RIMS, Ranchi), w.e.f. the date of your joining. The appointment will be for a term of three years.

The Terms of Reference of your membership has been attached. Please confirm by a return email your acceptance of this offer and willingness to join with immediate effect. Also share your CV as per the format in the attachment.

Director
RIMS, Ranchi.

AX1–V5/SOP01/V5.0

TERMS OF REFERENCE FOR MEMBERSHIP

a. The members are appointed by the Director, RIMS, Ranchi.
b. The members are appointed for a period of 3 years.
c. The members should submit with the appointing authority, a brief profile of yours, with relevant information, as per the prescribed proforma.
d. The members have to sign a Confidentiality Agreement at the start of your tenure. The confidentiality agreement protects the privacy and confidentiality of all parties whose information may be disclosed to the Committee in the course of its work.
e. The members have to sign a Conflict of Interests Declaration Form at the start of your tenure. Such declaration is essential to decide your eligibility for membership. During the tenure of your membership if any new conflict of interests arises that might influence or bias your role as a member of the Committee, you should forthwith declare the same to the appointing authority, i.e Director RIMS, Ranchi
f. The appointment becomes effective from the date the members receive the appointment letter and submit in writing their consent to join the Committee.
g. On expiry of this 3 years tenure, the membership may be renewed for another term, provided the member agrees. Extension of membership beyond this tenure will be decided by the Director, RIMS, Ranchi.
h. You are free to resign and withdraw your membership any time you wish, for which you need not have to give reasons. If you decide to resign you should send a written notification of resignation to the Director RIMS, Ranchi.
i. The members should be sufficiently aware about their role and responsibilities as a member of the Committee in their capacity as clinician/ basic scientist/ legal expert/ NGO representative/ Lay person from the community.
j. They should have exposure to and training experience in Good Clinical Practice (GCP) Guidelines and ICMR Biomedical Research Ethics Guidelines and their periodic amendments from time to time. You have to submit with the appointing authority, the copies of all such experience or participation certificates.
k. During the membership tenure, the members should always try to avail the opportunities to attend the workshops and seminars to upgrade your knowledge and understanding in this area. They should expeditiously forward a copy of all such training certificates to the Member Secretary of the Committee. Besides, the Committee will also periodically hold awareness seminars or training events; they should attend them and update their knowledge and understanding in the area.
l. They are required to act responsibly and attend the scheduled meetings of the Committee regularly, besides fulfilling the other responsibilities that are assigned to you by the Chairperson of the Committee.
m. If a member fails to attend more than 3 consecutive meetings of the Committee, he/she may be relieved of the membership. Besides, they may be terminated of membership in case their conduct is found to be unbecoming of a member of the Committee.

I have carefully gone through all the terms and understood them. I agree to comply with all.
Signature with date……. Name……..

AX2– V5/SOP01/V5.0

Consent Letter

Consent to be a member of IEC, RIMS, Ranchi

From: ……..
..……
……..

To
Director
RIMS Ranchi

Sub: Regarding Consent to be a member of Institute Ethics Committee (Human Studies)

Ref: Letter No: …… dated: ……..…….

Dear Sir,

In response to your letter stated above, I give my consent to become a member of IEC of RIMS Ranchi. 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: Address: Telephone No: (Off) (Res) email: _____

AX3– V5/SOP01/V5.0

Confidentiality Agreement Form for IEC Members, RIMS, Ranchi

(Form IA)

I, Dr./ Mr./ Mrs. …… have been appointed as a member of the Ethics Committee (IEC, RIMS, Ranchi), and am willing to join the Institutional Ethics Committee (IEC, RIMS, Ranchi) as a ……Member (mention membership category), hereby declare that as the member of this committee-

- I shall always keep in trust of confidence any information, ideas, data, discoveries, etc in respect of all clinical research studies (including clinical trials) that are disclosed/ revealed to me or that I would have accessed to, by virtue of the membership;

- I shall consider all such information and confidential, privileged or proprietary (if applicable);
- I shall use such information for contemplated purposes only; and

- I shall by no means disclose such information verbally, visually or in writing, to anyone other than in situations where it is statutorily or legally permitted/ bound.

…… ……

Name Signature with Stamp

Place ……. Date……

AX4– V5/SOP01/V5.0

Conflict of Interest Declaration Form for IEC Members at RIMS, Ranchi (Form 1B)

I, Dr./Mr./Ms. …….. have been appointed as a member of the Ethics Committee (IEC, RIMS, Ranchi), and am willing to join the Institutional Ethics Committee (IEC, RIMS, Ranchi) as a ……Member (mention membership category), hereby declare that, as on date,

I do not have any conflict of interest to disclose in reference to my role as a member of this committee.
I do have conflicts of interest in reference to my role as a member of this committee; and I hereby disclose them as follows:

……
……
……
……
……
……

…… ……
Name Signature with Stamp

…… ……
Place Date

AX5– V5/SOP01/V5.0

Office order of constitution of IEC, RIMS, Ranchi

Letter Ref Number Date:

OFFICE ORDER

I herewith establish and constitute an Ethics Committee of Rajendra Institute of Medical Sciences, Ranchi, to ensure a competent review of all ethical aspects of project proposal received and execute the same free from any bias and influence that could affect the objective.

The following members will constitute the Institute Ethics Committee (Human studies):

1.

2.

3.

4.

5.

6.

7.

The tenure of this membership will be for a period of 3 years from the date of appointment.

Director,
Rajendra Institute of Medical Sciences,

Ranchi

AX6- V5/SOP01/V5.0

Proforma to be submitted to the Institutional Ethics Committee, RIMS, Ranchi (Human Studies) for MD/MS/DM/MCh/PhD Students (for thesis or Dissertation)/MBBS student projects

Kindly submit 03 copies of proforma and consent forms in 2 parts (in English and Hindi/other local language) to the Member Secretary, IEC, RIMS, Ranchi.

1. Title of the project:
2. Name and department/address of the investigator:
3. Name of Faculty (Guide/Co-guide) with designation & department: 4. Date of approval by Institute Research Cell:
5. Sources of funding
6. Objectives of the study:
7. Justification for the conduct of the study:

8. Methodology: It should provide details of number of patients, inclusion criteria, exclusion criteria, control(s), study design, dosages of drug, duration of treatment, investigations to be done.

9. Permission from Drug Controller General of India (DCGI) if applicable

10. Ethical issues involved in the study: less than minimal risk/ minimal risk/ more than minimal risk to the study subjects

11. Do you need exemption from obtaining Informed Consent from study subjects-if so give justifications

12. Whether Consent forms part 1 and 2 in English and Hindi/Other local language are enclosed? (if the consent form in local language is not applicable, appropriate explanations must be provided)

13. Conflict of interest for any other investigator(s) (if yes, please explain in brief)

14. Whether soft copy of the proforma (CD) has been attached?

15. We, the undersigned, have read and understood this protocol and hereby agree to conduct the study in accordance with this protocol and to comply with all requirements of the ICMR guidelines (2017)

Date and Signature of the Investigators

Date and Signature of the Guide Signature of the Head of the Department

AX7- V5/SOP01/V5.0

Proforma for submission of research proposals involving human participants for ethical approval from IEC, RIMS, Ranchi

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. 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 during the research. Plan for statistical analysis of the study. Ethical issues in the study and plans to address these issues.
6. 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 Hindi/Other 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.
7. 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.
8. Usefulness of the project/trial
9. Expected 'benefits' to volunteers / community. 'Benefits' to other categories if any.
10. Explain all anticipated 'risks' (adverse events, injury, and 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, if applicable.
11. Agreement to report all Serious Adverse Events (SAE) to IEC, RIMS, Ranchi.
12. Other financial issues including those related to insurance.
13. An account of storage and maintenance of all data collected during the trial.
14. Research proposals approval by scientific advisory committee/Research Cell
15. 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)

16. For exchange of biological material in international collaborative study a MoU/ Material Transfer Agreement between the collaborating partners.
17. Statement of conflicts of interest, if any.
18. Agreement to comply with the relevant national and applicable international guidelines, Good Clinical Practices (GCP) protocols for clinical trials.
19. 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.
20. 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.
21. Curriculum vitae of all the investigators with relevant publications in last five years.
22. Plans for publication of results / positive or negative / while maintaining the privacy and confidentiality of the study participants.
23. Any other information relevant to the study.

Signature of the Principal Investigator with date.

AX8- V5/SOP01/V5.0

Annexure - 11

FORM TO BE FILLED BY PRINCIPAL INVESTIGATOR(PI) FOR SUBMISSION TO INSTITUTIONAL ETHICS COMMITTEE, RIMS RANCHI (FORM 2)

(For attachment to each copy of the proposal)

For office use only	
Serial number of IEC, RIMS, Ranchi	

To be filled by Pl				
Title of Project :				
Name, Designation, Department, Qualification		**Address, Telephone No., Mobile No., Email id**	**Number of projects already with investigator**	**Signature (with date)and seal**
Principal Investigator				
Co- Investigators				
1.				
2				
3				
4				
Please attach detailed Curriculum vitae of all Investigators (with subject specific publications limited to previous 5 years).				

Sponsor information (Tick appropriate box)						
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		Clinical Trial		Review	
Participating Centre:	Single centre		Multi centre		Other (Specify)				
2.Status Review:	New		Revised						

3.Clinical Trials: Drug/Vaccines/Device/Herbal Remedies:

I. Does the study involve use of :

	Drug		Devices		Vaccines	

Indian Systems of Medicine / AlternateSystem of Medicine		Any other		NA	

II. Is it approved and marketed

In India		UK & Europe		USA	
Other countries		Specify: _____			

III. Does it involve a change in use, dosage, route of administration?	Yes	No
If Yes, whether DCG I ' s /Any other Regulatory authority's Permission is obtained?	Yes	No
If yes, Date of Permission:		
IV. Is it an Investigational New Drug (IND)?	Yes	No
If yes, IND No.:		
a) Investigator's Brochure submitted	Yes	No
b) *In vitro* studies data	Yes	No
c) Preclinical studies done	Yes	No

d) Clinical Study is:	Phase I		Phase II		Phase III		Phase IV	

e) Are you aware if this study /simi lar study 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 word s):							
5.Subject selection:							
I. Number of Subjects:							
II. Duration of Study:							
111. Will subjects from both sexes be recruited?						Yes	No
IV. Inclusion / exclusion criteria given						Yes	No
V. Type of subject		Volunteers		Patients			
VI. Vulnerable subjects (Tick the appropriate boxes)		Yes		No			
Pregnant women		Children		Elderly			
Foetus		Illiterate		Handicapped			
Terminally ill		Seriously ill		Mentally/ Challenged			
Economically & socially backward		Any other					
VII. Special group subjects (Tick the appropriate boxes)		Yes		No			
Captives		Nurse/dependent					
Students		Institutionalised		Armed forces			
Any other		Staff					
6. Privacy and confidentially							
I. Study involves - Direct Identifiers							
Indirect Identifiers/coded							
Completely anonymized / delinked							
11. 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 therapy						Yes	No
111. Use of recombinant/gene therapy						Yes	No
If yes, has Department of Biotechnology (DBT) approval for DNAproducts 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 ionizing radiation / radioisotopes	Yes	No
If yes, has Bhaba Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained ?	Yes	No
VII. Use of infectious / bio hazardous specimens	Yes	No
VIII. Proper disposal of material	Yes	No
IX. Will any sample collected from the patients be sent abroad?	Yes	No
If Yes, justify with details of collaborators		
a) Is the proposal being submitted for clearance from Health Mini try ' sScreening 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 in accessible		
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		Contact information	
Purpose and procedures		Statement that consent is voluntary	
Risks & Discomforts		Right to withdraw	
Be ne fits		Consent for future use of biologicalmaterial	
Compensation for participation		Bene fits if any on future commercialization eg. Genetic basis drug development	
Compensation for study related injury			

*If written consent is not obtained, give reasons:

11. Who will obtain consent?	PI/ Co-Pl		Nurse/Counsellor	
	Research staff		Any other	

9. Will any advertising be done for recruitment of subjects? (posters, flyers, brochure, websites- if so attach a copy)	Yes	No
10. Risks & Benefits:		
I. Is the risk reasonable compared to the anticipated benefits to subjects/ community/country?	Yes	No
11. Is there physical / social / psychological/ discomfort?	Yes	No

If Yes , Minimal or no risk		
More than minimum risk		
High risk		
111. Is there a benefit a) to the subjects?		
Direct	Indirect	
b) Benefits to society		
11. Data Monitoring		
I. Is there a Data & Safety Monitoring Committee /Board (DSMB)?	Yes	No
11. Is there a plan for reporting of adverse events? If Yes, reporting is done to:	Yes	No
Sponsor **Ethics committee**	DSMB	
111. 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 lo ng ?	Yes	No
12. ls there compensation for participation?	Yes	No

If **Yes,** Monetary		In kind	
Specify amount and type:			
13. Is there compensation for injury?		Yes	No
If Yes, By sponsor		By Investigator	
By Insurance Company		By any other	
14. Do you have conflict of interest? (financial / nonfinancial) If **Yes, specify** :		Yes	No
Conflict of interest for any other investigator(s) (if yes, please explain inbrief)	1 _____ Yes N 2 _____ Yes N 3 _____ Yes N 4 _____ Yes N		
		Attached English version	
		Attached Hindi version	

15. Participant Information **Sheet** (mark √ if yes)		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.Whet her any work on this project has started or not?		(mark √ if yes, X if no) (Please enclose a separate certificate to this effect).
l8. In case of clinical trials CTRI status		

Checklist for attached documents:	
Covering letter, through proper channel	
Project proposal – 05 Copies	
Curriculum Vitae of Investigators	
Brief description of proposal	
Patient information she et	
Informed consent form	

Investigator's brochure for recruiting sub jects
Copy of advertisement / Information brochure
Copy of clinical trial protocol and / or questionnaire
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-centre study, I EC clearance of other centers must be provided

Definite undertaking as to who will bear the expenditure of injury related to the project
In case an insurance cover is in tended, Insurance certificate must be provided (as per ICMR guidelines)
Permission to use copyrighted Questionnaire/ Proforma
Investigator should provide undertaking what they will do the leftover sample tissue
Certificate / undertaking as mentioned in column 17
Others

AX10- V5/SOP01/V5.0

FORMAT TO ACCORD APPROVAL TO CLINICAL TRIAL PROTOCOL BY THE IEC, RIMS, RANCHI.

[Proforma for research proposal involving human subjects to be submitted to the Institute Ethics Committee for approval]

To
Dr. ……

Dear Dr. ……..…….

The Institutional ethics committee or independent ethics committee (state name of the committee, as appropriate) reviewed and discussed your application to conduct the clinical trial entitled "…….....
"on……(date). The following documents were reviewed:

(a) Trial protocol (including protocol amendments), dated…….version No.(s) ……
(b) Patient information sheet and informed consent form (including updates, if any) in English or vernacular language.
(c) Investigator's brochure, dated ..... , Version no…… Proposed methods for patient accrual including advertisements etc. proposed to be used for the purpose.
(d) Principal investigator's current Curriculum Vitae.
(e) Insurance policy or compensation for participation and for serious adverse events occurring during the study participation.
(f) Investigator's agreement with the sponsor.
(g) Investigator's undertaking (enclosed).

The following members of the ethics committee were present at the meeting held on (date, time, place). ……Chairperson of the ethics committee;
……Member-Secretary of the ethics committee;

……Name of each member with designation;
……

We (Approve / Approve with modifications /Reject) the trial to be conducted in its presented form. The ethics committee to be informed about the progress of the study, any Serious Adverse Events (SAE) occurring during the study, any changes in the protocol and patient information or informed consent and to be provided with a copy of the final report.

Yours sincerely,
Member Secretary,
Institutional Ethics Committee, RIMS, Ranchi.

UNDERTAKING BY THE INVESTIGATOR

1. Full name, address and title of the Principal Investigator (or Investigators when there is no Principal Investigator).
2. Name and address of the medical college, hospital or other facility where the clinical trial will be conducted: Education, training & experience that qualify the Investigator for the clinical trial (Attach details including Medical Council registration number, or any other statements of qualifications)
3. Name and address of all clinical laboratory facilities to be used in the study.
4. Name and address of the Ethics Committee that is responsible for approval and continuing review of the study.
5. Names of the other members of the research team (Co-or sub-Investigators) who will be assisting the Investigator in the conduct of the investigations.
6. Protocol Title and Study number (if any) of the clinical trial to be conducted by the Investigator.
7. Commitments:

(i) I have reviewed the clinical protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary ethics committee and regulatory approvals have been obtained.
(ii) I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol without agreement by the Sponsor and prior review and documented approval or favorable opinion from the ethics committee of the amendment, except where necessary to eliminate an immediate hazard to the trial subject or when the changes involved are only logistical or administrative in nature.
(iii) I agree to personally conduct or supervise the clinical trial at my site.
(iv) I agree to inform all trial subject, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent and ethics committee review and approval specified in the New Drugs and Clinical Trials Rules, 2019 and Good Clinical Practices guidelines are met.
(v) I agree to report to the Sponsor all adverse experiences that occur in the course of the investigation(s) in accordance with the regulatory requirements and Good Clinical Practices guidelines.
(vi) I have read and understood the information in the Investigator's brochure, including the potential risks and side effects of the drug.
(vii) I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about their obligations in meeting their commitments in the trial.
(viii) I agree to maintain adequate and accurate records and to make those records available for audit or inspection by the Sponsor, ethics committee, Central Licencing Authority or their authorised representatives, in accordance with regulatory provisions and the Good Clinical Practices guidelines. I will fully cooperate with any study related audit conducted by regulatory officials or authorised representatives of the Sponsor.
(ix) I agree to promptly report to the ethics committee all changes in the clinical trial activities and all unanticipated problems involving risks to human subjects or others.

(x) I agree to inform all serious adverse events to the Central Licencing Authority, sponsor as well as the ethics committee within twenty-four hours of their occurrence. In case, of failure to do so, I shall furnish the reason for the delay to the satisfaction of the Central Licencing Authority along with the report of the serious adverse event.

(xi) The report of the serious adverse event, after due analysis, shall also be forwarded by me to the Central Licencing Authority, the Chairperson of the ethics committee and the Head of the institution where the trial has been conducted within fourteen days in accordance with the regulatory requirements.
(xii) I will maintain confidentiality of the identification of all participating subjects and assure security and confidentiality of study data.
(xiii) I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical Investigators participating in clinical trials.

8. Signature of the Investigator with date.

RIMS IEC Office requires review of an approved study not less than once per six (06) months 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, IEC

AX11- V5/SOP01/V5.0

Data Elements for Reporting Serious Adverse Events (SAE) occurring in a Clinical Trial or bioavailability or bioequivalence study

1. *Patient Details*

Initials & other relevant identifier (hospital/OPD record number)*

Age/ DOB Weight

Height

2. *Suspected Drug(s)*

Generic name of the drug*

Indication(s) for which suspect drug was prescribed or tested Dosage form and strength

Daily dose and regimen (specify units - e.g., mg, ml, mg/kg)

Route of administration

Starting date and time of day

Stopping date and time, or duration of treatment

3. *Other Treatment(s)*

Provide the same information for concomitant drugs (including nonprescription/OTC drugs) and non-drug therapies, as for the suspected drug(s).

4. *Details of Suspected Adverse Drug Reaction(s)*

Full description of reaction(s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the reaction*

Start date (and time) of onset of reaction

Stop date (and time) or duration of reaction

Dechallenge and rechallenge information

Setting (e.g., hospital, out-patient clinic, home, nursing home)

5. *Outcome*

Information on recovery and any sequelae; results of specific tests and/or treatment that may have been conducted

For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction; Any post-mortem findings.

Other information: anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse; family history; findings from special investigations etc.

6. *Details about the Investigator**

Name
Address
Telephone number Profession (specialty)
Date of reporting the event to Licensing Authority:
Date of reporting the event to Ethics Committee overseeing the site:

Signature of the Investigator

*Note: Information marked * must be provided."*

AX12/ V5/SOP01/V5.0

Institute Ethics Committee, RIMS, Ranchi

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 _____

Progress:

Side Effect if any:

Amendments if any:

Discontinuation reasons:

Progress:

Period of six-monthly progress report: from_____to _____

Signature of Principal Investigator __

AX13/ V5/SOP01/V5.0

Proforma of the Subject Information Sheet

Institutional Ethics Committee (IEC)

RIMS, Ranchi

Title of the project:
Site of the investigation:
Name and address of the Principal Investigator:
Contact number of Principal Investigator:

1. Aims and methods of the research (A brief introduction about the investigation along with purpose of the study and procedure of investigation involving human subjects in simplified manner (10-15 lines).
2. Expected duration of the subject participation.
   The benefits to be expected from the research to the Participants or to others.
3. Alternative treatment/procedure options.
4. Right to prevent use of biological samples (DNA, cell line etc.) at any time during the research.
5. Any risk to the subject associated with the study.
6. Maintenance of confidentiality of records.
7. Provision of free treatment for research related injury.
8. Compensation of subjects for disability or death resulting from such injury.
9. Freedom of individual to participate or to withdraw from research at any time without penalty or loss of benefits to which the subject would otherwise be entitled.
10. Amount of clinical sample in quantity, to be taken should be mentioned.
11. Source of funding for the Investigation.
12. In case of drug trials:
    a) The chemical name of drug, date of its manufacturing and batch number must be mentioned.
    b) Initial bio equivalent study of the drug/references should be provided
13. Foreseeable extent for information on possible current and future usage of the biological material and of the data to be generated from the research and if the material is likely to be used for secondary purposes or would be shared with others, clear mention of the same.
14. Risk of discovery of biologically sensitive information.
15. Publication, if any, including photographs and pedigree charts.
16. Responsibility of Investigators.

Consent Form for research participants more than 18 years of age (Form 3A)

Participant Informed Consent Form

Study Title:

Study Number:

Subject's Initials: ……

Subject's Name: ……..

Date of Birth/Age: ……...

1. I agree voluntarily to take part in this study.
2. I have been explained the purpose and other details of the study. I have been given a full explanation of the procedures involved.
3. I have been given an opportunity to ask questions and all my questions have been answered to my satisfaction.
4. I am free to withdraw from the study at any time without any reason and without my medical care or legal right being affected.
5. I understand that the information in my medical records is essential to evaluate the results of the study. I agree to release this information on the understanding that will be treated confidentially.
6. I agree that I will not be referred to by name in any reports/documents/any other means concerning this study.
7. I have been explained the risks and benefits for the patients and society associated with the study.
8. I understand that if I am harmed as result of taking part in the study, treatment will be provided free of cost by the PI/Institution.
9. I agree/ do not agree that the biological samples collected during this study may be stored for future use.

I willingly agree to take part in the above study.

Signature of the participant/guardian Date:
Name:
Age:
Address:

Signature of the doctor/Principal Investigator: Date:

Signature of the witness: Date:

Note: Make 2 copies of the Subject Information Sheet and Consent Form, one copy for the Principal Investigator and the other copy for the patient.

AX15/ V5/SOP01/V5.0

Signature page for research involving children ages from birth to 6 years of age or unable to provide assent for other reasons

Parents/Legally accepted representative (LAR) Consent Form (Form 3B)

1. I agree that my child is voluntarily taking part in this study.
2. I have been explained the purpose and other details of the study. I have been given a full explanation of the procedures involved.
3. I have been given an opportunity to ask questions and all my questions have been answered to my satisfaction.
4. I know that my child is free to withdraw from the study at any time without any reason and without my medical care or legal right being affected.
5. I understand that the information in my child's medical records is essential to evaluate the results of the study. I agree to release this information on the understanding that will be treated confidentially.
6. I agree that my child will not be referred to by name in any reports/documents/any other means concerning this study.
7. I have been explained the risks and benefits for the patients and society associated with the study.
8. I agree that if my child is harmed as result of taking part in the study, treatment will be provided free of cost by the PI/Institution/University.
9. I agree that the biological samples collected during this study may be stored for future use

I willingly agree that my child will take part in the above study.

Allow Do not allow

Signature of the parent/guardian Date:
Name:
Age:
Address:

Signature of the doctor/Principal Investigator: Date:

Signature of the witness: Date:

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Waiver of assent

The assent of ---------- (name of child/minor) was waived because of:
Age:

Maturity:

Psychological state of the child:

Signature of the Parent/Legally authorized representative: Date:

Note: Make 2 copies of the Subject Information Sheet and Consent Form, one copy for the Principal Investigator and the other copy for the patient.

AX16- V5/SOP01/V5.0

Signature page for research involving children aged 7 through 17 years of age and able to provide assent (Form 2C)

1. I agree that my child is voluntarily taking part in this study.
2. I have been explained the purpose and other details of the study. I have been given a full explanation of the procedures involved.
3. I have been given an opportunity to ask questions and all my questions have been answered to my satisfaction.
4. I know that my child is free to withdraw from the study at any time without any reason and without my medical care or legal right being affected.
5. I understand that the information in my child's medical records is essential to evaluate the results of the study. I agree to release this information on the understanding that will be treated confidentially.
6. I agree that my child will not be referred to by name in any reports/documents/any other means concerning this study.
7. I have been explained the risks and benefits for the patients and society associated with the study.
8. I agree that if my child is harmed as result of taking part in the study, treatment will be provided free of cost by the PI/Institution/University.
9. I agree/ do not agree that the biological samples collected during this study may be stored for future use.

I willingly agree that my child will take part in the above study.

Signature of the parent/guardian Date:

Assent of child---------- (name of child/minor) has agreed to participate in above study

Signature of the child Date:

Name:
Age:
Address:

Signature of the doctor/Principal Investigator: Date:

Signature of the witness: Date:

Note: Make 2 copies of the Subject Information Sheet and Consent Form, one copy for the Principal Investigator and the other copy for the patient.

AX17- V5/SOP01/V5.0

lnformed Consent Document for Drug Clinical Trial (FORM 2D, FORM 2E)

(As per table 03 of New Drugs and Clinical Trial Rule 2019, dated 19th March, 2019)

INFORMED CONSENT

1**. Checklist of Review of informed consent documents for clinical trial subject**

1.1 Essential elements:

(i) Statement that the study involves research and explanation of the purpose of the research.

(ii) Expected duration of the participation of subject.

(iii) Description of the procedures to be followed, including all invasive procedures.

(iv) Description of any reasonably foreseeable risks or discomforts to the Subject.

(v) Description of any benefits to the Subject or others reasonably expected from research. If no benefit is expected Subject should be made aware of this.

(vi) Disclosure of specific appropriate alternative procedures or therapies available to the Subject.

(vii) Statement describing the extent to which confidentiality of records identifying the Subject will be maintained and who will have access to Subject's medical records.

(viii) Trial treatment schedule and the probability for random assignment to each treatment (for randomized trials).

(ix) Statement describing the financial compensation and the medical management as under:

(a) In case of an injury occurring to the subject during the clinical trial, free medical management shall be given when required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier.

(b) In the event of a trial related injury or death, the sponsor or his representative or the investigator or centre, as the case may be, in accordance with the rule 39, as the case may be, shall provide financial compensation for the injury or death.

(x) An explanation about whom to contact for trial related queries, rights of Subjects and in the event of any injury.

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

(xii) Responsibilities of subject on participation in the trial.

(xiii) Statement that participation is voluntary, that the subject can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the subject is otherwise entitled.

(xiv) Statement that there is a possibility of failure of investigational product to provide intended therapeutic effect.

(xv) Statement that in the case of placebo-controlled trial, the placebo administered to the subjects shall not have any therapeutic effect.

(xvi) Any other pertinent information.

1.2 Additional elements, which may be required:

(a) Statement of foreseeable circumstances under which the participation of the subject may be terminated by the Investigator without his or her consent.

(b) Additional costs to the subject that may result from participation in the study.

(c) The consequences of a Subject's decision to withdraw from the research and procedures for orderly termination of participation by Subject.

(d) Statement that the Subject or Subject's representative will be notified in a timely manner if significant new findings develop during the course of the research which may affect the Subject's willingness to continue participation will be provided.

(e). A statement that the particular treatment or procedure may involve risks to the Subject (or to the embryo or foetus, if the Subject is or may become pregnant), which are currently unforeseeable.

(f) Approximate number of Subjects enrolled in the study.

2. **Format of informed consent form for Subjects participating in a clinical trial:**

Participant Informed Consent Form to participate in a Clinical Trial (Form 2E)

Study Title:

Study Number:

Subject's Initials: _____

Subject's Name: _____

Date of Birth/Age: _____

Address of the Subject ___

Qualification _____

Occupation: Student or Self-Employed or Service or Housewife or Others (Please click as appropriate) .

Annual Income of the subject:

Name and address of the nominees and his relation to the subject (for the purpose of compensation in case of trial related death).

(i) I confirm that I have read and understood the information sheet [ ]

dated _____ for the above study and have had the opportunity to ask questions.

(ii) I understand that my participation in the study is voluntary and [ ]
that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

(iii) I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access.

However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purposes. [ ]

(v) I agree to take part in the above study. [ ]

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative:

Signatory's Name: _____

Signature of the Investigator: _____ Date: ____ / _

Study Investigator's Name: ___ _____

Signature of the Witness _____ Date: ____ / ____ /

Name of the Witness:_____

Copy of the Patient Information Sheet and duly filled Informed Consent Form shall be handed over to the subject his or her attendant.

AX18- V5/SOP01/V5.0

CHECKLIST FOR VERIFICATION OF PROPOSALS SUBMITTED TO IEC, RIMS, RANCHI [HUMAN STUDIES] (FORM4)

For official use only Proposal No.

	Yes	No	NA	Comments
Is all the documentation provided?				
Scientific importance and validity				
I. Will the study lead to improvements in human healthand wellbeing or increase knowledge?				
2. If the study is a replication of a previous study, is it justified?				
3. Can the intervention studied be practically implemented?				
4. Is there provision for dissemination of results of the research?				
5. Has the research protocol been approved by a competent body?				
6. Should the study be referred to a technical expert,policy marker or statistical expert? (If Yes, please inform the Secretary as soon as possible, suggesting a suitable person)				
7. Are the objectives stated clearly?				
8. Is the study design appropriate in relation to the objectives?				
9. Are the investigators' qualification, competence, and experience appropriate to conduct the study?				
10. Are the facilities at the site adequate to support the study?				
11. Is the manner in which the results of research will be reported and published ethical?				
Assessment of Risk / Benefits				
I. Is the involvement of human participants necessary to obtain the necessary information?				
2. Are the researcher's qualifications, competence and experience suitable to ensure safe conduct of the study?				
3. Is the justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participant and the concerned committee adequately?				

	Yes	No	NA	Comments
4. Are there any plans to withdraw or withhold standard therapy for the purpose of research and such actions if any justified?				
5. Is there provision for compensation for participants who sustain injuries?				
6. Have adequate provisions been made for dealing with and reporting adverse effects?				
7. Have adequate provisions been made for safety monitoring and termination of the research project?				
Respect for the dignity of the research participants				
Informed consent				
I. Is the process for obtaining informed consent appropriate?				
2. Are the pa1ticipants competent to give consent?				
3. Is the justification adequate for the intention to include individuals who cannot consent?				
4. Will dissent be respected?				
5. Is the written and oral information to be given to the research participants appropriate, adequate, complete and understandable?				
6. Do you approve the incentives offered?				
7. Is the consent given voluntarily and not due to deception, intimidation or inducement?				
Confidentiality				
I. Will the researcher collect only the minimum information/ samples required to fulfil the study objectives?				
2. Is the privacy of the research participant safeguarded?				
3. Are data/sample storage and disposal procedures adequate?				
Rights of the participants				
I. Is the participant's right to unconditionally withdraw from the research at any time safeguarded?				
2. Is there provision for participants to be informed about newly discovered risks or benefits during the study?				
3. Is there provision for the subjects to be informed of results of clinical research?				

	Yes	No	NA	Comments
Fair participant selection				
I. Has the study population been determined, primarily, based on the scientific goals of the study (and not on convenience, ethnicity, age, gender, literacy, culture or economic status?				
2. Is the selection of participants (inclusion and exclusion criteria) appropriate so that risks are minimized and benefits are maximized and the burden of research equitably distributed?				
3. Does the selection of participants stigmatize any group?				
4. Does selection of subjects favor any group?				
5. Is the research conducted on vulnerable individuals or groups?				
6. Is the research externally sponsored?				
7. Is the research a community research?				
8. Is the research a clinical trial?				
Responsibilities of the researcher				
I. Is the medical care to be provided to the research participants during and after the research adequate?				
2. Has the researcher obtained permission from the relevant authorities?				
3. Are there any conflicts of interest, including payment and other rewards?				
4. Are there any other/ legal/ social/ financial issues in the study?				

Additional Comments:

_____
_____
_____

Recommendation: Approve [ ] Reject [ ] Conditional Approval (please state the conditions)

_____
_____
_____

Name of the Reviewer

Signature

Date

AX19- V5/SOP01/V5.0