

Standard Operating Procedure
Institutional Ethics Committee,
Rajendra Institute of Medical Sciences, Ranchi
Version -2.0, dated : 20/09/2018
Page 1 to 14

SOP
1 May 2018
Next Review Date
2 May 2020

INSTITUTIONAL ETHICS COMMITTEE, RAJENDRA INSTITUTE OF MEDICAL SCIENCES, RANCHI, JHARKHAND.



Standard Operating Procedure
Effective Date: 20/09/2018
Next Review Date : 2nd May 2020

The location and business address of the committee:

INSTITUTIONAL ETHICS COMMITTEE,
RAJENDRA INSTITUTE OF MEDICAL SCIENCES, RANCHI
JHARKHAND -- 834009

Gari
23/04/18
(Prof. (Dr.) Manju Gari)

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

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Rajendra Institute of Medical Sciences, Ranchi**

I. Standard Operating Procedures (SOPs)

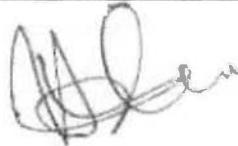
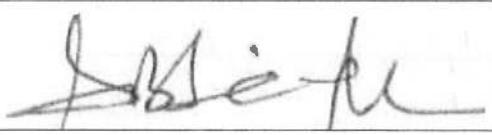
RIMS IEC SOP

Version: 2.0

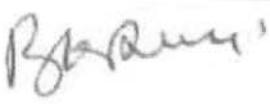
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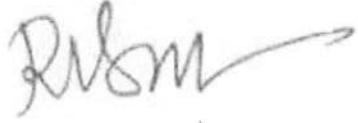
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| Name and Designation | Signature with date |
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III. SOPs reviewed and approved by: Institute Ethics Committee

| Name and Designation | Signature with date |
|--|--|
| Dr. B.K. Roy Chairperson, IEC, RIMS, Ranchi |  |

IV. SOPs accepted by:

| Name and Designation | Signature with date |
|--|--|
| Dr. (Prof) R.K Shrivastava Director RIMS, Ranchi |  |

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

REVISION HISTORY

| Serial No. | Current Version Number | Effective Date | Description (Changes from the previous) |
|-------------------|-------------------------------|-----------------------|---|
| 1. | 1.0 | 22 Jan 2016 | Not Applicable |
| 2. | 2.0 | 20 September 2018 | Revised to five years to earlier three years in clause no. 6.1 page no. 7 |
| 3. | | | |
| 4. | | | |
| 5. | | | |

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1. PURPOSE

The EC is established in order to provide independent guidance, advice, and decision (in the form of "approval/ recommendation/ stipulation/ disapproval") on health research with human participants, including biomedical, behavioral, social science, and epidemiological research (throughout this document, the term "research" is meant to include, and refers to, all of these domains).

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 and rules, Govt. of India

3. Functioning of RIMS, RANCHI IEC

This standard operating procedure (SOP) describes the framework for constitution of the institutional ethics committee responsible for safety and protection of research participants being conducted at the institute, Rajendra Institute of Medical Sciences, Ranchi, in accordance with the ICMR ethical guidelines for biomedical research on human subjects.

4. ROLE AND RESPONSIBILITIES OF RIMS, RANCHI IEC

- A. The RIMS, RANCHI IEC will review all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and wellbeing of all actual and potential research participants before approving the research proposals. the goals of research, however important, should never be permitted to override the health and wellbeing of the human participants.

- B. The RIMS, RANCHI IEC will ascertain whether all the cardinal principles of research ethics viz., autonomy, beneficence, non – maleficence, respect for free and informed consent, respect for human dignity, respect for vulnerable persons, respect for privacy and confidentiality and justice are taken care of in planning, conducting and reporting of the proposed research.

- C. it will look into the aspects of protocol review, selection of participants, voluntary participation of potential participants, informed consent process, risk benefit ratio, distribution of burden

and benefit, maintenance of privacy and confidentiality and provisions for appropriate compensations.

- 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. **RIMS, RANCHI IEC** will provide advice to the researchers on all aspects of the welfare and safety of the research participants after ensuring the scientific soundness of the proposed research.
- G. In case **RIMS, RANCHI IEC** revokes its approval accorded to a trial protocol, it will record the reasons for doing so and at once communicate such a decision to the investigator as well as to the licensing authority.
- H. in case of serious adverse event or death occurring to the clinical trial participant, **RIMS,RANCHI IEC** shall forward it's report 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. COMPOSITION OF RIMS, RANCHI IEC

The Dean of Faculty in consultation with 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-R when required.

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 number of persons in the committee shall be seven as minimum number and 15 maximum with equal representation of gender. The members shall be selected so as to have an equitable representation of all specialties in institute, Rajendra Institute of Medical Sciences, Ranchi

The committee shall have adequate representation of age, gender, community, etc. to safeguard the interests and welfare of all sections of the community/ society. Members shall be aware of local, social and cultural norms, as this is the most important social control mechanism.

The composition shall be as follows:

1. Chairperson (not – affiliated to Institute)
2. Member secretary (from Institute)
3. Dean
4. 5-6 members from different specialties (from Institute)
5. 1-2 Basic medical scientist (One pharmacologist compulsorily, one female member compulsory)
6. One legal expert or retired judge or medico-legal expert
7. One social scientist / representative of non-governmental voluntary agency/ philosopher / ethicist / theologian
8. One lay person from the community

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.

6. APPOINTMENT/NOMINATION AND MEMBERSHIP REQUIREMENTS

- a. The head of the institution of Rajendra Institute of Medical Sciences, Ranchi is responsible for making the appointment of committee members.
- b. The member secretary shall be appointed from the institute.
- c. Members are 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.
- d. 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 / Conflict of Interest Agreement. Members shall be required to sign a confidentiality agreement at the start of their term.
- e. The EC members shall appoint from among its Chairperson and co-chairperson.

6.1. TERM OF APPOINTMENT

- a. The membership of EC shall be for a period of five years and shall be renewed after the stated term of five years.
- b. At the end of the term, at least one third of the EC members shall be replaced such as to maintain the composition.
- c. Extension of membership may be considered due to non-availability of members of similar stature, qualification and intent to contribute to ethical human testing.
- d. In case of the resignation/ discontinuation/ disqualification/ death of any member, the Chairperson, Head and other administrative authorities of Institute before the completion of the tenure of the existing appointed committee may appoint a replacement. This appointment will be effective for the remaining tenure of the existing committee.

6.2. 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. 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.

6.3. 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 in case of internal members their membership would be considered withdrawn, if

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they resign from the Institute.

6.4. TERMINATION/ DISQUALIFICATION PROCEDURE

During the tenure, Chairperson shall have the authority to terminate/ disqualify any of the members in the event that the member 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.

6.5. QUORUM REQUIREMENTS

Minimum of 50% of committee strength and not less than 6 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 6 members with following representations:

- (a) Basic medical scientists (preferably one pharmacologist).
- (b) 2 members
- (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

6.6. HONORARIUM

The members of the institute, Rajendra Institute of Medical Sciences, Ranchi shall be allowed Rs 1000/- honoraria and transport facilities could be organized to and from an EC meeting at the discretion of the Director/Head of Institute Rajendra Institute of Medical Sciences, Ranchi.

6.6.1 Compensation and Reimbursements to External Members

All external members, and experts invited (if any) will be paid an honorarium Rs. 1500/- for each meeting attended and may also be reimbursed for travel and other actual costs incurred towards contributing to the workings of the EC according to the Institution 's norms.

Appropriate bills shall have to be submitted together with the claim form to the Member Secretary.

6.7. EC REVIEW FEE

The Ethics Committee (EC) shall charge an application fee for sponsored research projects. The EC may decide to minimise or exempt review fee for fee to government-funded research; Institutional Investigator initiated research or research supported by grants from non-profit foundations or organizations.

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 favour of EC and accounts thus maintained.

6.8. Initial Review Fee

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

Pharmaceutical Industry and Contract Research Organisation (CRO) Funded Projects

| | |
|--|------------------------|
| Investigator Initiated Projects (Funded by Non-Govt. Funding Agency) | Rs.25000/- |
| Investigator Initiated Projects (Funded by Govt. Funding Agency) | Rs.25000/- |
| Student research (thesis) | Rs.10000/- Rs 100/- |

6.9. 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.

7. APPLICATION PROCEDURES

1. All proposals should be submitted on any working day 1 month in advance of scheduled meeting in the prescribed application form. The applicant may ask for copy of SOP from the IEC, if the same has not been circulated earlier or not available on the website.
2. All relevant documents should be enclosed with application form.
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.
4. 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. 5. The decision of the committee on the proposal will be communicated in writing. If revision is to be made, the revised document in required number of copies should be submitted within a stipulated period of time as specified in the communication or before the next meeting.
6. All research proposals/clinical trials funded/sponsored by Pharmaceutical companies, Agencies, Multinationals etc. will be charged an administrative fee/ processing fee. Waiver of these fees is permissible for non-funded studies, departmental studies, and studies funded by organizations like ICMR, UGC, DST Government of India, State Science & Technology Department, UNICEF, WHO, USAID, Non Profitable Organizations etc.

8. DOCUMENTATION

All research proposals (6 HARD copies and one soft copy in CD) shall be submitted along with the information and documents.

9. REVIEW PROCEDURES

1. the meeting of the iec will be held on periodic intervals, i.e. 2nd week of Jan, 2nd week July, 2nd week nov, unless otherwise specified by the member secretary. Additional review meetings can also be held with short notice as and when required. Meetings will be planned in accordance with the need of the work load.
2. The proposals should be sent to the IEC at least 1 month in advance of scheduled meeting.
3. the IEC'S member-secretary or secretariat shall screen the proposals for their completeness and depending on the risk involved categorize them into three types, namely, exemption from review, expedited review and full review.

4. Decisions will be taken by consensus after discussion, and whenever needed voting will be done. Decision of chairperson will be final.
5. 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.
- 7 Independent consultants/experts will be invited to offer their opinion on specific research proposals if needed.
- 8 The decisions will be minuted and chairperson's approval taken in writing.

10. DECISION-MAKING

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

11. RESPONSIBILITIES OF SPONSOR/INVESTIGATOR

Responsibilities of Sponsor

- (i) The clinical trial Sponsor is responsible for implementing and maintaining quality assurance systems to ensure that the clinical trial is conducted and data generated, documented and reported in compliance with the protocol and Good Clinical Practice (GCP) Guidelines issued by the Central Drugs Standard Control Organization, Directorate General of Health Services, Government of India as well as with all applicable statutory provisions. Standard operating procedures should be documented to ensure compliance with GCP and applicable regulations.
- (ii) Sponsors are required to submit a status report on the clinical trial to the Licensing Authority at the prescribed periodicity.
- (iii) 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
- (iv) 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 under rule 21(b) under appendix XII of gazette notification dated 30th January 2013 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.
- (v) 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.
- (vi) 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.

Responsibilities of the Investigator(s)

(i) The Investigator(s) shall be responsible for the conduct of the trial according to the protocol and the GCP Guidelines and also for compliance as per the undertaking given in Appendix VII of schedule Y. Standard operating procedures are required to be documented by the investigators for the tasks performed by them. During and following a subject's participation in a trial, the investigator should ensure that adequate medical care is provided to the participant for any adverse events. Investigator(s) shall report all serious and unexpected adverse events to the Licensing Authority defined under clause (B) of rule 21 (Schedule Y and Gazette notification 30th January 2013), 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.

(ii) The investigator shall provide information to the clinical trial subject through informed consent process as provided in Appendix V of Schedule Y 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.

12. RECORD KEEPING AND ARCHIVING AT THE OFFICE OF RIMS-RANCHI IEC

1. All the documents and communications of IEC will be dated, filed and archived in a secure place.
2. Only the member secretary or persons, who are authorized by the Chairman of IEC will have the access to the various documents.
3. All the documents related to research proposals will be archived for a minimum period of 3 years in the Institute, following the completion /termination of the study.
4. No document (except agenda) will be retained by any IEC member.
5. At the end of each meeting, every member must return the cd/dvd containing all the research proposals and documents to IEC office staff. They will archive one copy in IEC office and other copies will be destroyed after one year.

13. REFERENCES

1. Schedule Y of the Drugs and Cosmetics Act
2. ICMR Ethical Guidelines for Biomedical Research in Humans
3. CDSCO-GCP
4. WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants.
5. AIIMS-P SOP 2013-2014