INSTITUTIONAL ETHICS COMMITTEE (IEC)

(Ethics Committee for Biomedical and Health Research Involving Human Participants)

Standard Operating Procedure (SOP) for Institutional Ethics Committee (IEC)

Institute of Teaching and Research in Ayurveda Jamnagar, Gujarat

Institutional Ethics Committee (IEC) , ITRA, Jamnagar Standard Operating Procedures (SOP)

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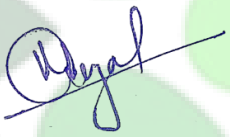
SOP prepared by	Prof. Mandip Goyal Member Secretary, IEC ITRA, Jamnagar	
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Institutional Ethics Committee (IEC) ITRA, Jamnagar

Standard Operating Procedures (SOP)

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1. Introduction:

The Institute of Teaching and Research in Ayurveda (ITRA) is India's first 'Institute of National Importance in the AYUSH sector, established through the 'Institute of Teaching and Research in Ayurveda Act, 2020,' effective from 15th October 2020. It offers undergraduate, postgraduate, and doctoral programs. ITRA emphasizes interdisciplinary and collaborative research, focusing on validating Ayurveda's principles, drug development, preclinical studies, and therapeutic approaches. Its goal is to enrich the Ayurveda Pharmacopeia and Formularies through evidence-based research. Biomedical research, in general, involves various ethical issues that must be addressed. The Institutional Ethics Committee (IEC) plays a key role in guiding researchers on ethical concerns and reviewing research proposals for scientific relevance and associated risks.

2. Objectives:

The objective of this Standard Operating Procedure (SOP) is to ensure the effective functioning of the Institutional Ethics Committee (IEC), maintaining quality, technical excellence, and a consistent ethical review process for all submitted biomedical research proposals, clinical trials, and ongoing approved studies involving human participants. This is in accordance with the ICMR National Ethical Guidelines and the New Drugs and Clinical Trials Rules (NDCTR), 2019.

3. Authority under which ITRA -IEC is constituted:

The ITRA IEC functions as an independent, institutional ethics committee. The Dean (Research), in consultation with the Director of ITRA, appoints the Chairperson and committee members based on their qualifications, competence, and experience in reviewing both the scientific and ethical aspects of biomedical research proposals. The tenure of IEC members is for three years or until further notice. The Dean (Research) issues invitation letters to prospective members, and those willing to join confirms their acceptance by signing the letter and providing the necessary documents for membership.

4. Composition:

The IEC consists of a minimum of seven and a maximum of fifteen members, representing both medical and non-medical backgrounds, as well as scientific and non-scientific fields. It is multidisciplinary and function independently. In line with the ICMR National Ethical Guidelines (2017) and NDCTR (2019), the ITRA IEC includes the following categories of members.

- Chairperson – Non-affiliated
- Member Secretary- Affiliated
- Basic Medical scientist/Medical scientist (preferably a pharmacologist)-Non-affiliated/affiliated
- Clinicians -Non-affiliated/affiliated
- Legal expert -Non-affiliated/affiliated
- Social Scientist /representative of NGO/Philosopher//ethicist/theologian-Non-affiliated/affiliated
- Lay person from the community -Non-affiliated/affiliated
- One woman member

The IEC consists of at least fifty percent of its members who are not affiliated with the institute at the time the committee is formed. Each IEC member is appointed to a specific role and cannot substitute for another absent member during meetings. The Chairperson and Member Secretary hold additional responsibilities based on their qualifications, allowing them to fulfil dual roles within the IEC.

5. Registration and renewal of registration of IEC:

As per the regulatory requirements, ITRA-IEC would get registered with the relevant authority such as DHR, CDSCO etc. On or a month before the expiry period of validity of registration, IEC shall make an application for renewal of registration to the relevant authority within specified time.

6. Responsibilities of ITRA-IEC:

The primary responsibility of the ITRA-IEC is to review all research proposals involving human participants to ensure the dignity, rights, safety, and well-being of the participants are protected before granting approval. The committee must verify that all ethical principles of research, such as autonomy, beneficence, nonmaleficence, respect for free and informed consent, respect for human dignity, protection of vulnerable individuals, privacy and confidentiality, and justice, are adhered to in the planning, execution, and reporting of the proposed research. The IEC shall conduct both scientific and ethical evaluations of each study proposal.

Members of IEC are expected to attend all IEC meetings and prior information should be provided if a member is unable to attend meeting.

The following table depicts the members and nature of duties to be carried out for proper functioning of the ITRA-IEC:

Sr. no.	Member	Responsibility
	Chairperson Non-affiliated Qualifications - A well-respected person from any background with prior experience of having served/ serving in an EC.	• Conduct IEC meetings and ensure active participation of all members during meeting. • Ratify minutes of the previous meetings. • Seek conflict of interest 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, etc • If the Chairperson is expected to be absent, the Chairman should nominate or the members may elect an acting Chairperson from within the committee. The acting Chairperson, who must be a non-affiliated member, will have all the powers of the Chairperson for that meeting.

2.	Member Secretary Affiliated Qualifications - • Should be a staff member of the institution • 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	• 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 members. • Ensure SOPs are updated as and when required and adherence of IEC 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 IEC review. • Assess the need for expedited review/ exemption from review or full review. • Assess the need to obtain prior scientific review, invite independent consultant, patient or community representatives. • Ensure quorum during the meeting and record discussions and decisions.
3.	Basic Medical Scientist(s) Affiliated/ non-affiliated Qualifications - • 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	• Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, serious adverse effects (SAE), protocol deviation, progress and completion report. In case of clinical trials, to review drug safety and pharmacodynamics.
4.	Clinician Affiliated/ non-affiliated Qualifications – • Should be individual/s with recognized medical qualification, expertise and training	• Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics • Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report) • Review medical care, facility and appropriateness of the principal investigator, provision for medical care, management and compensation

		• Thorough review of protocol, investigators brochure and all other protocol details.
5.	Legal expert Affiliated/ non-affiliated Qualifications - • Should have a basic degree in Law from a recognized university, with experience • Desirable: Training in medical law.	• Ethical review of the proposal, informed consent form (ICF) along with translations, memorandum of understanding, Clinical Trial Agreement (CTA), regulatory approval, insurance document, another 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 IEC members about new regulations if any
6.	Social scientist/ philosopher/ ethicist/theologian Affiliated/ non-affiliated Qualifications – • Should be an individual with social/ behavioural 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	• Ethical review of the proposal, ICF 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 unethical and societal concerns.
7.	Lay person Qualifications – • 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	• Ethical review of the proposal, ICF along with translations. • 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.

7. Procedure for resignation, replacement and removal of members

Dean (Research), Chairman, and Member Secretary shall be undertaking this procedure.

Term of appointment

Members of IEC shall be appointed for 3 years initially which could be extended for another term of 3 years. Membership extension shall be based on the recommendation of the Chairman & Member Secretary of IEC.

Policy for removal of a member:

- A member may be relieved or terminated of his/her membership in case of his/her conduct found inappropriate.
- If a member is found to be unable to participate in the meetings on any grounds for more than 3 meetings of IEC.
- The membership shall be reviewed by the Dean (Research) & Chairman if the member is a regular defaulter.
- If deemed necessary, the IEC may decide to terminate the membership and recommend to the Chairman IEC for essential action.
- The Director after receiving the complaint and reviewing the same shall take appropriate action.
- In all such situations/circumstances, the Dean (Research) shall serve a letter of termination to the member after approval from the Director.
- Documentation of the termination will be recorded in the meeting minutes of the next duly constituted IEC meeting and the IEC membership circular/roster will be revised.

Resignation / Replacement procedure

The members who have resigned may be replaced at the discretion of the appointing authority for the same. IEC members who decide to resign must provide the Chairman & member secretary of IEC the written notification of their proposed resignation date at least with month's advance notice

In case of resignation or death of the member, the Dean (Research) in consultation with the Director will nominate the members of IEC falling in the same category of membership.

8. Requirements for IEC Membership/Conditions for appointment

- All members shall serve for 3 years on a renewable basis. New members shall be included in the IEC in such a way that there will be a mix of recently included members and members with a few years of experience.
- During the term, the Dean (Research), in consultation with the Chairman after approval from the Director, can disqualify any member if the contribution is not adequate and/or there is a long period of member non-availability.
- A member can resign from their office of membership in the IEC to the Dean (Research) through the Chairperson after serving a one-month advance notice.
- The Director can replace a member of the IEC as and when required.
- Each member is required to sign the declaration and confidentiality agreement regarding the IEC (Annexure 1).
- Every EC member must provide an updated CV with signature, provide a consent letter, and submit training certificates on human research participant protection and Good Clinical Practice (GCP) guidelines.

- If not trained, they must undergo training and submit training certificates within 6 months of appointment.
- They should be willing to undergo training or update their skills/knowledge during their tenure.
- They must declare conflict of interest (COI) in accordance with the policy of the IEC, if applicable, at the appropriate time. (Annexure- 2)
- They should sign a confidentiality and conflict of interest agreement.
- They must be willing to place their full name, profession, and affiliation to the IEC in the public domain.
- They should be aware of relevant guidelines and regulations such as ICMR National Bioethical Guidelines, NDCT rules, etc.
- They must be able to read, understand, accept, and follow the COI policy of the IEC and declare it, if applicable, at the appropriate time.
- They should be committed to and understand the need for research and for imparting protection to research participants in research.
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Training of the Members

A team of trainers chosen for this purpose by Member Secretary will ensure that new and existing members of IEC-ITRA get trained within a month after being inducted. All IEC members will be made conversant with ICMR Guidelines for Research involving human Subjects 2017, and ICH-GCP guidelines

Training schedule for new members of IEC, ITRA, Jamnagar

S. No	Session Topic	Facilitator	Time period
1.	Roles & responsibilities of IEC and its Members	Member Secretary	1 hour
2.	Discussion on regulatory guidelines on IEC	IEC member nominated by Member Secretary	2 hours
3.	Interactive session	With at least two members nominated by Member Secretary	2 hours

Additionally, the Institutional Ethics Committee will hold retraining for all the members of IEC, ITRA once in 6 months for 2 to 3 hours on the topics listed in the above table.

9. Quorum requirements:

Dean (Research) in consultation with the Director will nominate the members of IEC, who have the qualifications and experience to review and evaluate the scientific, medical, and ethical aspects of integrity by sending an official request letter (Annexure 3)

Members will confirm their acceptance to the Dean (Research) by providing all the required information for membership (Annexure 4).

The regular members of the committee will include at least 7 individuals. The current committee is as follows:

1. Chairperson
2. One - two persons from the basic medical science area (One pharmacologist compulsorily, one female scientist compulsory)
3. One - two clinicians from various institutes
4. One legal expert or retired judge
5. One social scientist/ representative of a non-governmental voluntary agency
6. One philosopher/ ethicist/ theologian
7. One layperson from the community
8. Member Secretary

A minimum of 50% of committee strength + 1 member and not less than 5 members will be required to compose a quorum for the meeting of which at least one member will be from outside the institution, and one member will be a non-scientific member & one female member. All decisions will be taken in meetings and not by circulation of project proposals. The quorum will have 5 members with the following representations:
Basic medical scientists (preferably one pharmacologist).

a. Clinicians
b. Legal expert
c. Social scientist/ representative of non-governmental voluntary agency/philosopher/ethicist/theologian or a similar person
d. Layperson from the community

10. Convention and Conduct of IEC meetings:

- The Chairperson will conduct all meetings of the ITRA-IEC.
- In the absence of the Chairperson an alternate Chairperson will be elected from the other members on the day of meeting (or Chairperson should nominate a committee member as Acting Chairperson for that meeting) by the members present, who will conduct the meeting.
- The alternate or acting chairperson should have the powers of the chair person and should be a non-affiliated person.
- The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned.
- Member Secretary will prepare the minutes of the meetings and get it approved by the Chairperson and all the members.
- In the absence of Member Secretary, alternate Member Secretary among the members, will organize the IEC meeting.
- All proposals will be received at least 2 weeks before the EC meeting and after initial scrutiny by Member Secretary, the proposals will be circulated to the IEC members.
- The recommendations by the IEC will be communicated to all the PIs and guides/HODs in case of student's proposals.
- If required additional review meetings can also be conducted with a short notice period.

11. Application procedures

The project investigator has to apply in the prescribed format (Annexure 5) along with the study protocol & another study-related document necessary for review by IEC, after due approval from the Institutional Research Committee (IRC).

The following documents at the minimum will be reviewed by the ethics committee

- Trial Protocol (including protocol amendments)
- Patient Information Sheet, Informed Consent Form and Patient dairies (including updates if any) in English and/or vernacular language.
- Investigator's Brochure and available safety information (if applicable)
- Proposed methods for patient accrual including advertisement (s) etc. proposedto be used for the purpose.
- Principal Investigator's current CV and any document evidencing qualifications (applicable for sponsored project)
- Insurance Policy / Compensation for participation and serious adverse eventsoccurring during the study participation. (applicable for sponsored project)
- Investigator's Agreement with the Sponsor. (applicable for sponsors project)
- Investigator's Undertaking (Annexure 6)

Any other documents that the ethics committee may require to fulfill its responsibilities

- All research proposals must be submitted in English language only.
- Application may be submitted through the Dean (Research) to the office of member secretary, ITRA, Jamnagar (minimum three hard copies along with electronic of the same on at least 7 days before the date of the proposed ethicscommittee meeting.
- Receipt of the application will be acknowledged by IEC office. [Annexure 7]
- Every application will be allotted an IEC registration number to be used for future correspondence.

Applications can be **submitted online** **ethics@itra.edu.in** by uploading synopsis or research proposals

12. Details of elements of review

The submitted proposal shall be reviewed both for scientific content and ethical principles. The committee members shall review the proposal concerning the following:

- Scientific design of the study
- Justification/Rationale of the study
- Selection criteria for subjects
- Justification for use of placebo, if any
- Potential benefits to the study subjects
- Predictable risks to the study subjects
- Criteria for discontinuation/withdrawal of subjects
- Monitoring of serious adverse events
- Compensation to subjects for participating in the study (only for sponsored research projects)
- Subject recruitment procedures
- Patient retention activities
- Compensation for study related injury (only for sponsored research projects)
- Post-trial benefits
- Protection of privacy and confidentiality
- Statistical analysis
- Informed consent document in English and regional languages
- Competence of investigators, supporting staff and infrastructure facility
- Approval of regulatory authorities wherever applicable

13. Review Procedure

Procedure for initial scrutiny of the proposal

Office of Member Secretary will be undertaking this task.

1. Every proposal will be collected and compiled by the Dean's (Research) office.
2. The academic assistant will verify the proposal for completeness as per the list (Annexure 8)
3. In case of incomplete data, the investigators will be informed by the office after consulting the Member Secretary to make the necessary corrections and to resubmit the proposal.
4. Every proposal will be evaluated by IEC members on ethical issues as per ICMR Guidelines 2017 as amended thereafter, scientific soundness and technical excellence of the proposed research, before it is taken up for the main IEC interview, on the same day.
5. All members will evaluate the possible risks to the study participants with proper justifications, the expected benefit, and the adequacy of documentation for ensuring privacy, confidentiality, and justice issues.
6. The IEC review shall be done through formal meetings and shall not resort to decisions through the circulation of proposals.
7. Expert opinion of additional members would be obtained if necessary.

Summary of the procedure adopted

1. As per the routine adopted, approval of IEC should follow first before the synopsis of the thesis or any research project is submitted by the candidate for approval from the board of study committee.

2. Every HOD should ensure that the candidate undertaking any kind of research on humans (interventional/noninterventional/observational/investigational or any kind of study directly or indirectly dealing with humans) should submit a hard copy of the protocol along with the application and electronic version (in pen drive or e-mail at ethics@itra.edu.in of the same in prescribed Performa, well in advance to member secretary for IEC approval.

3. Every candidate appearing before the IEC should be directed to submit their presentation in an electronic format well in advance to the member secretary, which shall be circulated to all worthy members and the chairman for reference well in advance.

4. The responsibility of not getting prior IEC approval shall otherwise lie with respective heads of department at the time of any ethical audit of the institution.

5. The research protocol needs to be categorized by the candidates and presented only if falls in category A.

CATEGORY –A (FULL REVIEW / PRESENTATION REQUIRED):

Presentation has to be made as per serial number or as decided by IEC;

- Drug trials/studies
- Interventional Trials
- Surgical or diagnostic procedure trials being carried out for the first time in the institution other than the routine protocol
- New drug trial
- Trials on high-risk population

CATEGORY –B (EXPEDITED REVIEW/PRESENTATION OPTIONAL /BUT APPLICATION AND SUBMISSION OF PROTOCOL IN PRINT /ELECTRONIC FORMAT REQUIRED FOR RECORD*)*

Expedited Review Procedures

a. The committee may use an expedited review procedure in case of minor changes/ amendments in the previously approved research proposal that appear to involve no more than minimal risk to the study subjects.

b. Under an expedited review procedure, the review may be carried out by the Chairperson of the committee, or by one or more experienced reviewers designed by the chairperson from among the members of the committee. The reviewers may exercise all of the authorities of the committee except that the reviewers may not disapprove of the research.

c. The committee will keep all members of the committee informed of these approvals under the expedited review procedure.

d. Only the Chairperson and Member Secretary shall decide to allow an expedited review.

CATEGORY –C (EXEMPTION FROM REVIEW & PRESENTATION ONLY APPLICATION REQUIRED) (Annexure – 9)

1. It is requested that a 5-minute presentation for each candidate with a maximum of 8 slides in PowerPoint be presented in front of the IEC on a fixed date and time, who have submitted proposals for approval.
2. The guide and Co-guide can join the meeting for scientific interaction.
3. Not more than 30 projects shall be considered in one day or as the situation demands
4. Independent projects as per the same SOP shall be considered first followed by thesis research protocols.
5. Investigator/candidate is requested to make and present PowerPoint slides of the project proposal which should include the following points/guidelines depicted below.
   i. Introduction and background of the subject
   ii. Rationale/ justification of undertaking the project
   iii. What new the research/project is going to contribute to scientific community & present setup
   iv. Is the research/project following all basic principles of bioethics- principles of essentiality
   v. Research is necessary for the advancement of knowledge-should add new information

vi. Rationale justification of research question

vii. Principles of precaution and risk minimization

viii. Principles of the maximization of the public interest

ix. Principles of non-exploitation

x. Principles of voluntariness, informed consent, and community agreement

xi. Respect for persons: dignity and rights of each trial participant

xii. Is there a provision for participants to withdraw at any time?

xiii. Is there any provision to ensure/ protect confidentiality

xiv. Is there any provision for compensation

6. Aims and Objectives
7. Materials and Methods to undertake the project
8. Statistical Methods intend to use
9. Flow chart of your project/CONSORT
10. Timeline of the research project

- **The following types of studies will be reviewed under biomedical and health research**
  - Clinical research including trials, observational studies and Ayurvedic interventions related to postgraduate studies including dissertation and thesis work.
  - PhD research studies focused on Ayurvedic therapies or integrative medicine.
  - Investigator initiated studies by faculty or scholars or researchers within the institution.
  - External proposals will be considered if they align with the institution's principles and focus areas. External investigators must comply with the ITRA-IEC's ethical and regulatory requirements.
- **Review Fee Structure**

Internal proposals: For PG, PhD and Investigator initiated studies by institutional scholars there will be no fee.

External proposals: Research proposals/ clinical trials by external agencies will be charged an administrative fee/processing fee of 5% of their sanctioned budget.

Studies funded by organizations like ICMR, UGC, DST, Government of India , State science and technology department, UNICEF, WHO will be charged no fee.

14. Review of a clinical trial:

1. The IEC, with a basic composition, will review and accord approval of the clinical trial or bioavailability/bioequivalence protocol and other related documents.

2. In the event of possible overlap between an academic clinical trial and a clinical trial, or if there is any doubt regarding the nature of the study, the IEC will inform the Central Licensing Authority in writing, indicating its views within thirty working days from the receipt of the application.

3. In case of protocol rejection, modification requests, or other notifications, the IEC will communicate its reasons in writing. A copy of these reasons shall also be made available to the Central Licensing Authority.

4. Members of the IEC shall follow NDCTR 2019 rules, Good Clinical Practice Guidelines, and other regulatory requirements to safeguard the rights, safety, and well-being of trial subjects.

15. Review of Informed consent process

IEC shall review informed consent form that has been submitted by the investigator both in English and vernacular language and also shall check the patient information sheet and consent form.

- IEC shall review the following components in the informed consent form.
- Details on purpose of the research study, foreseeable risks and discomforts, voluntary participation and duration of participation with number of participants.
- Statements of those subjects are entitled to free medical management as long as required in case of injury.
- Financial compensation details in case of trial related injury or death
- The study information provided to the participants is complete and in simple understandable language, simple words.
- Procedures for obtaining informed consent such as Audio-Video recording from the research participant prior to enrolling into a research study, especially vulnerable subjects
- Getting consent from a Legally Acceptable Representative (LAR) in case of unconscious or minor or suffering from severe mental illness or disability
- Consent from impartial witness in case of participant /LAR is unable to read or write
- In pediatric studies written informed consent from the parent or legal guardian and assent from pediatric participants aged 7 years and above.
- Contact details of researcher/ PI / chairperson IEC
- Statement related to steps taken for ensuring confidentiality
- IEC shall review on fresh or re-consent process in case of availability of new information which would necessitate deviation of protocol, when a research participant regains consciousness from unconscious state or is mentally competent to understand the study, when long term follow-up or study extension is planned later and when there is change in treatment modality, procedures, site visits and before publication, if there is possibility of disclosure of identity through data presentation or photographs.

Policy for Waiver of Written Informed Consent:

- The IEC may grant waiver from obtaining written informed consent after due consideration.
- The Chairperson / Member Secretary / IEC members will review the request taking into consideration the types of studies for which waiver of consent may be granted.
- If the consent waiver is granted, the IEC should 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.

16. Review of Subject recruitment procedures

The IEC will review the subject recruitment procedures, recruitment plan and strategy that have been mentioned in the protocol and common subject recruitment methods are inpatient services, outpatient services, medical camps, outside referrals, advertisements, telephonic/e-mail communications, private clinics etc.

The following details are to be included in the research under recruitment procedures,

- Demographic characteristics of the sampling cohort (from the which the study participants are to be recruited/ included)
- The personnel involved in participant recruitment (PI, Co-PI, Research Associates, or others)

- Appropriate and timely review of recruitment goals and strategies during the conduct of the trial
- If a combination of above recruitment methods planned to use and the same can be mentioned in the protocol.

17. Clinical trial site visit and GCP compliance monitoring by the IEC for the approved/on-going

clinical trials

- IEC shall review of ongoing clinical trials at appropriate intervals and check for the GCP compliance and other applicable regulatory requirements.
- The review shall be based on periodic study progress reports furnished by the investigators or monitoring and internal audit reports furnished by the sponsor or by visiting the study sites. Applications for continuing review (Annexure 10), amendments (Annexure 11), or any deviations in the ongoing trial protocol (Annexure 12) must be submitted to the IEC. The committee will evaluate these submissions to ensure that the rights, safety, and well-being of trial subjects remain safeguarded throughout the study period.

IEC shall review the following at the site:

- To check whether the study team is using the approved version of ICF and getting signature on the correct form of ICF.
- To observe the consenting process and its documentation, laboratory and other facilities necessary for the study.
- After the visit, the IEC representative shall submit a report/comment within 2 weeks describing the findings during the visit which will be reviewed in the full committee meeting. The approved report will be shared with the study investigator for their documentation.
- If SAE occurs during a clinical trial/study (Annexure 13 (A)/ (B)) the IEC should analyze the relevant documents about such event and forward its report to the Central Licensing Authority.
- At any stage of a clinical trial, if the IEC concludes that the trial is likely to compromise the right, safety, or well-being of the trial subject, the committee may order the discontinuation or suspension of the clinical trial. The same should be intimated to the head of the institution conducting the clinical trial and the Central Licensing Authority. If such actions are taken, the PI must submit a comprehensive report (annexure 14) detailing the circumstances of the termination, suspension, or discontinuation.
- At the end of the trial, an application regarding the completion of the study shall be submitted (Annexure 15).

18. Review of research proposals involving vulnerable population

Vulnerable persons are those individuals who are relatively or absolutely incapable of protecting their own interests and providing valid informed consent. Include economically and socially disadvantaged; children (up to 18 years); women in special situations; tribals and marginalized communities; refugees, migrants, homeless, persons or populations in conflict zones, riot areas or disaster situations; afflicted with mental illness and cognitively impaired individuals, differently abled –mentally and physically disabled; terminally ill or are in search of new interventions having exhausted all therapies; suffering from stigmatizing or rare diseases; or have diminished autonomy due to dependency or being under a hierarchical system and unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate which may lead them to give consent.

IECs should carefully determine the benefits and risks of the study and examine the justification provided and risk minimization strategies.

Additional safety measures should be strictly reviewed and approved by the IECs. IEC must ensure that the informed consent process should be well documented and recordings of assent in case of research studies involving children aged 7 to 18 years and reconsent, when applicable.

Informed consent from vulnerable populations may be obtained from LAR (Legally authorized representative) in presence of impartial witness after through explanation of risks and benefits.

In case of research proposals related to Human Immunodeficiency Virus (HIV) or genetic disorder, specific patient group may also be included in the Ethics Committee.

19. Review of multi-centric research-

Multicentre research is conducted at more than one centre by different researchers usually following a common protocol.

- All sites are 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.
- The ECs/Secretariats of all participating sites should establish communication with one another
- If any EC does not grant approval for a study at a site the reasons must be shared with other ECs and deliberated upon.
- The EC can suggest site-specific protocols and informed consent modifications as per local needs.
- Separate review may be requested 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.
- Common review for all participating sites in multi-centric research - In order to save time, prevent duplication of effort and streamline the review process, the ECs can decide to have one designated main EC, the decisions of which may be acceptable to other ECs.
- Common review process may be applied to research involving low or minimal risk, survey or multi-centric studies using anonymized samples or data or those that are public health research studies determined to have low or minimal risk.
- The common review is applicable only for ECs in India. In case of international collaboration for research and approval by a foreign institution, the local participating sites would be required to obtain local ethical approval.

20. Independent consultant/Invited subject experts

Subject experts will be called to provide special review for selected research proposals/Clinical trial protocols, if required. They can give their opinion/specialized views but they do not take part during decision making by IEC members.

21. Decision-making & Communication of decision

- A decision will only be taken when sufficient time has been allowed for review and discussion on the application occurred in the absence of the investigator from the meeting
- Decisions will only be taken at meetings where a quorum (minimum of five members) is complete.
- The decision will only be taken after reviewing the complete application with all required documents necessary for the proposal.
- The decision will arrive with consensus of members; if consensus appears unlikely voting

- can be resorted to. The decision will be taken in a specified format (Annexure 16)
- A negative decision would always be supported by a clearly defined reason.
- The Member Secretary would communicate the decision in writing to the Principal Investigator in the prescribed format (Annexure-17)
- If one of the members has her/his proposal for review then s/he would withdraw from the IEC while the project is being discussed.

The communication of the decision will include:

1. Name and address of IEC.
2. The date, place and time of decision.
3. The name and designation of the applicant.
4. Title of the research proposal reviewed.
5. The clear identification of protocol no., version no., date, amendment no., date.
6. Along with protocol, other documents reviewed- clear description of these documents along with Version No. and Date.
7. List of IEC members who attended the meeting- clear description of their role, affiliation and gender.
8. A clear statement of decision reached.
9. Any advice by the IEC to the applicant including the schedule / plan of ongoing review by the ITRA-IEC
10. In case of conditional decision, any requirement by IEC, including suggestions for revision, and the procedure for having the application re-reviewed.
11. In case of rejection of the proposal, reason(s) for the rejection will be clearly stated.
12. Signature of the member secretary with date.

22. Record keeping and archiving of documents

Ethics committee will maintain data, record, registers and other documents related to the functioning and review of research proposals/clinical trial or bioavailability study or bioequivalence study, The documents will be archived for a minimum period of 3 years and for sponsored clinical trials for 5 years after completion/termination of the study.

IEC members should not retain any documents with them after the meeting is over.

List of documents to be filed and archived by the office of IEC:

1. Constitution and composition of IEC

2. SOPs followed by IEC

3. CV & consent of IEC members

4. National and international guidelines followed by the Ethics Committee

5. IEC Registration

6. Honorarium details, Income and expenses

7. Agenda & minutes of the meetings

8. Copies of the protocol, data collection formats, case report forms, investigators brochures, etc., submitted for review

9. Correspondence with committee members and investigators regarding application, decision and follow up;

10. Agenda and MOM of IEC meetings with signature of chairperson

11. Copies of decisions communicated to applicants;

12. Records relating to any order issued for premature termination of study with a summary of the reasons thereof;

13. Final report of the study including microfilms, compact disks or video recordings;

14. Recommendation of IEC for determination of compensation;

15. Records relating to the SAE, medical management of trial subjects &compensation paid.

- The Ethics Committee shall furnish the information maintained to the Central Licensing

Authority or any other officer authorized on its behalf when required.

23. Compensation

In the cases of clinical trial /bioavailability and bioequivalence trials /biomedical and health research, study related injury or death, SAE of permanent disability and reversible SAE in case it is resolved, the ethics committee shall forward it's report on the serious adverse event of death, after due analysis, along with its opinion on the financial compensation (quantum of compensation will be calculated as per the formulas of NDCTR 2019 (SEVENTH SCHEDULE (rules 39, 40, and 42)), if any, to be paid by the Sponsor or their representative, whosoever had obtained permission from the central Licensing Authority within a period of thirty days of receiving the report of the serious adverse event of death from the investigator.

FORMULAE TO DETERMINE THE QUANTUM OF COMPENSATION IN THE CASES OF 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 18 (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:

- 0.5 - Terminally ill patient (expected survival not more than (NMT) 6 months)
- 0.1- Patient with high risk (expected survival between 6 to 24months)
- 2.0- Patient with moderate risk
- 3.0- Patient with mild risk
- 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. 2lacs 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 in the below table.

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.

(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 any one or both the parents 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

(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 hospitalization 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 hospitalization 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 hospitalization 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.

Where,

W = Minimum wage per day of the unskilled worker (in Delhi)

N = Number of days of hospitalization

24. Terms of Reference

To maintain the records and to initiate procedures for appointment, removal, replacement, or resignation of IEC members, conducting of meetings, and payment of remuneration for the members for the IEC, ITRA, Jamnagar

The Dean (Research), member secretary, and staff of the office of the Dean are responsible for implementing this SOP.

Procedure

Member secretary in consultation with Dean (Research) and chairman will maintain the records and initiate the procedures for appointment or removal, replacement, or resignation of the members of the IEC, to conduct meetings and payment of remuneration for the members of the IEC, ITRA, Jamnagar

Terms of reference will be maintained in the office of Dean, ITRA, Jamnagar. This includes:

A. Membership Requirements

B. Terms of Appointment concerning the duration of the term

C. The policy for removal, replacement, and resignation procedure

D. Frequency of meetings

E. Payment of processing fee to the IEC for review, honorarium/ consultancy to the members/ invited experts, etc.

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

25. Administration and management

- ITRA Jamnagar shall have an office for the IEC which have adequate space, infrastructure and staff to the EC for maintaining full-time secretariat, safe archival of records and conduct of meeting.
- There should be provision for allocating reasonable amount of funds for smooth functioning of the IEC. Honorarium of INR 1000/-per sitting will be paid by the institute to the Non-affiliated members attending the meeting

26. Web page for IEC:

Details of composition, SOP, registration details, circulars/notifications related to IEC meetings, submission forms, guidelines and contact details will be displayed on this page www.itra.ac.in

27. Contact details:

Prof. Mandip Goyal

Member Secretary, IEC, ITRA, Jamnagar-361008

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