Standard Operating Procedures

Institutional Ethics Committee

Tech4Health Foundation

Standard Operating Procedures (SOP)

for

Institutional Ethics Committee (IEC)

Tech4Health Foundation (T4H)

Bengaluru

Version – 04

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This document (Standard Operating Procedures) after being prepared by the Member Secretary, has been duly approved by the Chairman and all members of the Institutional Ethics Committee effectively on July 2025.

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Abbreviations

ADR	Adverse drug reaction
AE	Adverse events
COI	Conflict of interest
ICD	Informed consent document
ICF	Informed consent form
ICMR	Indian Council of Medical Research
IEC	Institutional ethics committee
GCP	Good clinical practices
LAR	Legally authorized representative
MOM	Minutes of the meeting
MoU	Memorandum/memoranda of understanding
NGO	Non-governmental organizations
SAE	Serious adverse events
SOP	Standard operating procedures
TOR	Terms of reference
T4H	Tech4Health Foundation

Introduction

The institutional ethics committee (IEC) of the Tech4Health Foundation (T4H) is intended and designed to serve the role of safeguarding the rights and confidentiality of the participants in biomedical and behavioral research. Apart from issues involving research ethics, the IEC will also conduct reviews of the relevance and risks involved for all submitted proposals.

The IEC intends to review research proposals to assess the issues of ethics involved, and to ensure the voluntary and informed participation of the subjects related to the research. This document lists the standard operating procedures (SOPs) that will govern the functioning of the IEC, and is designed to follow the four principles of research ethics — beneficence, nonmaleficence, autonomy, and justice. The SOP document clearly defines the composition and respective roles of the members of the IEC along with other details such as necessary qualification for selection, tenure, as well as procedures for resignation or removal of members. The document also outlines in detail the processes of submission of research proposal and auxiliary documents, review of the proposal, decision-making and the communication of the decision. Annexures provided at the end of the SOP document contain forms and letters necessary for the regular functioning of the IEC.

This version of the SOP for the IEC was created in July 2025.

1. Declaration

The composition and working procedure of the Institutional Ethics Committee (IEC) of Tech4Health Foundation (T4H) draws on Operational Guidelines for Ethics Committees Reviewing Biomedical Research by World Health Organization, 2000, International Conference on Harmonization-Good Clinical Practices (ICH-GCP) Guidelines, 1996, New Drugs and Clinical Trials Rules, 2019, Indian GCP Guidelines, 2016, and Ethical Guidelines for Biomedical Research on Human Participants by ICMR, 2017.

2. Aims and objectives of IEC

2.1. Aims of IEC

The Institutional Ethics Committee of Tech4Health Foundation (herein after referred to as T4H's IEC) aims to provide public assurance of protection, by reviewing and approving the study protocol, the suitability of the investigator(s), and the methods and materials to conduct clinical research at T4H under compliance of New Drugs and Clinical Trials Rules, 2019, National Ethical Guidelines for Biomedical Research on Human Participants by ICMR.

2.2. Objectives of IEC

The objective of these SOPs of the IEC for research involving human subjects is

a) To maintain effective functioning of the IEC.
b) To ensure technical excellence and comprehensive ethical review of all submitted research proposals and ongoing or approved research projects involving participants in accordance with the ICMR Ethical Guidelines for Biomedical Research on human subjects.

3. Terms of reference of the committee

The terms of reference (TOR) of the members provide the framework for the constitution, selection, roles, and responsibilities of the IEC and procedures for maintaining the confidentiality of all activities and documents.

3.1. Purpose of IEC

The Institutional Ethics Committee of Tech4Health Foundation aims to provide public assurance of protection, by reviewing proposed studies and their methods and materials to conduct clinical research at T4H under, and to ensure they conform to nationally accepted ethical guidelines.

3.2. Scope of IEC

To review the ethical considerations of study proposals received, and to advise and recommend on ethical matters arising in relation to research involving human participants. The IEC will ensure that any research is designed and conducted in accordance with national guidelines without conflicts of interest, and that the research conducted conforms to the proposal that has been approved by the IEC.

3.2.1 To act as an independent ethics committee (review of external applications)

An institution that does not have its own EC may utilize the services of the EC of Tech4Health Foundation. Relevant requirements as listed below must be fulfilled before they do so.

- The two institutions (T4H and applicant) should enter into a Memorandum of Understanding (MoU) for utilizing the services of T4H EC.

- The EC of T4H should have access to all research records including the source documents and research participants for continuing review of the implemented project, including site visits.

- The T4H EC can undertake site monitoring and will have all the rights and responsibilities related to ethical review of the projects submitted by the applicant.

3.2.1.1 For multicentric biomedical and health research, all participating sites may decide to utilize the services of Tech4Health Foundation EC from a participating site identified as designated main EC for the purpose of primary review. However, the local site requirements, such as informed consent process, research implementation and its monitoring, etc. may be performed by the local EC. 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 must be followed.

3.2.1.2 Any multicenter study (national or international) conducted under the organization must be reviewed and approved by the IEC, following ethical clearance from the local IEC(s) involved in the study.

3.2.1.3 All clinical trials must be approved by Institutional Committee for Stem Cell Research (IC-SCR), which in turn should be registered with National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT). All such studies should also be registered with Clinical Trials Registry – India (CTRI). The EC should give final approval before initiation of the clinical trial. As T4H does not have an IC-SCR, it will not accept proposals involving stem cell research.

3.2.1.4 Independent researchers who have no institutional attachments can use the services of T4H EC for reviewal of their research proposals. The T4H EC will not accept proposals from investigators affiliated to institutions that have their own ECs unless there is a MoU.

3.2.2 Review ethical approval requests for research studies in human participants involving interventions in the form of a drug or any similar substance, procedure, modification of dose, dosage form or duration of treatment, any health intervention

The IEC will review the following types of projects:

- Scientific and ethical aspects of research studies in human participants involving interventions in the form of a drug or any similar substance, procedure, modification of dose, dosage form or duration of treatment, any health intervention

- Clinical trials of drugs and medicinal products, product evaluation, case reports and case series, diagnostic tests and devices, medical devices, AI in healthcare, genome sequencing/technology, epidemiological studies in dietetics, surveys/interviews, database and big data analytics, biobanks of biomedical specimens, public health surveillance, medical records review

- Sponsored by pharmaceutical companies, Government of India / NGOs, studies in collaborations with international organizations/universities, all dissertation projects (postgraduate students: MD, MS, DM, MCh, Ph.D., MSc, MPH and any other course run by

Institution as applicable), research projects of undergraduate students carried out under the guidance of teachers (e.g. Indian Council for Medical research studentship, GJ STRAUS or any other) and investigator-initiated research studies which are self-funded / funded by institutional funding bodies / Govt funding agencies.

All research proposals funded or sponsored by pharmaceutical companies, agencies, multinationals etc. will be charged a processing fee. Appropriate permissible fee would be charged for non-funded studies, departmental studies, and studies funded by organizations such as ICMR, UGC, Department of Science and Technology Government of India, State science & technology departments, etc.

3.3. Types of projects reviewed by IEC

The IEC will review the following types of projects:

a) Scientific and ethical aspects of research studies in human participants involving interventions in the form of a drug or any similar substance, procedure, modification of dose, dosage form or duration of treatment, any health intervention.

b) Clinical trials of drugs and medicinal products, product evaluation, case reports and case series, diagnostic tests and devices, medical devices, AI in healthcare, genome sequencing/technology, epidemiological studies in dietetics, surveys/interviews, database and big data analytics, biobanks of biomedical specimens, public health surveillance, medical records review.

c) Sponsored by pharmaceutical companies, Government of India / NGOs, studies in collaborations with international organizations/universities, all dissertation projects (postgraduate students: MD, MS, DM, MCh, Ph.D., MSc, MPH and any other course run by Institution as applicable), research projects of undergraduate students carried out under the guidance of teachers (e.g. Indian Council for Medical research studentship, GJ STRAUS or any other) and investigator-initiated research studies which are self-funded / funded by institutional funding bodies / Govt funding agencies.

All research proposals funded or sponsored by pharmaceutical companies, agencies, multinationals etc. will be charged a processing fee. Appropriate permissible fee would be charged for non-funded studies, departmental studies, and studies funded by organizations such as ICMR, UGC, Department of Science and Technology Government of India, State science & technology departments, etc.

3.4. Composition of IEC

The IEC will be multidisciplinary and multi-sectoral in composition, and will have seven to fifteen members from medical, non-medical, scientific, and non-scientific backgrounds. At least 50 percent of members will be non-affiliated with the institution (T4H). The members of the committee will represent a diverse range of genders, age, and social background. In line with the ICMR guidelines, the IEC will have the categories of members as mentioned in the next sub-section.

3.5. Qualifications, affiliations, member specific roles and responsibilities of IEC

a) **Chairperson (Tech4Health Foundation non-affiliated)**
Qualifications: A well-respected, non-affiliated person from any background with prior experience of having served/ serving on an ethics committee.

Duties

- Conduct IEC meetings and ensure the independent, regular, and efficient functioning of the

committee.

- Ensure active participation of all members in all discussions and deliberations.
- In case of anticipated absence of the Chairperson at a scheduled meeting, the Chairperson should nominate a committee member as an 'Acting Chairperson'. Alternatively, the members attending the meeting may elect an 'Acting Chairperson' for that meeting.
- Seek a conflict of interest (COI) declaration from members, ensure quorum and fair decision-making.
- Handle applications such as complaints against researchers, IEC members, COI issues and requests for use of IEC data.

b) **Member Secretary/ Co-member Secretary (Tech4Health Foundation-affiliated)**
Qualifications: An affiliated staff member of the institution with knowledge and experience in research and research ethics. She/he must be motivated and have effective communication skills as well as be able to devote adequate time to IEC activities.

Duties

- 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.
- Ensure completeness of documentation at the time of receipt of proposals and timely inclusion in agenda for IEC review.

c) **Basic Medical Scientist(s) (Tech4Health Foundation affiliated or non-affiliated)**
Qualifications: An affiliated/ non-affiliated, non-medical or medical person with qualifications in basic medical sciences. In case of IEC reviewing clinical trials with drugs, the basic medical scientist should preferably be a pharmacologist.

Duties
Conduct a scientific and ethical review with emphasis on the following

- Intervention proposed
- Risk-benefit analysis
- Research design
- Methodology and statistical tools
- Continuing review process
- Serious adverse events (SAE)
- Protocol deviation, progress, and completion reports.

d) **Legal expert(s) (Tech4Health Foundation affiliated or non-affiliated)**
Qualifications: An affiliated/ non-affiliated individual with a basic degree in law from a recognized university, and with work experience.

a. Desirable qualification: Training in medical law.

Duties

- Ethical and legal review of the proposal, MoU, regulatoryapprovals, insurance documents, other site approvals, researchers' undertaking, protocolspecific other permissions, compliance with

guidelines etc.

- Inform IEC members about new regulations and their interpretations, if any.

e) **Social scientist(s) (Tech4Health Foundation affiliated or non-affiliated)**
Qualifications: An affiliated/ non-affiliated individual with social/behavioral science/ philosophy/ religious qualification and training and/or expertise. She/he should be sensitive to local cultural and moral values and can be from an NGO involved in health-related activities.

Duties

- Ethical review of the proposals.
- Assess the impact on community involvement, socio-cultural context, religious or philosophical context, if any.

f) **Lay person(s) (Tech4Health Foundation non-affiliated)**
Qualifications: A non-affiliated, literate person from the public or community who has not pursued medical science/ health-related career in the last five years.

i. She/he may be a representative of the community from which the participants are to be drawn.
ii. She/he must be aware of the local language (as per the study area of the proposed research), cultural and moral values of the community.
iii. Desirable qualification: involved in social and community welfare activities.

Duties

- Ethical review of the proposal, informed consent documents along with their translation.
- Evaluate benefits and risks from the participant's perspective and opine on whether benefits justify the risks.
- Assess societal aspects of the proposed research study, if any.

3.6. Selection criteria for IEC members

a) All IEC members will be appointed by the Head of the Institution.
b) New members will be identified by the Chairperson according to the membership requirements and after discussions with the members of the committee. They may also be suggested by the IEC members and the Chairperson to the Head of the Institution. The final decision on the appointment of members will be taken by the Head of the Institution.
c) Members will be appointed to the IEC for a specific role. Members cannot stand in for any other IEC member who is absent from a meeting. However, the roles of the Chairperson and Member Secretary are additional responsibilities to their primary responsibility based on their qualifications. For instance, if the Chairperson is a lawyer, she or he can serve as both the lawyer and the Chairperson.

3.7. Basic requirements for IEC members

a) Every IEC member must provide a consent letter, an updated and signed CV with training certificates on human research protection and good clinical practice (GCP), if applicable. If not trained, the members must undergo GCP training and share certificates of completed training courses within six months of appointment.
b) All committee members are honorary members, aware of relevant guidelines and regulations. If they are not aware, they must be willing to improve their knowledge about the same within their tenure.

c) All committee members must read, understand, accept, and follow the conflict of interest (COI) policy agreement of the IEC and declare agreement. (Annexure 1). If applicable, COI is to be declared by the committee members at the appropriate time, preferably prior to the IEC review meetings.
d) Each committee member must sign and declare the confidentiality agreement regarding IEC activities (Annexure 2). All members must maintain absolute confidentiality regarding all discussions during the meeting.
e) All members must be willing to disclose her/his full name, profession, and affiliation to the IEC in the public domain
f) Every member must be committed to research and extending protection to research participants.
g) Every member must devote adequate time to ensure the fulfillment of the IEC objectives. Members must allocate sufficient time to review relevant proposals, participate in meetings, and partake in monitoring progress as required.
h) All committee members must be graduates with good moral character
i) No committee member should be convicted for any offence at the time of appointment.

For more details, refer to Section 3.12 on roles and responsibilities of the IEC members.

3.8. Tenure of membership

Members of the IEC will be appointed for a period of three years. The ICMR guidelines state that the duration can be extended, and a defined percentage of IEC members can be changed or replaced at the end of their tenure. In accordance with this, at the end of the three years, the IEC will be reconstructed with at least 50 percent of the members being replaced.

For detailed procedures of resignation, removal or replacement of IEC members, refer to Section 3.5 on roles and responsibilities of IEC members.

3.9. Conditions of appointment

Appointed members will be selected based on their personal and professional attributes which include qualifications, work experience, interest, commitment, and willingness to volunteer time for the IEC.

3.9.1. Required qualifications of the IEC members

a) **Chairperson:** A well-respected, non-affiliated person from any background with prior experience of having served/ serving on an ethics committee.
b) **Member Secretary/Co-member Secretary:** An affiliated staff member of the institution with knowledge and experience in research and research ethics. She/he must be motivated and have effective communication skills as well as be able to devote adequate time to IEC activities.
c) **Basic Medical Scientist(s):** An affiliated/ non-affiliated, non-medical or medical person with qualifications in basic medical sciences. In case of IEC reviewing clinical trials with drugs, the basic medical scientist should preferably be a pharmacologist.
d) **Clinician(s):** An affiliated/ non-affiliated individual/s with recognized medical qualification, expertise and training.
e) **Legal expert/s:** An affiliated/ non-affiliated individual with a basic degree in law from a recognized university, and with work experience.
    i. Desirable qualification: Training in medical law.
f) **Social scientist/ philosopher/ ethicist/theologian:** An affiliated/ non-affiliated individual with social/behavioral science/ philosophy/ religious qualification and training and/or expertise. She/he should be sensitive to local cultural and moral values and can be from an NGO involved in health-related activities.

g) **Lay person(s):** A non-affiliated, literate person from the public or community who has not pursued medical science/ health-related career in the last five years.
   iv. She/he may be a representative of the community from which the participants are to be drawn.
   v. She/he must be aware of the local language (as per the study area of the proposed research), cultural and moral values of the community.
   vi. Desirable qualification: involved in social and community welfare activities.

3.9.2. Other conditions of appointment

a) For appointment, medical scientists and clinicians must possess a postgraduate qualification with some work experience in significant positions and be aware of their roles and responsibilities as committee members.
b) Professional integrity and commitment to human welfare are important criteria for inclusion as members of the IEC.
c) All IEC members must be willing to disclose their full name, profession, designation, and affiliations.
d) Post initial constitution, subsequent appointment is guided by the quorum requirements and activity of the members involved. Any members with obvious undue influence over other members' decisions due to institutional association, financial liability, kinship, or authority will be excluded from the quorum (if deemed so by at least two other IEC members).
e) A maximum of 50 percent of the members of the committee can belong to the institution.
f) All members must maintain absolute confidentiality of discussions, meetings, documents circulated for review, unless required by law. The IEC members have to sign a confidentiality agreement at the time of appointment regarding meeting deliberations, applications, information on research participants and related matters, the terms of which shall be binding on them even after the termination of the contract.
g) New members will be appointed under the following circumstances:
   i. A regular member completes her/his tenure.
   ii. A regular member resigns from her/his role before their tenure is completed.
   iii. A regular member ceases to be a member for any reason (e.g., resignation/ retirement/ disqualification/ death).
   iv. To fulfill the membership requirements as stated in membership requirements.
h) Every IEC member will have tenure of 36 months (three years).
   i. At the end of the term, 1/3 of the members will be replaced, such as to maintain 50 percent of the initial composition.
   ii. Rotation/replacement will start from the 3rd year of the IEC constitution after which 1/3 will be replaced on a yearly basis.
   iii. Appointments can be renewed based on their contribution to the work of the IEC.
   iv. During the term, the Chairperson can disqualify any member if their contribution is deemed to be not adequate.
   v. Members can also be disqualified if there is an extended period of non-availability (three or more meetings consecutively) without providing prior reasons to the Chairperson/Member Secretary, except under exceptional circumstances.
   vi. Members can discontinue from IEC membership after giving at least 1-month advance notice.
   vii. The Chairperson can replace the members of IEC as and when required.
i) Every non-institutional committee member (members not affiliated to T4H) is paid an honorarium for each meeting.
j) All IEC members, including the Chairperson, shall be appointed by the Head of the Institution, as recommended by the IEC. The appointment of the IEC member will be confirmed after receiving their

consent to abide by the GCP guidelines and maintenance of confidentiality. The Chairperson will appoint the other coordinating staff for the IEC.

For detailed procedures of 3.5 resignation, removal or replacement of IEC members refer to 3.7 Roles and Responsibilities of the IEC members.

3.10. Procedure for resignation, replacement, or removal of IEC members

Members who have resigned may be replaced by the appointing authority. Members of the IEC who wish to resign must notify the Head of the Institution and the Chairperson of the IEC in writing at least 30 days (about 4 and a half weeks) prior to the next scheduled IEC meeting.

3.10.1. Resignation

a) If the member opts to step down due to a genuine cause, she/ he may do so with prior notice and proper information to appointing authority.
b) A member can resign by submitting a resignation letter addressed to the IEC Chairperson, emailed/delivered to the Member Secretary and the same will be informed by the Member Secretary to the appointing authority for formal acceptance and initiation of the necessary replacement/recruitment procedure to fill up the vacancy.

3.10.2. Disqualification for unsuitable conduct

A member can be disqualified if she/ he has been absent without prior notice for three consecutive meetings or has been involved in any event that imposes serious doubt on the member's integrity or ethics.

a) During tenure, the administrative officials, in consultation with the Chairperson will have the authority to replace any of the members who have not followed the conditions of appointment.
b) A member can be disqualified from continuance if the IEC decides such by a majority of three-fourths, during a meeting specifically called for the purpose of discussion of inappropriate behavior of the specific IEC member.
c) The process will be initiated after the IEC Chairperson or Member Secretary receives written notice (provided by a committee member) alleging misconduct by a member.
d) The Chairperson will satisfy herself/ himself that a prima facie case exists before initiating action. If the Chairperson believes the matter is of grave importance and the integrity of IEC is in jeopardy, the Chairperson may suspend the membership of the concerned IEC member until a final decision is taken by IEC. During the tenure of suspension, the concerned member will not have any rights, responsibilities or privileges as an IEC member and will not perform any duties.
e) The Chairperson may call a meeting with other IEC members to discuss the issue raised or the matter could be discussed in any regular IEC meeting. The allegation will be discussed in the IEC meeting, and the accused member would be given enough opportunity to defend themselves.
f) The member would stand disqualified if their disqualification is approved by voting (a two-thirds majority of members present in the meeting). The concerned member would be conveyed via a written notice of disqualification by the Chairperson.

3.10.3. Disqualification for not attending IEC meetings

A member may be disqualified from the IEC membership if she/he fails to attend three meetings consecutively and without prior intimation.

a) The Member Secretary will inform the Chairperson in writing if a member fails to attend more than three consecutive meetings of the IEC without prior information.
b) The Chairperson will initiate a process to review the membership of the IEC member in question by including the matter in the agenda of the next scheduled IEC meeting.

c) A communication will be sent to the concerned member in writing, informing her/him that the issue of disqualification will be discussed in the next meeting, inviting the member to defend their case. Alternatively, the concerned IEC member will be allowed to present her/ his arguments regarding the uninformed absence through a letter addressed to the Chairperson of the IEC.
d) The matter will be discussed and reviewed in the next IEC meeting. The concerned member will be provided with an adequate opportunity to represent their case. A written communication from the member in question, if received, will be reviewed in the meeting.
e) The Chairperson or Member Secretary will inform the IEC members about the termination of membership, if so decided, by a confidential communication in writing to other members of the IEC or will inform them at the next meeting of IEC.

3.11. Training for new and existing committee members along with standard operating procedures

Any new guidelines, if relevant to the functioning of the IEC, should be brought to the attention of all IEC members. IEC members should be encouraged to attend national and international research ethics training programs to maintain and improve quality in ethical review and to be aware of the latest developments in this field. Certificates of the members' participation should be kept in the IEC's record.

3.12. Roles and responsibilities of the IEC members

3.12.1. Hierarchy

The Chairperson, Member Secretary and Co-member Secretary are appointed amongst the members of the IEC.

a) The Chairperson will head the committee.
b) The Member Secretary and the Co-member Secretary will be the guardian of all documents, records, and funds in the possession of the committee.
c) Other IEC members will be regular members with equal ranking.

3.12.2. Chairperson

The chairperson will handle the conduct of all IEC meetings, leading all discussions and deliberations relevant to review the research proposals. The chairperson will:

a) Preside over all elections and administrative matters pertinent to the committee's functions.
b) Represent the IEC at different meetings and forums.
c) Be responsible for signing all the documents and communications related to the functioning of the IEC.
d) Nominate a committee member as an Acting Chairperson in case of an anticipated absence of the Chairperson at a planned meeting.

3.12.3. Member Secretary

The role of the IEC Member Secretary will be:

a) To accept research study/ project proposals.
b) To prepare, maintain and distribute study files.
c) To organize effective and efficient tracking procedures for each proposal received.
d) To schedule and organize IEC meetings after consultation with the Chairperson.
e) To prepare and maintain meeting agenda and minutes.
f) To maintain IEC records and to archive them.
g) To keep the records of all IEC members — their appointment letters, biodata, and consent forms. On written request to the Chairperson, this list and a copy of the working procedures would be made available to any investigator for the purpose of filing research projects.

h) To sign documents and communications related to IEC functioning.
i) To communicate with the IEC members and applicants/ investigators.
j) To notify the Principal Investigator regarding committee decisions related to the submitted research proposal.
k) To arrange for training of personnel and IEC members.
l) To organize the preparations for an upcoming meeting, reviews, revisions and distribution of procedures and guidelines.
m) To provide necessary administrative support for IEC related activities to the Chairperson.
n) To provide updates on relevant and contemporary issues related to research ethics as well as relevant contemporary literature to the committee members.
o) To receive IEC processing fees and issue official receipts to the researchers for the payment.
p) To delegate various responsibilities to appropriate and authorized persons.
q) To ensure adherence of IEC functioning as per SOPs.
r) To prepare for audits and inspections.
s) To prepare and make available the annual reports/ annual financial statements for scrutiny by auditors/ inspectors of the IEC.

The **Co-member Secretary** will assist the Member Secretary in the completion of the above duties, and will perform the above in the absence of the Member Secretary.

3.12.4. Coordinating Staff

The coordinating staff will:

a) Support the Member Secretary in executing functions of the IEC.
b) Facilitate correspondence with the IEC members and investigators.
c) Arrange meetings for the committee.
d) Receive all research study/ project proposals.
e) Assist in preparing agenda and minutes of the meetings.
f) Perform any other functions as instructed by the IEC Secretariat.

3.12.5. Responsibilities of IEC members

The basic responsibilities of an IEC member will be:

a) To ensure the protection of dignity, human and animal rights, safety, and well-being of all research participants.
b) To attend meetings arranged by the IEC and participate in discussions and deliberations for appropriate decisions.
c) To review, discuss and consider research proposals submitted for evaluation.
d) To monitor SAE reports and recommend appropriate action(s).
e) To ensure that universal values of research ethics and international scientific standards are adhered to while keeping in mind local community values and customs.
f) To review progress reports as well as monitor ongoing studies/ projects.
g) To maintain confidentiality of the documents and deliberations of IEC meetings.
h) To declare COI (if any), at each meeting.
i) To participate in continuing educational activities in research ethics.
j) To provide information and documents related to training in research ethics to the IEC Secretariat.
k) To provide an updated CV when requested by the IEC Secretariat.
l) To carry out the work delegated by the Chairperson and Member Secretary.
m) To assist the Chairperson and Member Secretary in carrying out IEC work as per SOP.

n) To review progress reports of approved projects, final reports and AE/SAE reports, and provide suggestions to ensure the safety and well-being of the research participants and minimizing risk, if applicable.
o) To recommend appropriate compensation for injuries attributable to the research, wherever necessary.
p) To remain updated on relevant laws and regulations.

3.13. Policy to monitor or prevent conflicts of interest

A conflict of interest (COI) is a set of circumstances in which a professional decision on a primary interest, such as the welfare of participants or the validity of research, is unfairly impacted by a secondary interest, either financial or non-financial (personal, academic, or political). COI can be at the level of researchers, IEC members, institutions, or sponsors.
Although it is acknowledged that COI will always exist, the IEC and its Chairperson are trusted to resolve conflict situations in a way that maintains the protection of study participants as the ultimate objective.

3.13.1. Dealing with COI

a) When a member has a COI, the Chairperson should be notified, and the member may not participate in the IEC review or approval process unless the Committee requests information.
b) If an applicant considers that a member of the IEC has a potential COI, the investigator may request that the member be excluded from the protocol evaluation.
c) The Chairperson must be addressed in writing about the request by the investigator. The request must provide documentation to back up the claim that there is a conflict with the IEC member in question. The committee may elect to investigate the applicant's statement of a potential COI.
d) If COI is inherent in the research itself, it is important to declare this at the outset and establish appropriate mechanisms to manage it.
    i. The IEC must ensure that the documents submitted by the researcher include a disclosure of interests that may affect the research, if any.
    ii. The IEC members must evaluate each research project or study in light of any disclosed interests and ensure that appropriate means of mitigation are taken.

3.13.2. Examples of COI cases may be

a) A member is involved with a competing research program.
b) Access to funding or intellectual property could give an unfair competitive advantage.
c) A member’s personal biases or prejudices may interfere with his or her impartial judgment.

4. General procedures

The general procedures provide the framework for standard protocol and how to conduct a meeting, and ensure basic quorum required for IEC meeting.

4.1. Standard protocol

a) Attend IEC meetings and participate in discussions and deliberations.
b) Review, discuss and consider research proposals submitted for evaluation.
c) Monitor SAE reports and recommend appropriate action(s).
d) Review progress reports and monitor ongoing studies as appropriate.
e) Do onsite visits wherever needed.
f) Evaluate final reports and outcomes.
g) Maintain confidentiality of the documents and deliberations of IEC meetings.
h) Declare COI (if any) in writing to the Chairperson.

i) Provide information and documents related to training obtained in biomedical ethics and biomedical research to the IEC Secretariat
j) Carry out work delegated by Chairperson, Member-secretary, and co-member secretary. Also help the Chairperson, Member secretary, and Co-member secretary in carrying out IEC work as per SOPs.
k) Be updated on relevant laws and regulations related to the functioning of the IEC.
l) Committee meetings will be held monthly.
m) Applicants, sponsors, or investigators may be invited to make a slide presentation on the proposal or elaborate on specific issues.
n) A decision will be taken only when sufficient time has been allowed to the Principal Investigator (PI) for presentation of protocol and to the committee for review and discussion.
o) The IEC will evaluate possible risks to the research subjects with justifications and expected benefits, and document necessary measures to ensure privacy, confidentiality, and justice issues.
p) A complete quorum is essential to make decisions.
q) Members will have access to the study proposals and relevant documents at least 10 days before they are brought up for review in an IEC meeting.
r) IEC meetings will be minuted, and all proceedings and deliberations will be documented.
s) At the end of each meeting of the IEC, signatures from all IEC members will be collected on the final draft of the minutes of meeting.
t) A decision will be taken only after reviewing a complete application with all the documents necessary and relevant to the proposal.
u) Only members who participated in review and discussion will participate in the decision.
v) Wherever possible, decisions will be taken through consensus and not by vote. However, when a consensus appears unlikely, a short voting exercise may be performed. Decisions will be taken by a vote of simple majority by members attending the meeting.
w) Members having the COI will indicate to the Chairperson prior to the review of application and the same will be recorded in the minutes.
x) Members will withdraw from decision making procedures in case of COI.
y) In case of conditional approval of a proposal the same will be communicated to the investigators, with clear suggestions for modifications and re-review procedure.
z) Negative decisions will be supported clearly by stated reasons.

4.2. Conduct of IEC meetings

a) The Chairperson will conduct and oversee every meeting of the IEC.
    i. In the absence of the Chairperson, an Acting Chairperson will be elected from the other members by consensus of the members present on the day of the meeting or by the Chairperson herself/ himself.
    ii. The Acting Chairperson will have the powers of the chairperson and should be a non-affiliated person as far as possible.
b) The Member Secretary is responsible for organizing meetings, maintaining records, and communicating.
    i. She/he will prepare the minutes of the meeting and get it approved by the Chairperson and all the members.
    ii. In the absence of a Member Secretary, the Co-member Secretary among the members will organize the IEC meeting.
c) The IEC may call upon subject experts for special review of selected research protocols, if necessary.
    i. These experts may be specialists in ethical or legal aspects, specific diseases, or methodologies, or represent specific communities, patient groups or special interest groups. For example, cancer patients, HIV/AIDS positive persons or persons ethnic minorities.

ii. They will be required to give their specialized views but will not be involved in the decision-making process, which is solely done by the IEC.
iii. Experts will be subject to the applicable confidentiality agreement.

d) The committee will be non-functional, and a dissolution will be considered in the following instances:
   i. No meeting for a continuous period of six months.
   ii. Meeting attendance is below five independent members for four consecutive meetings.

4.3. Quorum requirement

The quorum for reviewing regulatory clinical trials must be updated with current New Drugs and Clinical Trials Rules 2019 as well as Central Drugs Standard Control Organisation (CDSCO) requirements. As per WHO guidelines, all IEC members should not belong to one gender, or one profession and at least one member should be an expert in a non-scientific area.

a) The quorum will include
   i. Medical member (clinicians with appropriate medical qualifications)
   ii. Non-medical or technical member (persons with qualifications related to a particular branch in which the study is conducted)
   iii. Non-technical member
   iv. At least one non-affiliated (non T4H) member
   v. At least one female member

b) According to the Drugs and Cosmetics Act, 1940, the committee approving a research proposal should include in the quorum at least:
   i. One basic medical scientist
   ii. One clinician
   iii. One legal expert
   iv. One social scientist/ representative of non-governmental voluntary agency/ philosopher /ethicist / theologian or a similar person
   v. One lay person from the community

c) The Chairperson, Member Secretary and Co-member Secretary as well as the primary/secondary reviewer should be a part of the quorum.

d) For a decision on a proposal, five to eight members must be present in the quorum.
   i. A minimum of 50 percent of committee strength +1 member and not less than five members is necessary for the quorum.
   ii. No decision is valid without the fulfillment of the quorum.

e) All decisions of the IEC will be taken during the meetings of the IEC, and not by circulation of project proposals.

f) To maintain the quorum, the IEC may nominate alternate members who can participate in IEC operations in the absence of regular members. The IEC may invite members of specific patient groups or other special interest groups for an IEC meeting (if necessary, based on the research area's requirements, such as HIV/AIDS, genetic disorders, stem cell research, etc.) to hear their perspectives. Such individuals will attend the meeting in the capacity of 'Observer' and will not have the right to vote.

5. Application procedures and submission requirements

The application process and submission requirements outline how to submit the application and relevant documents, document protocol and informed consent form in the IEC meeting.

5.1. Application procedures

a) All proposals will be received on working days at least 2-3 weeks before the review meeting on the prescribed application along with relevant documents.
    i. An initial scrutiny will be done by the Member Secretary for completion of the application, after which the proposals will be circulated to the IEC members.
    ii. If required, additional review meetings can also be conducted with a short notice period.
    iii. Eight to eleven hard copies or one soft copy of the proposal along with the application and documents in prescribed format duly signed by the Principal Investigator (PI) and co-investigators/ collaborators should be submitted to IEC.
b) All applications should be submitted to the Chairperson, through the Member Secretary. Receipt of the application will be acknowledged by the IEC Secretariat. Every application sent to the IEC will be allotted a unique registration number used for future correspondence and reference.
c) The date of the IEC meeting will be communicated to the study's PI. The PI may be asked to
    i. Attend the meeting.
    ii. Make a brief presentation on the proposal.
    iii. Clarify any points raised by the IEC members.
d) IEC can suggest online meetings and virtual presentations of the investigators in special situations such as the COVID-19 pandemic, etc.
e) If revisions are required, the revised proposal in the required number of copies should be submitted within the stipulated period as specified in the communication on or before the next meeting.
f) All research proposals funded or sponsored by pharmaceutical companies, agencies, multinationals etc. will be charged a processing fee of five percent of their sanctioned budget. Waiver of these fees is permissible for non-funded studies, departmental studies, and studies funded by organizations such as ICMR, UGC, Department of Science and Technology Government of India, State science & technology departments, and global institutions like WHO, UNICEF, USAID etc.

5.2. Types of projects reviewed by the IEC

The IEC will review the following types of projects:

a) Scientific and ethical aspects of research studies in human participants involving interventions in the form of a drug or any similar substance, procedure, modification of dose, dosage form or duration of treatment, any health intervention
b) Clinical trials of drugs and medicinal products, product evaluation, case reports and case series, diagnostic tests and devices, medical devices, AI in healthcare, genome sequencing/technology, epidemiological studies in dietetics, surveys/interviews, database and big data analytics, biobanks of biomedical specimens, public health surveillance, medical records review.
c) Sponsored by pharmaceutical companies, Government of India / NGOs, studies in collaborations with international organizations/universities, all dissertation projects (postgraduate students: MD, MS, DM, MCh, Ph.D., MSc, MPH and any other course run by Institution as applicable), research projects of undergraduate students carried out under the guidance of teachers (e.g. Indian Council for Medical research studentship, GJ STRAUS or any other) and investigator-initiated research studies which are self-funded / funded by institutional funding bodies / Govt funding agencies.

5.3. Relevant documents to be submitted for review

For all applications, the following documents should be submitted to the Member Secretary of the IEC:

a) Cover letter
b) Type of review requested
c) Application form for initial review

d) Proposals should be submitted with all relevant enclosures like proforma, case report forms, survey tools, follow-up cards, etc.
e) Permission of using copyrighted proforma/ questionnaire
f) Complete protocol
g) CVs of all the investigators with relevant publications in the last five years.
h) The correct version of the informed consent document (ICD) in English as well as local language(s). (Annexure 3)
i) Case record form/questionnaire
j) In case of HIV testing/genetic screening, pre-test and post-test counselling forms
k) Recruitment procedures: advertisement, notices, if applicable
l) Patient instruction card, diary, etc., if applicable
m) Investigator's brochure (as applicable for drug/biologicals/device trials)
n) Details of the funding agency or sponsor and allocation of funds , if applicable
o) A statement on COI, if there isn't any conflict, it should state so in the COI
p) GCP training certificate (preferably within the last five years) of investigators (in case of sponsored clinical trials)
q) Any other evidence relevant for research ethics, if applicable.
r) List of all ongoing research studies under the PI supervision, if applicable
s) Undertaking with signatures of investigators
t) Regulatory permissions, as applicable
u) Relevant administrative approval(s)
v) MoU in cases of studies involving collaborations with other institutions, if applicable
w) Clinical trial agreement between the investigator and sponsors of the study, if applicable
x) Insurance policy, if applicable

5.4. Documentation protocol

Details of what the protocol should include:

a) The first page carries the title of the proposal with signatures of the investigators, along with
    i. Name of the applicant with designation.
    ii. Name of the institute/ hospital / field area where the research will be conducted.
b) Brief summary/ lay summary of the study.
c) Background with rationale of why a human study as well as inclusion/exclusion of vulnerable populations is needed to answer the research question, if applicable.
d) Clear research objectives and endpoints/ outcome.
e) Eligibility/ inclusion criteria and participant recruitment procedures.
f) Detailed description of the methodology of the proposed research, including sample size (with justification), type of study design (observational, experimental, pilot, randomized, blinded, etc.), types of data collection, intended intervention, dosages of drugs, route of administration, duration of treatment and details of invasive procedures, if any.
g) Duration of the study.
h) Justification for use of placebo, benefit-risk assessment, plans to withdraw and rescue medication, if applicable.
i) Procedure for seeking and obtaining written informed consent with a sample of the participant information sheet and participant informed consent forms in English and local languages.
j) Informed consent for storage of samples, assent, re-consent.
k) Plan for statistical analysis of the study.
l) Plan to maintain the confidentiality of information related to the study participants.
m) List of ethical issues in the study and plans to address these issues.

n) An account of management of risk or injury to study participants, especially for research involving more than minimal risk.
o) Proposed compensation, reimbursement of incidental expenses and management of research related injury/illness during and after research period and insurance policy.
p) Providing ancillary care to study participants for unrelated illness during research.
q) An account of storage and maintenance of all data collected during the trial.
r) Plans for publication of results – positive or negative – while maintaining confidentiality of personal information/ identity.
s) Ethical considerations and safeguards for protection of participants.
t) Depending on the type of study (particularly the ones involving stigma, for e.g., HIV and genetic diseases), Pre-test and Post-test counselling are required along with the relevant documents.

5.5. Consent process

a) Informed Consent - The researcher should obtain voluntary written informed consent from prospective participants for any research involving human participants.
b) Informed consent is a continuous process with three components
    i. Providing relevant information to potential participants
    ii. Ensuring competence of the individual
    iii. Ensuring the information is easily comprehended by the participants and assuring voluntariness of participation to the researcher in order to give consent.
c) Electronic consent - The researchers can also use electronic media to provide information as in the written informed consent document, which can be administered and documented using electronic informed consent systems.
d) Waiver of consent - The IEC may grant consent waiver if:
    i. Research cannot be practically carried out without the waiver of consent, and the waiver can be scientifically justified.
    ii. Retrospective studies, wherein the study participants are de-identified and cannot be contacted in at the present time.
    iii. Research on anonymized biological samples/data.
    iv. Certain types of public health studies/surveillance programmes /programme evaluation studies.
    v. Research based solely on data available in the public domain
    vi. Research proposed during humanitarian emergencies and disasters when the participant is not able to give consent. In such cases, attempts should be made to obtain the study participants' consent at the earliest possible moment.
    vii. Research involves less than minimal risk to study participants, and the waiver will not adversely affect their rights and welfare.
e) Re-consent is required when:
    i. The latest information pertaining to the study becomes available which has implications for participants, or which changes the benefit to risk ratio.
    ii. A research participant who was unconscious regains consciousness or who has suffered loss of insight regains mental competence and is able to understand the implications of the research.
    iii. A child becomes an adult during the course of the study.
    iv. Research requires long-term follow-up or requires extension.
    v. A change in procedures and data collection methods, site visits or tenure of participation which may impact the participant's decision to continue in the research.
    vi. A possibility of disclosure of participant's identity through data presentation or photographs (that was unforeseen at an earlier stage) in an upcoming publication.

vii. Partner or spouse of the study participant may also be required to give additional re-consent in some of the above cases, if applicable.

6. Review

This section outlines the review procedures, type of review and decision-making process. The Member Secretary/ Secretariat shall examine the proposals for their comprehensiveness and, depending on the risk category, segregate them into three types, namely, (a) exemption from review, (b) expedited review, and (c) full committee review.

6.1. Review procedures

a) The IEC meeting will be held atleast twice a year unless otherwise specified by the Member Secretary. Additional review meetings can also be held with short notice as and when required.
b) The proposals should be checked for completeness before the review meeting by the IEC Secretariat.
c) The proposals should be sent to the IEC at least 2-3 weeks in advance of the scheduled meeting.
d) Decisions will be taken by consensus after discussion, and voting will be done whenever needed. However, the decision of the Chairperson will be final.
e) The PI / Research Scholar will present the proposal in person in the meeting.
    i. In case of the PI's absence, the Co-PI will be allowed to present the proposal.
    ii. If needed, researchers will be invited to offer clarifications on a case-to-case basis.
f) If required, independent consultants/experts will be requested to attend to provide their opinion on specific research proposals.
g) The review discussions and decisions will be charted down, and the Chairperson will approve the final minutes of the meeting.
h) After the IEC meeting, the decision of the IEC members on the discussed proposals will be declared on the same day.
i) The meeting proceedings will be video recorded with prior permission from all the members attending the meeting.

The type of IEC reviews is based on risks involved in the research and is categorized as follows:

Less than minimal risk	a) The probability of harm or discomfort anticipated in the research is nil or unexpected. b) Research on anonymous or non-identified data/samples, data available in the public domain, meta-analysis, etc.
Minimal risk	a) The probability of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in daily life activities of the general population. The chances of severe injury or an adverse event are unlikely. b) Research involves routine questioning or history taking, observing, physical examination, chest X-ray, and obtaining body fluids without invasive intervention, such as hair, saliva, or urine samples.

Minor increase over minimal risk or low risk	a) The probability of harm or discomfort is little more than the minimal risk threshold. b) Research involves routine research on children, adolescents, or people incapable of consent. It also includes the use of minimally invasive procedures that might cause no more than temporary pain, tenderness, small bruises, or very slight, temporary distress, such as drawing a small sample of blood for testing or trying a new diagnostic technique in pregnant and breastfeeding women etc. c) Research should have a social value. The use of personal identifiable data research also imposes indirect risks. d) Social risks, psychological harm and discomfort may also fall into this category.
More than minimal risk or high risk	a) The probability of harm or discomfort anticipated in the research is invasive and greater than minimal risk. b) Research involving any intervention study using a drug, device, or invasive procedure such as lung or liver biopsy, lumbar puncture, endoscopic procedure, or intravenous sedation for diagnostic procedures.

j) A separate institutional ethics committee will review academic research proposals submitted by post-graduate and undergraduate students with identified members constituted by the Chairperson.
k) The use of organization trainees/employees as trial participants unless students are prohibited. Staff have the same rights as any other potential subject to participate in the research project, irrespective of the degree of risk.

6.2. Reviews types

The IEC Secretariat will examine the proposals for their comprehensiveness and, depending on the risk categories and segregate them into -

6.2.1 Expedited review
6.2.2 Full committee review
6.2.3 Exemption from review

6.2.1. Expedited review

a) The proposals with "no more than minimal risk" to research participants may be able apply for expedited review. Minor deviations from the initially approved research protocol during the period of approval. For instance:
   i. Revised proposals that have been previously approved by full review or are continuing review of approved proposals where there is no additional risk or activity is limited to data analysis.
   ii. In the case of nationally relevant proposals requiring urgent review.
   iii. Research involving non-identifiable specimens and human tissue from sources like blood banks, tissue banks and left-over clinical samples
   iv. Modification or amendment to an approved protocol with administrative changes or correction of typographical errors and researcher(s) changes.
   v. All revised proposals will be assessed in a meeting of identified members organized by the Chairperson to expedite decision-making unless specifically required to go to the main committee

b) To expedite a review, a sub-committee consisting of the Secretariat, a non-scientific and a scientific member may be established under the Chairperson to review and approve the proposal.
c) For nationally relevant proposals requiring urgent review, expedited review may also be taken up.
d) Research involving clinical materials (documents, data, specimens, or records) that have been collected for non-research (clinical) purposes. For example:
    i. In **emergencies** like severe disasters or outbreaks, when a full review of the research is not possible, written permission from IEC may be taken before conducting a test intervention. Such research can only be approved for preliminary work or pilot study to study the efficacy and safety of the intervention/ study, and it should be ensured that the same participants are not included in the clinical trial, which may take off later based on the findings of the pilot study.
    ii. **Research on interventions in emergency situations**: When proven prophylactic, diagnostic, and therapeutic methods cease, physicians may use new interventions such as investigational drugs (IND) / devices/vaccines to provide emergency medical care to their patients in life-threatening conditions. Research in such conditions could be allowed in patients:
        - When consent of the patient/person/ responsible relative or custodian/ team of designated doctors in such an event is not feasible. However, information about the research/ intervention should be given to the relative/ legal guardian when available later.
        - When the intervention has undergone examination for safety before its use in emergency situations and the sponsor has obtained prior approval of DCGI (Annexures 6 & 7).
        - Only if the local IEC reviews the procedure since institutional responsibility is of vital importance in such instances.
        - If Data Safety Monitoring Board (DSMB) is constituted to review the data.
    iii. **Research on disaster management:** It may be unethical sometimes not to do research during a disaster. The following items need to be considered when reviewing such research:
        - Research designed to be conducted after a disaster should be culturally sensitive, essential, and specific in nature with possible application in future disaster situations.
        - Extra care must be taken to protect the privacy and confidentiality of participants and communities.
        - Protection must be ensured so that only minimal additional risk is imposed.
        - The research undertaken should stipulate direct or indirect benefits to the participants.
        - Transfer of biological material, if any, should be as per Government rules taking care of intellectual property rights issues.

6.2.2. Full Committee review

All research with "more than minimal risk," proposals/ protocols which do not qualify for exempt or expedited review shall be subjected to the full committee review by all the members.
Examples-
a) Research involving vulnerable populations, even if the risk is minimal
b) Studies involving deception of participants
c) Research proposals that have received an 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

d) Amendments of proposals/related documents (including but not limited to informed consent documents, investigator's brochure, advertisements, recruitment methods, case record forms etc.) involving an altered risk.
e) Significant deviations and violations in the protocol.
f) Any new information that emerges during the research for deciding whether or not to terminate the study given the altered benefit-risk assessment.
g) Research during emergencies and disasters through expedited review/ scheduled or unscheduled full committee meetings. Depending on the urgency and need, this may be decided by the Secretariat.
h) Prior approval of research on predictable emergencies or disasters before the actual crisis occurs for implementation later when the actual emergency or disaster occurs.

6.2.3. Exemption from review

Proposals with less than minimal risk fall under this category.

a) Research on educational practices such as the effectiveness of or the comparison among instructional techniques, or instructional strategies, classroom management methods, and curricula.
b) Research involving the use of educational tests (aptitude, cognitive, diagnostic, achievement); survey/interview procedures; observation of public behaviour), unless:
    i. Information collected is logged in a way which can reveal the identity of the human subjects either directly or by identifiers linked to the subjects and
    ii. Any disclosure of the human subjects' answers outside the research could place them at risk of civil or criminal liability or could damage the subjects' financial standing, reputation or employability.
c) Research involving the collection or study of documents, existing data, pathological specimens, records, or diagnostic specimens, if these (i) sources are publicly available, (ii) the information is logged by the investigator in a way that the subject's identity cannot be revealed either directly or by identifiers linked to the subjects. This includes research and demonstration projects that are designed to study, evaluate, or otherwise examine:
    i. public interest or service programs
    ii. procedures for attaining benefits or services under these programs
    iii. possible changes in or alternatives to these programs or procedures
    iv. potential changes in methods and/or levels of payment for benefits or services under these programs
d) Research conducted on data available in the public domain for systematic reviews or meta-analysis.
e) Consumer acceptance studies related to taste and food quality.
f) Public health programs by government agencies like program evaluation with the sole purpose of refinement and improvement of the program or monitoring (where there are no individual identifiers).

Exceptions include:

a) Research on educational tests, surveys or interview procedures, or observation of public behaviour can identify the human participant directly or through identifiers, and the disclosure of information outside research could subject the participant to the risk of civil or criminal or financial liability or psychosocial harm.
b) Interviews involve a direct approach or access to private papers
c) Research involving vulnerable persons.

6.3. Considerations

a) Scientific design and conduct of the study
b) Approval by appropriate scientific review committees/research committees.

c) Examination of predictable risks/harms
d) Examination of potential benefits
e) Procedure for selection of subjects, including inclusion, exclusion and withdrawal criteria, and other issues like advertisement details
f) Management of research-related injuries, adverse events
g) Compensation provisions
h) Justification for placebo in the control arm, if any
i) Availability of products and benefits to subjects after the study is completed, if applicable
j) Patient information sheet and informed consent form in English and local languages
k) Protection of privacy and confidentiality
l) Involvement of the community, wherever necessary
m) Plans for data analysis and reporting
n) Adherence to all regulatory requirements and applicable guidelines
o) Competence of investigators, research and supporting staff
p) Facilities and infrastructure of study sites
q) Criteria for withdrawal of patients/ study subjects, suspending or premature termination of the study

6.4. Decision-making

a) Proposal decisions will be communicated by the Member Secretary in writing to the PI / Research Scholar within ten working days after the meeting at which the decision was taken.
b) An approval certificate will be sent to the applicant within two weeks.
    i. Approvals will be valid for one year or the project's duration, whichever is less.
    ii. If necessary, the investigator has to get his or her project re-approved after one year.
c) The communicated decision will include the following:
    i. Name and address of IEC.
    ii. Date, place, and time of decision.
    iii. Name and designation of the applicant.
    iv. Title of the research proposal reviewed.
    v. The clear identification of protocol number, version number, date, amendment number, and date.
    vi. Along with protocol, other documents reviewed. Clear description of these documents along with version number and date.
    vii. List of IEC members who attended the meeting. clear description of their role, affiliation and gender.
    viii. A clear statement of decision reached.
    ix. Any advice by the IEC to the applicant including the schedule / plan of ongoing review by the IEC
    x. In case of conditional decision, any requirement by IEC, including suggestions for revision, and the procedure for having the application re-reviewed.
    xi. In case of rejection of the proposal, reason(s) for the rejection will be clearly stated. Signature of the member secretary with date.

6.5. Communicating the decision

a) Members will discuss the several issues before arriving at a consensus decision. However, when consensus is not arrived at, the decision will be made by voting procedure.
b) Decisions will be made only in meetings where the quorum is complete.

c) An IEC member with COI should leave the meeting during the decision procedure. This should be specified to the Chairperson before the review of the application and should be recorded in the minutes.
d) Only members can make the decision. Experts/ consultants can only offer their opinions, and not participate in the decision-making.
e) Decisions may be to approve, reject or revise the proposals. Specific suggestions for modifications, reasons for modifications and reasons for rejection will be given. The IEC can give the following decisions -
    i. Approved – with or without suggestions or comments
    ii. Conditionally Approved - Revision required with minor modifications/amendments
    iii. Conditionally Approved - Revision required with major modifications for resubmission
    iv. Not approved (or termination/revoking of permission if applicable)
f) In case of conditional decisions, well-defined suggestions for revision, and the procedure of application revision will be specified.
g) Modified proposals will be reviewed by an expedited review through identified members. Procedures for appeal by the researchers will be clearly defined.
h) Decisions that may be provisionally taken by the Member Secretary in communication with the Chairperson, without a formal meeting and are subject to approval at the next scheduled meeting are:
    i. Extension of the study beyond the approved period.
    ii. Amendment to the study related document not involving the study design.
    iii. Restarting a previously discontinued research project.
    iv. All notifications related to adverse events.

i) While considering amendments, the IEC may ask for fresh or re-consent and report if:
    i. New information arises, deviating from previous protocol.
    ii. Research participants regain consciousness from an unconscious state or are mentally competent to understand the study. If such an event is expected, then steps to address it should be spelt out at the start itself in the informed consent form.
    iii. In the case of studies where a long-term follow-up or extension is planned.
    iv. When there are changes to the modality of treatment/ procedures/site visits.
    v. A possibility of identity disclosure through data presentation or photographs which should be camouflaged effectively in publications, the fresh/re-consent is to be taken prior to publication.

7. Continuing review activities

In this section, we provide the framework for the resubmission /amendment of the study, review of serious adverse events and also the follow-up with the PI.

7.1. Resubmitted study protocols

7.1.1. Resubmission

It is the duty of the IEC Secretariat to ensure the comprehensiveness of the re-submitted documents and to notify/inform the Chairperson that a protocol previously approved with conditions for revision has been re-submitted to the IEC for reconsideration.

a) A re-submitted protocol may be either reviewed and approved by the Chairperson or some IEC members/reviewers, or full IEC.

b) Decision for the review of the protocol should be determined by the IEC at the time of the initial review and mentioned in the minutes of the IEC meeting in which the proposal was discussed.

7.1.2. Receive protocol of resubmitted package

It is the responsibility of the IEC Secretariat to check the received digital/ hardcopy packages for the following:

a) Response to the comments by investigator's checklist.
b) Revised versions of protocol and related documents such as the data collection or case report forms, informed consent document, diary sheets, etc. should be included as part of the package.
c) Changes made to the documents should be bold and the deleted matter should be made strikethrough for easy verification of the corrections done by the investigators.
d) Put the stamp, write date, and acknowledge the receipt of the protocol.

7.1.3. Review the revised protocol by affiliated members

a) Check the received protocol as per checklist
b) Refer to the meeting minutes as guidance for the review.
c) Ensure that the response to comments of IEC members as mentioned in the minutes is given by the investigator and page numbers where changes are made are mentioned in the proposal.
d) Make further comments if the response is not satisfactory and the changes have not been incorporated in the study proposal.
e) Internal reviewers will write the comments on the Project Review Report form and will put a signature with the date.
f) Notify the IEC Secretariat.
g) Ask the PI to make the necessary revisions.
h) Send the resubmitted proposal with incorporated changes to reviewers /full board as per the decision in the minutes.

7.1.4. IEC meeting required post resubmission

If the IEC previously decided that major modifications are to be made in the proposal, then the revision will be processed as:

a) The primary reviewer presents a brief oral or written summary of the study design and her/ his comments to the IEC members. (Annexure 4)
b) The Chairperson entertains discussion on the protocol revision.
c) Further recommendations for modifications to the protocol, consent form as requested by the committee are noted in the meeting minutes as 'with modifications made by IEC and will be communicated to the investigator.
d) The Chairperson takes a consensus of the IEC members on the revision. The decision on the protocol is declared as:
    i. Approved
    ii. Approved with suggestions/ conditional
    iii. Minor modification/ amendments
    iv. Major modification for full board review
    v. Disapproved

7.1.5. Written communication of the decision

a) The Secretariat then prepares the approval letter and gets the Chairperson's signature.
b) If the study is approved, the committee determines the frequency of continuing review for each study site (usually it should be once a year).

c) The Secretariat sends an approval letter to the investigator notifying the IEC decision and schedule of continuing review. The letter contains, at a minimum, a listing of each document approved, the date set by the committee for frequency of continuing review, and a review of other obligations and expectations from the investigator throughout the course of the study.
d) If the committee requires modifications to any of the documents, the Secretariat sends a written request the specific changes to the investigator to make the necessary changes.

7.2. Reviews of serious adverse events

7.2.1. Adverse Event (AE)

Any untoward medical occurrence in a patient or clinical investigation participant administered an investigational product which does not necessarily have a causal relationship with this treatment. The adverse event can therefore be any unfavorable or unintended sign or experience associated with the use of the investigational product, whether or not related to the product.

7.2.2. Serious Adverse Event (SAE)

The adverse event is SERIOUS and should be reported when the patient outcome is any one of these following listed:

a) **Death** – Report if the patient's death is suspected as being a direct outcome of the adverse event.
b) **Life-Threatening** – Report if the patient was at substantial risk of dying at the time of the adverse event or it is suspected that the use or continued use of the product would result in the patient's death. Examples: Pacemaker failure; gastrointestinal hemorrhage; bone marrow suppression; infusion pump failure which permits uncontrolled free flow resulting in excessive drug dosing.
c) **Hospitalization** (initial or prolonged) – Report if admission to the hospital or prolongation of a hospital stay results because of the adverse event. Examples: Anaphylaxis; pseudomembranous colitis; or bleeding causing or prolonging hospitalization.
d) **Disability** – Report if the adverse event resulted in a significant, persistent, or permanent change, impairment, damage or disruption in the patient's body function/structure, physical activities, or quality of life. Examples: Cerebrovascular accident due to drug-induced hypercoagulability; toxicity; peripheral neuropathy.
e) **Congenital anomaly** – Report if there are suspicions that exposure to a medical product prior to conception or during pregnancy resulted in an adverse outcome in the child. Examples: Vaginal cancer in female offspring from diethylstilbestrol during pregnancy; malformation in the offspring caused by thalidomide.
f) **Requires intervention to prevent permanent impairment or damage** – Report if it is suspected that the use of a medical product may result in a condition that quires medical or surgical intervention to prevent permanent impairment or damage to a patient.
g) Examples include: Acetaminophen overdose-induced hepatotoxicity requiring treatment with acetylcysteine to prevent permanent damage; burns from radiation equipment requiring drug therapy; breakage of a screw requiring replacement of hardware to prevent malunion of a fractured long bone.
    i. The SAE must be reported by the investigators to the IEC within 24 hours of the incident. The unexpected events should be included in the continuing review report submitted to IEC.
    ii. It is the responsibility of the IEC to review all the clinical trial-related events at the site promptly.
    iii. The PI should submit within 24 hours the initial SAE report or the unexpected adverse event report to the Sponsor, IEC, DCGI and Head of the Institution through hard copies or by mail (Annexure 5).

iv. The report of SAE of due analysis shall be sent by the Investigator to IEC, DCGI, sponsor and Head of the Institution within 14 calendar days of occurrence SAE.
    - The report should be accompanied by a detailed narrative of the SAE
    - It should be submitted as per the checklist detailed by the Licensing Authority.

h) SAE review members/IEC members will review the PI submitted SAE documents and documents submitted in the full board meeting and IEC opinion/ MOM will be communicated with the DCGI and PI within 30 days of SAE occurrence.

i) The sponsor or his representative shall pay the financial/ other compensation in case of clinical trial related ro injury or death within 30 days (about four and a half weeks) of the receipt of such an order from the Licensing Authority.

j) The IEC Secretariat is supposed to initatite an initial screening of the research studies/reports and assessing whether they need a review of the full board, Chairperson, other qualified IEC members or experts.

k) Member Secretary will read out the minutes of the SAE sub-committee meetings including the recommendations and decisions of the SAE sub-committee (if constituted).
    i. In case the SAE occurring at the site to be discussed in full review at the meeting, the Member Secretary will also provide the relevant information including updates on SAE that have occurred earlier at the site.
    ii. The decision can be taken by consensus. If not taken by consensus, the issue would be put for voting.
    iii. The decision will be documented in the minutes of the meeting and circulated.

l) Type of actions taken by IEC on review of SAE report:
    i. Suggest changes in protocol, participant information sheet/investigators' brochure/ informed consent document/any other study-related documents.
    ii. Suspending the study till additional information is presented.
        - Suspend the study till review is completed (safety monitoring of ongoing patients to be continued). (Annexures 6 & 7)
        - Suspend the study till amendments requested for by IEC are carried out.
        - Suspend enrollment of new participants.
        - Suspend certain activities under the protocol.
    iii. Direct the PI to inform participants already enrolled in the study about the AEs and if required obtain their consent again (re-consent) regarding continuation in the research trial.
    iv. Direct the PI to inform participants already enrolled in the study about the AE and request them to undertake additional visits, additional procedures, additional investigations etc. as prescribed in the amendment.
    v. If any other action is taken, it shall be documented in the minutes of the IEC meeting.
    vi. The decision of the IEC which requires immediate action from the PI will be communicated to the PI through email or letter/telephone within 24 hours. Such ommunication will be documented by the IEC Secretariat in the study file.
    vii. A formal letter will be sent to the PI notified about the IEC recommendations in such situations within five working days of the IEC meeting.

Research participants who suffer direct physical, social, legal, psychological, or economic harm because of their participation in the study are entitled (after due assessment) to financial/ other assistance to compensate them equitably for any temporary/permanent impairment. In case of death, participant's dependents are entitled to financial/other compensation.

7.3. Following up on approved proposals by PI / sponsor

IEC will review the progress of studies with a positive decision from the time of decision till the termination of the research.

a) Research proposal progress will be followed at a regular interval (at least once a year). Exceptions - IEC will conduct follow-ups at shorter intervals based on the need, nature, and events of the research project.
b) Periodic status reports should be submitted at prescribed intervals for review, along with information and documents. The interval will be specified in the Letter of Communication of Decision to the PI from the IEC.
c) The final report should be submitted at the end of the study.
d) The following instances and events will require the follow-up review/renewed approval:
    i. Any protocol amendment is likely to affect rights, safety, or well-being of research subject of conduct of study.
    ii. Serious or unexpected ADR related to study or product, action taken by investigator, sponsor and regulatory authority.
    iii. Any event or information that may affect the benefit/risk ratio of the study.
e) Protocol deviation, if any, should be informed with adequate justifications.
f) Any new information related to the study should be communicated.
g) Premature termination of study shall be notified with reasons along with a summary of the data obtained so far.
h) Change of investigators/sites must be informed to the office of IEC.
i) Monitoring: Oversight mechanism will be in place to monitor the approved studies. Actual site visits can be made especially in case of reporting of adverse events or violations of human rights and appropriate action will be taken when required and communicated to the applicant indicating modification/suspension/termination /continuation of the project. Reports of the monitoring completed by the sponsor and the recommendations of the DSMB may also be required, if the IEC desires so.
j) Applicants must be informed of the time of completion of study and must send the result summary to IEC. IEC must receive a copy of the final summary of study completed from the applicant (Annexure 8 & 9).

8. Procedures for vulnerable population

Apart from the other requirements which apply to scientific research irrespective of the specialty of research, there are also distinct problems about specialized areas that necessitate additional safeguard/ protection and specific considerations for the IEC to take note of. Examples of such instances are research involving children, pregnant and lactating women, other vulnerable participants, and those with reduced autonomy, as well as difficulties pertaining to the commercialization of research and international collaboration.

Vulnerable persons are those individuals who are absolutely or partially incapable of protecting their own interests due to personal disability, environmental burdens, social injustice, lack of power, understanding, or ability to communicate or are in a situation that prevents them from doing so.

8.1. Characteristics of vulnerable individuals

a) Individuals who are disadvantaged socially, economically, or politically, and hence vulnerable to exploitation.

b) People who are unable to make voluntary informed decisions for themselves or whose autonomy is temporarily or permanently affected, such as those who are unconscious or differently abled.
c) People who are capable of giving consent, but whose voluntariness or comprehension is compromised by their circumstances.
d) Individuals who might be unduly persuaded by the expectation of advantages or the fear of retaliation if they refuse to participate, leading them to provide consent.

8.2. Examples of vulnerable populations or groups

a) Economically and socially disadvantaged people (unemployed people, orphans, abandoned people, people living in poverty, ethnic minorities, sexual minorities – people from the LGBT community, for example).
b) Children (under 18 years).
c) Individuals unduly persuaded by the possibility of benefits or the threat of retaliation if they refuse to engage, which may cause them to consent.
d) Women in particular circumstances (pregnant or breastfeeding women, or those with limited decision-making abilities or healthcare access).
e) Tribal and marginalized communities.
f) Individuals who are refugees, migrants, homeless, or who live in conflict zones, riot zones, or disaster zones.
g) Mentally ill and intellectually impaired people, as well as people who are differently abled (both mentally and physically).
h) Terminally ill or in need of new treatment after exhausting all other options.
i) Suffering from stigmatizing or rare diseases.
j) Have less autonomy because of dependency or being in a hierarchical structure (students, employees, subordinates, defense services personnel, healthcare workers, institutionalized individuals, individuals under trial, and prisoners).

8.3. Principles of research among vulnerable populations

a) Vulnerable groups have an equal right to be involved in research so that the research's benefits can be shared with them.
b) If a vulnerable group is to be mainly recruited, the research must address the group's health requirements.
c) Participants must be given as much power as possible so that they can determine for themselves whether or not to offer their assent/consent to participate.
d) When potential participants lack the ability to consent, an LAR (legally authorized representative) should be involved in the decision-making process.
e) Participants' privacy and confidentiality must be protected with great care, especially as a violation of confidentiality may enhance vulnerability.
f) If vulnerable groups are to be included in research, all stakeholders must ensure appropriate safeguards are in place to protect these individuals' dignity, rights, safety, and well-being.

8.4. Policy on protection of vulnerable populations

a) Research on genetics should not lead to promotion of racial inequalities.
b) Persons who are economically or socially compromised should not be used for the benefit of those who are better than them.
c) The rights and welfare of mentally challenged and mentally differently abled persons who are incapable of granting informed consent or those with behavioral disorders must be protected.
d) Adequate justification is required for the involvement of subjects such as prisoners, students, subordinates, employees, service personnel etc., who have reduced autonomy as research subjects.

8.5. Additional safeguards and protection mechanism

When vulnerable individuals are being recruited as research volunteers, extra attention should be given to avoid exploitation, retaliation, reward/credits, and other forms of exploitation, as they may feel frightened and incapable of disagreeing with their caregivers or feel a desire to please them. They may be subjected to unnecessary pressure in the first situation, while they may be readily exploited in the second. If they assume their caregivers want them to participate in research, or if the caregiver stands to benefit from the dependent's participation, the sense of being pressured to participate may be irresistible, undermining the consent's possible voluntariness.

a) The inclusion of vulnerable population in the research must be justified.
b) The IEC must be satisfied with the justification offered and record it in the IEC meeting's proceedings.
c) The IEC should carefully consider and approve any additional safety measures.
d) The method of obtaining informed permission should be properly documented. Additional safeguards, such as the recording of assent and consent, should be in place.
e) The IEC should also carefully consider the advantages and dangers of the research, as well as risk minimization options.
f) Since potential participants are reliant on others, no coercion, force, pressure, undue influence, threat, or misrepresentation should be used to urge them to participate throughout the research period.
g) Vulnerable people may need to be educated/ informed about the research, its advantages, hazards, and alternatives, if any.
h) Research on sensitive topics such as mental health, sexual practices/preferences, HIV/AIDS, substance misuse, and so on may expose research participants to additional hazards.
i) Researchers should be mindful of the possibility of a COI between the prospective participant and the LAR and use greater caution.
j) When a volunteer is enrolled as a normal control or is recruited from the general community in some types of research, they may be subjected to stigma or discrimination.
k) Efforts should be made to establish support networks to address medical and social issues that may arise.
l) Their privacy, confidentiality, and rights must be always protected, including during research and after it is completed.
m) When possible, auxiliary care may be offered by the research team, such as the establishment of a facility, a school for the participants' unattended children, a hospital, or a counselling center.

8.6. Obligations/duties of IEC

All stakeholders have different responsibilities to protect vulnerable participants. The duties of the IEC, T4H are -

a) To determine, during review, whether the prospective participants for the particular research project/study are vulnerable.
b) Examine whether inclusion/exclusion of the vulnerable population is justified.
c) To ensure that conflicts of interest does not increase the harm or reduce the benefits to the participants.
d) To carefully determine the benefits as well as risk of the participants and recommend risk minimization strategies whenever possible.
e) Suggest additional safeguards, such as more frequent review and monitoring, including site reviews.
f) Only the full committee should do the initial and continued review of such proposals. It is desirable to have empowered representatives from specific populations during deliberations.
g) The IEC has special responsibilities when research is conducted on volunteers who are suffering from mental illness/cognitive impairment. They should be cautious and require researchers to demonstrate exceptions to the regular participation requirements or the necessity of departing from

the study principles. The IEC should make sure that these exclusions are kept to a minimum and that they are explicitly stated in the ICD.

h) The IEC should have SOPs for handling proposals involving vulnerable populations.

8.7. Research on women in special situations

Women have the same right to volunteer in research as men, and they should not be denied this right arbitrarily. For some women, the process of informed consent can be difficult due to cultural factors. As a result, if necessary, women may contact their husbands or family members. Despite the importance of women's autonomy, the researcher must adhere to the standards of local cultural traditions in order to avoid upsetting the household/family/harmony of the community.

a) **Risks for women participants in clinical trials/ intervention studies:**

i. For pregnant and nursing women to be included in clinical studies aimed to address the health requirements of such women, their fetuses, or nursing infants, researchers must give the IEC with adequate explanation. Some examples of justifiable inclusion are trials designed to test the safety and efficacy of a drug for reducing perinatal transmission of HIV infection from mother to child, trial of a device for detecting fetal abnormalities or trials of therapies for conditions associated with or aggravated by pregnancy, such as nausea, vomiting, hypertension, or diabetes.

ii. If women in the reproductive age group are to be included in the research, they should be informed of the risk involved to the fetus if they become pregnant. They should be encouraged to adopt an effective contraceptive technique and informed about their options if contraception fails.

iii. When there is no proof of possible danger to the fetus, a woman who falls pregnant should not be automatically withdrawn from the study. The situation should be thoroughly investigated, and she should be given the option of withdrawing or continuing. If the woman chooses to continue participating, researchers and sponsors must keep a close eye on her and provide support for as long as she needs it.

b) **Prenatal diagnostic studies**

According to the Pre-Conception and Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994, amended in 2003, research on prenatal diagnostic techniques in pregnant women should be limited to detecting fetal abnormalities or genetic disorders, not for sex determination of the fetus.

c) **Research on sensitive topics**

When conducting research on sensitive topics such as domestic abuse, genetic disorders, rape, and so on, absolute secrecy and privacy must be maintained. Appropriate support systems, such as counselling centers and police protection, should be implemented as part of risk mitigation initiatives. Information obtained from a female participant should never be inappropriate, harmful, or appear voyeuristic. When it comes to these delicate subjects, the IEC should be extra cautious.

8.8. Research on children

Individuals who have not reached the legal age of consent are referred to as children (under 18 years). Children are deemed sensitive at a youthful age because their autonomy is affected as they lack the cognitive ability to completely comprehend the study's intricate elements and make informed decisions. Even if individuals have the cognitive ability to grasp the research as they get older, they nevertheless lack the legal competence to consent. As a result, the choice about a child's participation in research and withdrawal must be made by the parents/LAR in the best interests of their child/ward.

a) The IEC should conduct a benefit–risk analysis to evaluate whether additional safeguards/protections for the conduct of research in children are required. For example, studies should be done in kid-

friendly environments, with the parents being present, and where child participants can receive proper medical and psychological care.

b) The IEC should assess the age, health state, and other factors of the children who will be enrolled in the study, as well as the possible advantages to other children with the identical disease or condition, or to society as a whole.
c) Consent of the parent/LAR is required when the research involves children.
d) Children aged 7–18 years old should give verbal/oral or written approval, as approved by the IEC, in addition to parental/LAR consent. Children's mental capabilities improve as they grow, and they gain the ability to understand and respond. Respecting the kid's reaction, the researcher includes the child in the consent process by explaining the intended research in simple terms and using language that guarantees the child understands the request to participate in the study. Assent is a term used to describe a child's willingness to participate in research. If the child objects, the child's wishes must be honored.
e) Simultaneously, failing to oppose should not be seen as consent. However, if the test intervention is likely to save a kid's life and is only available if the child participates in the study, the child's disagreement may be ignored if parental consent and prior IEC permission are obtained.

8.8.1. Conditions of research for children

Children can be included in research if the situation, condition, disorder, or disease fulfils one of the following conditions:

a) It is exclusively seen in childhood.
b) Both adults as well as children are involved, but the issues involved are likely to be significantly different in both these populations.
c) Adults and children are involved in the same way and have similar outcomes in terms of morbidity, severity, and/or death, where applicable, and studies in adults have shown the required level of safety and efficacy.
d) Individual kid participants are expected to benefit from test interventions at least as much as any accessible alternative intervention.
e) When compared to the importance of the knowledge supposed to be learned, the risk of test interventions that are not meant to benefit the individual child participant is low (minor increase over minimal risk).
f) Research on children is normally approved if the safety of the adult population has been established or if the information anticipated to be generated cannot be gained through other means.

8.8.2. Consent of Parent/LAR

The IEC should consider if consent of one or both parents should be obtained before a child could be enrolled.

a) Usually, one parent/LAR's consent may be sufficient for research/ study involving no more than minimal risk and/or that offers direct benefit to the child.
b) However, both parents may have to provide consent when the research/ srudy involves more than minimal risk and/or offers no benefit to the child.
c) If the other parent is unknown , deceased, incompetent, or reasonably unavailable, or if only one parent has legal duty for the child's care and custody, only one parent's agreement is allowed, regardless of the risk involved.
d) In addition to all components described in the participant information sheet, the protocol form should include a parent/LAR information sheet whenever applicable. This sheet should contain information about specific aspects relevant to the child, such as effects on development and growth, psychological well-being, and school attendance.

e) When the research concerns delicate issues such as child neglect or abuse, the IEC may suspend the necessity for parental/LAR approval and instead prescribe an acceptable procedure to protect the child's interests.
f) Children with cognitive impairments or developmental abnormalities are among the most vulnerable groups. In fact, their parents are vulnerable as well, and there is a great risk of therapeutic misunderstanding. The possible benefits and risks of the planned research must be carefully described to parents for them to understand it.
g) The consent of the kid, the consent of the parents/LAR, and the permission of the applicable institutional authorities are all required for study involving institutionalized children (for example, for research in a school setting: the child, parents, teacher, principal, or management may be involved).
h) The content of the consent form must be appropriate for the developmental level and maturity of the children who will be enrolled, and it must be explained in light of individual variances in comprehension. The language used in the assent form must be suitable for the child's cognitive, social, and emotional state. It should be straightforward and appropriate for the child's age. The points to be included in the consent form are the following:
    i. An explanation about the study and how it will help the child.
    ii. An explanation of what will be done in the study, including a description of any discomfort that the child is likely to feel.
    iii. The contact information of the person whom the child can approach if she/ he needs an explanation.
    iv. A paragraph emphasizing that the child can refuse to participate in the study and if she/he chooses to do so, the treatment at the center will not be compromised.

8.8.3. Waiver of consent

All the conditions that apply to waiver of informed consent in adults also apply for waiver of assent in children. For further details refer to Section 5. If the available intervention is anticipated to definitely benefit the child but would be available only if the child takes part in the study, waiver of assent could be allowed. However, this situation should be accepted only in exceptional cases where all forms of assent/consent have failed. In such cases, approval of the IEC should be obtained.

8.8.4. Considerations for assent

a) There is no need to document assent for children under seven years of age.
b) For children between 7 and 12 years, verbal/oral assent must be obtained in the presence of the parents/LAR and should be recorded.
c) For children between 12 and 18 years, written assent must be obtained. This assent form also has to be signed by the parents/LAR.
d) Adolescents may have the capacity to give consent like adults. However, as they have not attained the legal age to provide consent, it is termed as assent and the consent of the parents/LAR should be obtained. If the latter will affect the validity of the study, waiver of consent from the relevant adult should be taken and recorded with the approval of the IEC, for example, in behavioral studies in IV drug users where parental consent may not be possible.

8.9. Research involving sexual minorities or sex workers

There are specific challenges associated with research on sexual minorities and sex workers such as privacy, confidentiality, possibility of stigma, discrimination and exploitation resulting in increased vulnerability.

a) Protection of their dignity and provision of high-quality healthcare should be addressed in the research project, preferably in cooperation with the community before it is finalized.

b) It would be advisable to have a representative of the sexual minority group or the LGBT community as a special invitee/member to participate in the meeting of the IEC if there is a research proposal involving these participants.
c) The IEC can suggest setting up a community advisory board to act as an interface between the researcher(s) and the community
d) Among the LGBT community there are inhibitions between the different groups, so details of the research should be explained to each group separately.
e) Peer educators or LGBT community champions could be the first to be informed and sensitized. They would then explain the specifics to potential community participants, who would then be able to comprehend them better.

8.10. Research involving individuals with mental illness or cognitively impaired/affected individuals

a) **Mental illness: -** According to the World Health Organization (WHO), mental disorders cover a wide spectrum of issues, each with its own set of symptoms. They are characterized by a combination of abnormal thoughts, feelings, behavior, and interpersonal connections. According to the Mental Healthcare Act, 2017, "mental illness" means a substantial disorder of thinking, perception, mood, orientation, or memory that wholly impairs behavior, judgment, capacity to identify reality or ability to meet the ordinary needs of life, mental conditions related with the abuse of drugs and alcohol, but does not include mental retardation which is a condition of arrested or incomplete development of the mind of a person, especially characterized by sub-normality of intelligence. The presence of a mental condition does not imply a lack of comprehension or the inability to grant informed consent.
b) **Cognitively affected/impaired: -** Cognition is described as conscious mental activities such as thinking, understanding, learning, and remembering. Those who are unable to completely participate in these activities are considered intellectually challenged. Individuals or groups who are intellectually disabled (formerly known as mentally retarded), unconscious, or suffering from a variety of neuropsychological disorders such as dementia or delirium, as well as those who are unable to fully comprehend or participate in the informed consent process, either temporarily or permanently, fall into this category. Other causes of cognitive impairment that affect the ability to give informed consent include being too young (children do not yet develop the necessary cognitive abilities to give informed consent); being in excruciating pain; being under the influence of medication, illicit drugs, or alcohol; mental retardation; and traumatic brain injury (that causes unconsciousness or cognitive impairment while conscious).
c) There are some psychiatric conditions that may lead people to cause risk or harm to themselves or others: -
    i. During the informed consent procedure, prospective participants must be told about how the researcher will handle suicidal thoughts or other risks of damage to themselves or others.
    ii. It should be made clear to the participant that his or her privacy may be violated for the purpose of reporting to family members, police, or other authorities, or that they may be admitted to the hospital if they express such intentions of harming themselves or others.
    iii. Interventions should be of short duration, as least restrictive as possible and invoked only, when necessary, in accordance with relevant laws.
    iv. While some interventions, such as hospitalization and treatment for suicidality/homicidal ideation, may be largely for the participants' benefit, they may not see them that way and may decline to participate in a study if such measures are required.
    v. Some research designs may reduce or violate human participant protections/rights or specific requirements of informed consent by resorting to deception in order to achieve

the objectives of the research for public good. All such studies should be reviewed by the IEC very carefully before approval.

8.11. Research on individuals who have diminished autonomy due to dependency or being under a hierarchical system

While reviewing protocols that include students, employees, subordinates, defense services personnel, healthcare workers, institutionalized individuals, under trials, prisoners, and others the IEC must ensure the following -

a) Enrolling participants as described above is specifically relevant to the said research questions and is not merely due to the convenience.
b) Individuals in a hierarchical position may not be able to disagree to participate for fear of authority and therefore extra efforts are required to respect their autonomy.
c) The participant has the option to refuse permission and/or withdraw from the study at any time without affecting her/ his care.
d) The protocol should provide mechanisms for avoiding coercion because of being a member of an institution or hierarchy.

8.12. Research on patients who are terminally ill

Patients who are terminally ill or in quest of novel interventions after exhausting all available treatment options are vulnerable because they are willing to consent to any intervention that offers them a ray of hope. These studies are permitted so that the scientific community or professional bodies do not dismiss the possibility of a new solution that has not yet been validated for such patients.

a) Because there is such a high level of therapeutic misunderstanding, suitable consent processes should be in place, and the IEC should carefully assess such protocols and recruitment procedures.
b) Additional monitoring should be carried out in order to identify any adverse events as soon as possible.
c) The potential participant's views on th benefits and risks should be considered when performing a benefit-risk analysis.
d) If the medication is beneficial to the participant, the IEC should carefully consider post-trial access to it.

8.13. Research on other vulnerable groups

Other vulnerable groups include the economically and socially marginalized, the homeless, refugees, migrants, and individuals or populations living in conflict zones, riot zones, or catastrophe zones. When such individuals are to be recruited as research volunteers, further precautions should be taken to avoid exploitation, retaliation, rewards/credits, and other inducements.

a) Autonomy of such individuals is already compromised, and researchers have to justify their inclusion.
b) The IEC has to satisfy itself with the justification provided to include these participants and record the same in the proceedings of the IEC meeting.
c) Additional protections suggested earlier in the guidelines should be strictly followed by the IEC.
d) The process of informed consent should be clearly documented. Participation should not be compelled or rewarded in any way. A person's refusal to engage should be honored, and no consequences should be imposed.

The IEC should also carefully determine the benefits and risks of the study and examine risk minimization strategies

9. IEC's annual activity report

The Member Secretary prepares the annual report to brief the yearly activity report, submitted to the Head of the Institute with the following elements:

a) Number and dates of the IEC meetings of full board
b) Number and dates of expedited review and SAE committee meetings, as applicable
c) Number and type of proposals (pharma/ government sponsored/ dissertations/ investigator initiated) reviewed in a year.
d) Status of each study proposal whether completed / ongoing / terminated.
e) Number of approvals for full board review/ expedited review with decisions.
f) Brief details about workshops, training programmes and other activities undertaken by the IEC and those attended by the IEC members.
g) Miscellaneous activities, if any.

10. Data archive and retrieval

a) Every IEC documentation and communication must be dated, filed, and preserved according to written procedures in hard/soft copies.
b) Confidentiality must be kept during access and retrieval procedures by designated persons.
c) All active and inactive (closed) files must be correctly labeled and archived separately in designated areas for 15 years.
d) Every record must be archived for at least three years post-completion/termination of the study.
    i. Regulatory clinical trial documents must be archived for five years post-study completion/termination.
    ii. Records may be archived for a longer period, if required by the sponsors/regulatory bodies.
e) IEC records should be accessible for inspection by authorized representatives of regulatory agencies.
f) Retrieval of documents can only be done with a request form signed and dated by the IEC Chairperson or the Member Secretary.
g) The requestor must also sign and date the log of request.
h) The Secretariat retrieves archived documents and documents in the inventory (register) maintained by IEC. After retrieval:
    i. Return the file back to its place.
    ii. Record, sign, and date when the document has been returned and kept.

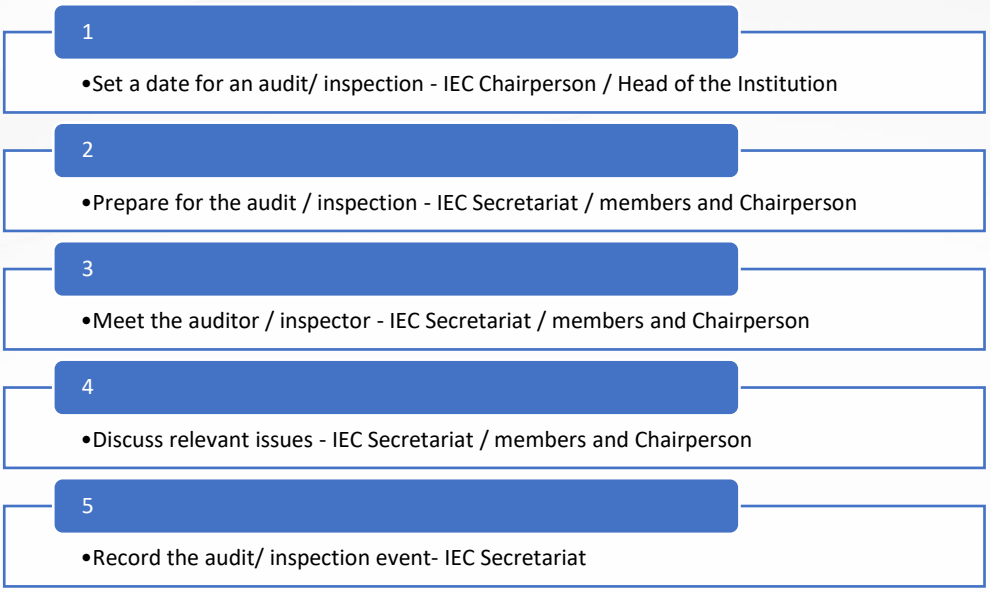
11. Audit and inspection

The audit and inspection procedure is a guide to preparing for an audit or inspection of the IEC processes. The IEC Secretariat and the Members bear the responsibility to comply with SOPs and to be available to answer questions during the evaluation, inspection, and auditing.
Definitions:

Audit - A systematic and impartial assessment of research trial approval activities and documentation to determine whether data were recorded and accurately reported in accordance with SOPs, GCP, the Declaration of Helsinki, and applicable regulatory requirements.
Inspection - The act of a regulatory authority conducting an official review of documents, facilities, records, and any other resources deemed by the authorities to be related to a clinical trial and located at the trial site, the sponsor's and/or contract research organizations (CRO)

facilities, Office of Ethics Committee, or other areas deemed appropriate by the regulatory authorities.

Flow Chart for plan of action:



Following is a list of detailed instructions during an audit/ inspection of the IEC.

11.1. Receive a call for an audit/ inspection

a) Receive a notice of audit/ inspection of the inspection visit.
b) The Member Secretary/ Chairperson should inform the Head of the Institution about the notice.
c) The Chairperson informs the IEC to get prepared for the audit/ inspection.

11.2. Prepare for the visit

a) Get a checklist. (See Annex 1).
b) Go through all steps on the list.
c) Check if all documents are labelled and kept in the proper order for easy and quick searches.
d) Check for any missing or disorganized records:
    i. Background and training records of IEC members.
    ii. Application submission records.
    iii. Protocol assessment records.
    iv. Communication records.
    v. Amendment approval.
    vi. Meeting agenda, minutes, and approval letters.
    vii. Active files.
    viii. Continuing and final reports.
e) Reserve a meeting room and all necessary facilities.
f) Review the IEC SOPs.
g) Make sure that no omission or deviation exists.
h) Make sure to have good reasons for any omission or deviation.

i) Inform IEC members about the inspection date so that they are able to attend the audit/inspection meeting.

11.3. During the audit/ inspection

a) The Chairperson or the Secretariat welcomes and accompanies the auditors/inspectors to the reserved meeting room.
b) Members and some key staff must also be present in the meeting room.
c) The conversation starts with the auditor/inspector telling the purpose of the visit and what kind of information and data are needed.
d) Answer questions of the auditors/inspectors clearly, politely, and truthfully with confidence and straight to the point.
e) Find and get all information and files requested by the auditors/inspectors.
f) Take note of the comments and recommendations of the auditors/inspectors.

11.4. Discuss the issues

a) Review comments and recommendations of the auditors/inspectors.
b) Draft a report and have it approved by the Chairperson.
c) The Chairperson then calls for the correction.
d) Allow appropriate time for the correction and improvement process.
e) Carry out an internal follow-up audit.
f) Evaluate the outcome.
g) Report the outcome to the Chairperson.

11.5. Record the audit/ inspection event

a) Keep a record of the audit report/ inspection file compiled by the auditor/ inspector.
b) Record also the findings from the internal follow-up audit in the internal audit file.
c) Keep a record of all documents related to the audit/ inspection for subsequent audits.

12. References

The following documents, guidelines and publications were referred to in the process of drafting the SOP for the IEC.

1. *International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. (2016). ICH Harmonised Guideline: Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2).*
2. *Indian Council of Medical Research. (2017). National Ethical Guidelines for Biomedical and Health Research involving human participants.*
3. *New Drugs and Clinical Trials Rules. (2019).* https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf
4. *Standard Operating Procedures (SOP) For Institutional Human Ethics Committee (IHEC) Of Rajiv Gandhi Centre for Biotechnology (RGCB), Thiruvananthapuram*.
5. *Institutional Ethics Committee, Tata Memorial Center. (2013)*.
6. *Institutional Ethics Committee standard operating procedure, Indira Gandhi Govt. Medical college. (2020). Nagpur, India.*
7. *SAE report. (2019). Institutional Ethics Committee, KLE University.*
8. *ICMR-NIRRH Ethics Committee for Clinical Studies. (2019)*.
9. *Independent Ethics Committee Standard Operating Procedures. (2018). Fortis Healthcare Limited, Fortis Escorts Heart Institute, New Delhi, INDIA.*
10. *Institutional Ethics Committee Standard Operating Procedure. (2013). Public Health Foundation of India.*
11. *Standard Operating Procedure for Institutional Animal Ethics Committee. (2021). All India Institute of Medical Sciences, Bibinagar.*
12. *Standard Operating Procedures for Institutional Ethics Committee.* (*2011*). *Sri Venkateswar Institute of Medical Sciences, Tirupati*.
13. *Institute Ethics Committee (Human Studies) Standard Operating Procedures.* (2013). *All India Institute Of Medical Sciences, Bhubaneswar, Odisha*.
14. *IEC for Intervention Studies. (2019). JIPMER*.
15. *IEC for Human Studies. (2020). JIPMER*.
16. *Institutional Ethics Committee (IEC). (2018). Seth G.S. Medical College and K.E.M. Hospital*.

13. Annexures

Annexure 1: Conflict of Interest agreement form for IEC members

Declaration

Conflict of Interest

It is recognized that the potential for conflict of interest will always exist but the undersigned has faith in the Institutional Ethics Committee (IEC) and its Chairperson to manage the conflict issues so that the ultimate outcome is the protection of subjects.

As a policy of the IEC, no member may participate in the review, comment, or approval of any activity in which she/he has a conflict of interest except to provide information as requested by the committee.

The undersigned will immediately disclose to the Chairperson of the IEC any actual or potential conflict of interest that she/he may have in relation to any particular proposal submitted for review by the committee. She/he will also abstain from any participation in discussions or recommendations in respect of such proposals. When a member has a conflict of interest, the member will not participate in the IEC approval except to provide the information requested by the committee.

Consent

[Please sign and date this declaration, if you agree with the terms and conditions set forth above. The original (signed and dated declaration) copy will be kept on file in the custody of the IEC. Please keep a copy of the signed declaration with you for your own records.]

Whenever I, (undersigned), have a conflict of interest, I shall immediately inform the IEC Chairperson not to count me towards a quorum for voting. I have read and accepted the aforementioned terms and conditions as explained in this declaration. I will abstain from any participation in discussions or recommendations in cases of proposals where I observe actual or potential conflict of interest.

(Signature) Date
IEC member

(Signature) Date
IEC Chairperson

Annexure 2: Confidentiality agreement form for IEC members

This declaration encompasses any information deemed confidential or proprietary provided to me, (undersigned), in conjunction with my duties as a member of the Institutional Ethics Committee (IEC) of the Tech4Health Foundation (T4H).

I have been asked to assess research studies involving human subjects to ensure that they are conducted in a humane and ethical manner, adhering to the highest standards of care as specified in the Standard Operating Procedures (SOPs) of the IEC.

I understand that my appointment is based on individual merits and not as an advocate or representative of the community, territory nor as a delegate of any organization or for private interest. My fundamental duty is to independently review both scientific and ethical aspects of research protocols involving human subjects and decide the best possible objective recommendations, based on the merits of the submissions under review.

Any written information provided to me that is of a confidential, proprietary, or privileged nature will be held in strict confidence and will not be disclosed to any third party unless required legally. I will not copy or retain any written confidential information provided for my review. All confidential information (and any copies and notes thereof) will remain the sole property of the IEC.

(Signature) Date
IEC Member

I acknowledge that I have received a copy of this agreement.

(Signature) Date
IEC Chairperson

Annexure 3: Checklist for informed consent form

The Informed Consent Form has two parts:

- Information Sheet (to share information about the research with you)
- Certificate of Consent (for signatures if you agree to take part)

PART I: Information Sheet

Introduction

Briefly state who you are and explain that you are inviting them to participate in the research you are doing.

Purpose

Explain in lay terms why you are doing the research.

Type of Research Intervention

Briefly state the type of intervention that will be undertaken.

Participant selection

State why this participant has been chosen for this research.

Voluntary Participation

Indicate clearly whether they can choose to participate or not. State, only if it is applicable, that they will still receive all the services they usually do whether they choose to participate or not.

Information on the Trial Drug [Name of Drug]

Include this section only if the protocol is for a clinical trial

1) give the phase of the trial and explain what that means. Explain to the participant why you are comparing or testing the drugs.

2) provide as much information as is appropriate and understandable about the drug such as its manufacturer or location of manufacture and the reason for its development.

3) explain the known experience with this drug

4) explain comprehensively all the known side-effects/toxicity of this drug, as well as the adverse effects of all the other medicines that are being used in the trial

Procedure and Protocol

Describe or explain the exact procedures that will be followed on a step-by-step basis, the tests that will be done, and any drugs that will be given. Explain from the outset what some of the more unfamiliar procedures involve (placebo, randomization, biopsy, etc.) Indicate which procedure is routine and which is experimental or research.

Firstly, explain that there are standards/guidelines that will be followed for the treatment of their condition. Secondly, if as part of the research a biopsy will be taken, or surgery carried out, then explain whether it will be under local anesthesia, sedation or general anesthesia, and what sort of symptoms and side effects the participant should expect under each category.

For any clinical study (if relevant)

If blood samples are to be taken explain how many times and how much, in a language that the person understands. It may, for example, be inappropriate to tell a tribal villager that blood equal to a wine-glass full will be taken but it may be very appropriate to use pictures or other props to illustrate the procedure if it is unfamiliar.

If the samples are to be used only for this research, then explicitly mention here that the biological samples obtained during this research procedure will be used only for this research, and will be destroyed after _____years, when the research is completed.

Description of the Process

Describe to the participant what will happen on a step-by-step basis.

Duration

Include a statement about the time commitments of the research for the participant including both the duration of the research and follow-up, if relevant.

Side Effects

Potential participants should be told if there are any known or anticipated side effects and what will happen in case of a side effect or an unexpected event.

Risks

Explain and describe any possible or anticipated risks. Describe the level of care that will be available if harm does occur, who will provide it, and who will pay for it.

Discomforts

Explain and describe the type and source of any anticipated discomforts that are in addition to the side effects and risks discussed above.

Benefits

Mention only those activities that will be actual benefits and not those to which they are entitled

regardless of participation.

Incentives

State clearly what you will provide the participants with because of their participation. WHO does not encourage incentives. However, it recommends that reimbursements for expenses incurred because of participation in the research be provided.

Confidentiality

Explain how the research team will maintain the confidentiality of data, especially with respect to the information about the participant which would otherwise be known only to the physician but would now be available to the entire research team.

Sharing the Results

Where it is relevant, your plan for sharing the information with the participants should be provided.

Right to Refuse or Withdraw

This is a reconfirmation that participation is voluntary and includes the right to withdraw.

Alternatives to Participating

Include this section only if the study involves administration of investigational drugs or use of new therapeutic procedures. It is important to explain and describe the established standard treatment.

Who to Contact

Provide the name and contact information of someone who is involved, informed and accessible (a local person who can be contacted. State also that the proposal has been approved and how.

PART II: Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked to have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research and understand that I have the right to withdraw from the research at any time without in any way affecting my medical care.

Print Name of Participant_____

Signature of Participant _____

Date _____Day/month/year

If illiterate

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team).

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____**AND Thumb print of participant**

Signature of witness _____

Date _____(Day/month/year)

I have accurately read or witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print Name of Researcher_____

Signature of Researcher _____

Date _____(Day/month/year)

A copy of this Informed Consent Form has been provided to participants _____(Initialed by the researcher/assistant)

Annexure 4: Review of resubmitted study protocol form

Project No:	Date of Initial Submission: <dd/mm/yyyy>	
Study Protocol Title:		
Total Participants:	c 2nd Review c 3rd Review	
Principal Investigator: <Title, Name, Surname>	Tel.:	
Initial Review Date: <dd/mm/yyyy>	Last Review Date: <dd/mm/yyyy>	
Recommendations from last review: 1. 2. 3. 4. 5.	Were the recommendations met (Yes/No)? Explain 1. 2. 3. 4. 5.	
RECOMMENDATION OF PRIMARY REVIEWER: **a)** APPROVE **b)** MINOR MODIFICATION **c)** MAJOR MODIFICATION **d)** DISAPPROVE **e)** PENDING, IF MAJOR CLARIFICATIONS ARE REQUIRED BEFORE A DECISION CAN BE MADE	**JUSTIFICATION FOR RECOMMENDED ACTION**:	
PRIMARY REVIEWER	Signature	
Date: <dd/mm/yyyy>	Name	<Title, Name, Surname>

Annexure 5: Serious Adverse Event (SAE) report

SERIOUS ADVERSE EVENT REPORT **T4H**	**PROJECT NO:**
	Reg with DCGI: Yes/ No **CTRI Reg. No:**

As per ICH-GCP:
Serious Adverse Event (SAE) or Serious Adverse Drug Reaction (Serious ADR) is Any untoward medical occurrence (due to the participation in the concerned trial) that at any dose that:

a) **results in death,**
b) **is life-threatening,**
c) **requires inpatient hospitalization or prolongation of existing hospitalization,**
d) **r esults in persistent or significant disability/incapacity,or**
e) **is a congenital anomaly/birth defect**

Investigator(s) shall report all SAE's including Death to the IEC, Sponsor and CDSCO within 24 hours of theiroccurrence of the knowledge of the PI. If a delay is expected kindly notify the same by email.

For DSMSC Office use:
(Strike out what is not applicable)
Item No: - -/N/A

Recd on:

Date of occurrence of event:

Notification/ Follow-up

1. Title of project:		
2. Principal Investigator:		
3. Report date:		
Report type □ Initial 1. Follow up_____ If Follow-up report, state Date of Initial report _____ 2. Final		
4. Date of Occurrence of SAE:		
5. Patient Case No:	6. a. Age:	5 b Gender:
6. Mention the total number of SAE (prior) occurred at this site:_____Other site(s):_____		
7. Mention number of similar SAEs (prior) occurred for same study at this site:_____Other site(s):_____		
8. A] State SAE Event term: (Kindly refer to CTCAE V3.0 and/or V4.2 where applicable)	B] CTCAE Grade: (Where applicable)	
9. Does the Principal Investigator feel this SAE is related to participation in the trial □ Yes □ No □ Cannot say		
10. Tick whichever is applicable for serious adverse event: (Kindly note that this refers to IP/intervention being evaluated and NOT disease process) A] □expected event □ unexpected event		

B] □ hospitalization □ increased hospital stays □ death □ others in case of Death, state probable cause of death (If others, please specify):	
C] □ No permanent significant functional/ cosmetic impairment □ Permanent significant functional/ cosmetic impairment □ Not applicable	
11. If there was a research related injury/hospitalization, the cost of treatment/hospitalization was borne by, □Patient □ Institute □ Sponsor/CRO	
Suspect drug information (refers to drug/ device/ procedure under investigation)	
12. Suspect drug (include generic name)/device/intervention:	
13. Dose Dosage Form:	14. Route(s) of administration:
15. Therapy dates (from/to):	16. Therapy duration:
17. Did the reaction decline after stopping the drug/procedure (Dechallenge & Rechallenge information) □ YES □ NO □ NA	
Concomitant drugs and history (drugs that the patient maybe on and /or used for management of the SAE	
18. Concomitant drug(s) and date of administration:	
19. Patient relevant history (e.g., diagnosis, allergies):	
SAE Details	
20. Description of adverse event (indicate if this is follow-up report and if so, include follow-up information only)	

21. Describe the medical treatment provided (if any) to the research subject: This is an update on treatment given during hospitalization.

Medication	Dose	Start date	End date

22. Outcome was

□ resolved □ ongoing □ death

23. Was the research subject continued the research protocol

□ yes □ no □ NA (Mark 'NA' in case of death)

24. What phase of the research protocol is the patient in?

□ On active treatment □ Short term follow-up □ Long term follow-up □ Surveillance/ Monitoring

25. In your opinion, does this report require any alteration in the trial protocol?

□ yes □ no

If yes, then please specify.

Name of Principal investigator:

Profession (Specialty):

Signature of Principal investigator_____Date:

Contact No. of PI: _____

Upon receipt of this report, the IEC/DSMSC will decide whether additional information is needed or whether further investigation of the incident is required. A follow-up report with further details should be submitted by PI within 10 days or earlier (of occurrence of the SAE) to the IEC

For IEC use only

I_____agree_____disagree with the assessment of the principal investigator.

DSMSC Reviewer_____date: _____

Explanation:

Annexure 6: Off-site safety reports classification form

Note to principal investigator (PI):
The following questions will act as a guide for submission of the “Safety Reports.” This form ismerely providing guidance for reporting / logging of Offsite Safety Reports.’

If the answer to all three questions is "**Yes", prompt reporting is required,** and such off-site safety reports need to be reported to IEC along with the log.
If any one answer is "**No", it needs to be logged as prescribed format. This** log should be submitted to the IEC Secretariat every three months and/or along with the Continuing Review report.

1. Project Number:
2. Project Title:

Questions	Yes	No
Is adverse event serious?		
Is adverse event related?		
Is adverse event unexpected?		

Date of reporting (date/ month/ year):

Signature of PI:

Name of PI:

Annexure 7: Off-site safety reports log

Note to principal investigator (PI):

a) Please log in details of Off-Site Safety Reports.
b) The following log has to be maintained continuously until the end of the study.
c) This log should be submitted to the IEC Secretariat every three months and/or along with the Continuing Review report.
d) The log must be submitted to the IEC Secretariat immediately, if prompt reporting is required and/or if a trend related to the occurrence of SAE is observed.
e) Please note the complete set of Offsite Safety Reports need not be sent to the IEC Secretariat as and when received. If the IEC needs to review the reports, they can request copies at any time.

Project No.:
Project Title:
Total Sample Size-
Total No of patients to be enrolled -
No. of Participants already enrolled -
No. of patients active on Treatment-
No. of patients on FU-
No of Patients lost to follow up-
No of Consent Withdrawn-
No of patients withdrawn by Principal Investigator-
No of patients completed treatment-

S. No.	Country	Date of Onset	Adverse event	Out Come	Remarks

PI Assessment:

Do you observe a trend?

- Yes ¨No

Date of reporting (date/ month/ year):

Signature of PI:

Name of PI:

Annexure 8: Study completion report form

To be filled by principal investigator

IEC Protocol No		
Protocol Title: _____		
Principal Investigator		
Department		
Total no. of study participants recruited		
Total no. of study participants approved by the IEC for recruitment		
Duration of the study		
*Introduction, Aims & Objectives, Material & methods, Results, Conclusion: (use extra blank paper,if more space is required). _____ _____ _____ *Note: If the final report is not available from a sponsor, it may be submitted later to the IEC once it isready.		
Number of SAEs at our center:		
Whether all SAEs intimated to the IEC	Yes	No
No. of patients withdrawn and reasons for withdrawal:		
Signature of Principal Investigator	Date: -	

Annexure 9: Study completion statement

Project number and title:
Principal investigator:
Department:
Date of project approval:

Status reports received so far						
Date of meeting						

Documents approved after the first approval:

1.
2.

SAE at our sites (details)

Sr. No.	Date	SAE

Signature of Member Secretary:

Name of Member Secretary:

Date (date/ month/ year):

Annexure 10: Audit and inspection checklist

Internal Audit, External Audit, Audit Inspection	Date:
The date(s) which the audit/inspection has been agreed for:	
Review the SOPs and note details of any omissions or deviations, with reasons.	
Check the files for the presence of all signed documents. Note any that are missing, and actions taken. a) Background and training records of IEC members. b) Application Submission Records. c) Protocol Assessment Records. d) Communication Records. e) Amendment Approval. f) Meeting Agenda, Minutes, Approval letters. g) Active files. h) Continuing and Final reports.	
Are any documents known to be missing from the study master file?	
Which personnel and members will be available? Give details of times and dates.	
What arrangements are there in the event the auditor/inspector needs to make copies of documents?	
Completed by: …… Name and Signature	Date:

Confidentiality Agreement Form for Auditors/inspectors

I,_____ from_____ as an Auditors/inspectors of Institutional Ethics Committee Tech4Health Foundation (T4H) , understand that the copy(ies) given to me by the Ethics Committee is (are) confidential. I shall use the information only for the indicated purpose as described to the Institutional Ethics Committee and shall not duplicate, give, or distribute these documents to any person(s) without permission from the IEC. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as Confidential.

I have received copies of the following IEC documents:

IEC office uses only

Signature of the recipient and date:

Signature of Member Secretary and date:

Signature of Chairperson of the IEC and date: