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Education | Health | Social

CODE OF ETHICS

INDEX

SMBT Sevabhavi Trust's
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SOP-INSTITUTIONAL ETHICS COMMITTEE

SMBT Ayurved college and Hospital will follow **Indian Council of Medical Research Guidelines for preparing Standard Operating Procedures (SOP) for Institutional Ethics Committee for Human Research**

1. Objective:

The objective of this SOP is to contribute to the effective functioning of the Institutional Ethics Committee (IEC) so that a quality and consistent ethical review mechanism for health and biomedical research is put in place for all proposals dealt by the Committee as prescribed by the Ethical guidelines for biomedical research on human subjects of ICMR

2. Role of IEC

IEC will review and approve all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and well being of all actual and potential research participants. The goals of research, however important, should never be permitted to override the health and well being of the research subjects.

The IEC will take care that all the cardinal principles of research ethics viz. Autonomy, Beneficence. Non- maleficence and Justice are taken care of in planning. conduct and reporting of the proposed research. For this purpose, it will look into the aspects of informed consent process, risk benefit ratio, distribution of burden and benefit and provisions for appropriate compensations wherever required. It will review the proposals before start of the study as well as monitor the research throughout the study until and after completion of the study through appropriate well documented procedures for example annual reports, final reports and site visits etc. The committee will also examine compliance with all regulatory requirements. applicable guidelines and laws.

The mandate of the IECS will be to review all research projects involving human subjects to be conducted at the Institute, irrespective of the funding agency. The role of IEC can be modified according to the requirement of each Institute

3. Composition of IEC

IECs should be multidisciplinary and multi- sectorial in composition. Independence and competence are the two hallmarks of an IEC.

The number of persons in an ethical committee should be kept fairly small (7-9) members). It is generally accepted that a minimum of five persons is required to compose a quorum. There

is no specific recommendation for a widely acceptable maximum number of persons but it should be kept in mind that too large a Committee will make it difficult in reaching consensus opinions. 12-15 is the maximum recommended number.

The Chairperson of the Committee should preferably be from outside the Institution and not head of the same Institution to maintain the independence of the Committee. The Member Secretary who generally belongs to the same Institution should conduct the business of the Committee. Other members should be a mix of medical/non-medical scientific and non scientific persons including lay public to reflect the differed viewpoints.

The composition may be as follows

1. Chairperson

2. Member Secretory

3. 1 or 2 basic medical scientists.

4. 1 or 2 clinicians from various Institutes One legal expert or retired judge

5. One social scientist/representative of non-governmental voluntary agency

6. One philosopher/ethicist/theologian One lay person from the community

Member-Secretary

The ethical committee at any institution can have as its members, individuals from other institutions or communities if required. There should be adequate representation of age, gender, community, etc. in the Committee to safeguard the interests and welfare of all sections of the community/society. Members should be aware of local, social and cultural norms, as this is the most important social control mechanism. If required, subject experts could be invited to offer their views, for example for drug trials a pharmacologist, preferably a clinical pharmacologist, should be included. Similarly, based on the requirement of research area, for example HIV, genetic disorders etc. specific patient groups may also be represented in the Committee. The membership of IEC will include Epidemiologist(s), Sociologist(s), Lawyer(s), Theologian, Statistician(s). Clinician(s), Basic scientists, Pharmacist(s)/Clinical Pharmacologist(s) etc They integrity, and could be drawn from any public or private Institute from anywhere in the country.

should be appointed by the Head of the Institute based on their competencies and

JEC should be constituted in the following pattern:

i) A Chairperson

ii) A Deputy Chairman if need be,

iii) A Member Secretary,

iv) 5-15 members from different Departments / Specialties/ disciplines or areas etc.

4. Authority under which IEC is constituted:

The Institutional Head constitutes the IEC.

5. Membership requirements:

a. The duration of appointment is initially for a period of 2-3 years

b. At the end of 05 years, as the case may be, the committee is reconstituted, and 50% of the members will be replaced by a defined procedure.

c. A member can be replaced in the event of death or long-term nonavailability or for any action not commensurate with the responsibilities laid down in the guidelines deemed unfit for a member.

d. A member can tender resignation from the committee with proper reasons to do

e. All members should maintain absolute confidentiality of all discussions during the meeting and sign a confidentiality form. £ Conflict of interest should be declared by members of the IEC

6. Quorum requirements:

The minimum of 5 members are required to compose a quorum. All decisions should be taken in meetings and not by circulation of project proposals.

7. Offices

The Chairperson will conduct all meetings of the IEC. If for reasons beyond control, the Chairperson is not available, the Deputy Chairperson or an alternate Chairperson will be elected from the members by the members present, who will conduct the meeting The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/she will prepare the minutes of the meetings and get it approved by the Chairman before communicating to the researchers with the approval of the appropriate authority.

8 Independent consultants

IEC may call upon subject experts as independent consultants who may provide special review of selected research protocols, if need be. These experts may be specialists in ethical or legal aspects, specific diseases or methodologies, or represent specific communities, patient groups or special interest groups e.g. Cancer patients, HIV/AIDS positive persons or ethnic minorities. They are required to give their specialized views but do not take part in the decision making process which will be made by the members of the IEC.

9. Application Procedures:

a. All proposals should be submitted in the prescribed application form, the details of which are given under Documentation

b. All relevant documents should be enclosed with application form

c. Required number of copies of the proposal along with the application and documents in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators Collaborators should be forwarded by the Head of the Departments/Institution to the ethics committee.

d. The date of meeting will be intimated to the researcher, to be present, if necessary to offer clarifications.

e. The decision will be communicated in writing. If revision is to be made, the revised document in required number of copies should be submitted within a stipulated period of time as specified in the communication or before the next meeting.

f. Prescribed fee if any, should be remitted along with the application

10. Documentation:

For a thorough and complete review, all research proposals should be submitted

with the following documents:

1. Name of the applicant with designation

2. Name of the Institute/ Hospital / Field area where research will be conducted.

3. Approval of the Head of the Department/Institution

4. Protocol of the proposed research

5. Ethical issues in the study and plans to address these issues.

6. Proposal should be submitted with all relevant enclosures like proformae,report forms, questionnaires, follow-up cards, etc.case

7. Informed consent process, including patient information sheet and informed consent form in local language(s).

8. For any drug device trial, all relevant pre-clinical animal data and clinical trial data from other centres within the country/countries, if available.

9. Curriculum vitae of all the investigators with relevant publications in last five years.

10. Any regulatory clearances required.

11. Source of funding and financial requirements for the project.

12. Other financial issues including those related to insurance

13. An agreement to report only Serious Adverse Events (SAE) to IEC.

14. Statement of conflicts of interest, if any.

15. Agreement to comply with the relevant national and applicable international guidelines.

16. A statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants; a description of the arrangements for indemnity, if applicable (in study-related injuries); a description of the arrangements for insurance coverage for research participants, if applicable; all significant previous decisions(e.g., those leading to a negative decision or modified protocol) by other ECs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of the modification(s) to the protocol made on that account. The reasons for negative decisions should be provided.

17. Plans for publication of results - positive or negative- while maintaining the privacy and confidentiality of the study participants.

18. Any other information relevant to the study

11. Review procedures:

a. The meeting of the IEC should be held on scheduled intervals as prescribed and additional meetings may be held as and when the proposals are received for review.

b The proposals will be sent to members at least 2 weeks in advance

c Decisions will be taken by consensus after discussions, and whenever needest

d Resembers will be invited to offer clarifications if need be

e Independent consultants Experts will be invited to offer their opinion on specific research proposals if needed

The decisions will be minted and Chairperson's approval taken in writing

12. Element of review

-Scientific design and conduct of the study

-Approval of appropriate scientific review committees.

-Examination of predictable risks/harms.

--Examination of potential benefits

-Procedure for selection of subjects in methodology including inclusion/ exclusion, withdrawal criteria and other issues like advertisement details.

- Management of research related injuries, adverse events.

- Compensation provisions

-Justification for placebo in control arm, if any.

-Availability of products after the study, if applicable.

-Patient information sheet and informed consent form in local language.

-Protection of privacy and confidentiality.

-Involvement of the community, wherever necessary

-Plans for data analysis and reporting

-Adherence to all regulatory requirements and applicable guidelines

-Competence of investigators, research and supporting staff

-Facilities and infrastructure of study sites

-Criteria for withdrawal of patients, suspending or terminating the study

13. Expedited review

All revised proposals, unless specifically required to go to the main committee, will be examined in a meeting of identified members convened by the Chairman to expedite decision making. Expedited review may also be taken up in cases of nationally relevant proposals requiring urgent review. The nature of the applications, amendments, and other considerations that will be eligible for expedited review should be specified.

14. Decision-making

a. Members will discuss the various issues before arriving at a consensus decision.

b. A member should withdraw from the meeting during the decision procedure

concerning an application where a conflict of interest arises and this should be

indicated to the chairperson prior to the review of the application and recorded in the minutes.

c. Decisions will be made only in meetings where quorum is complete.

d. Only members can make the decision. The expert consultants will only offer their opinions.

c. Decision may be to approve, reject or revise the proposals Specific suggestion for modifications and reasons for rejection should be given

In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed should be specified.

Modified proposals may be reviewed by an expedited review through members

Procedures for appeal by the researchers should be clearly defined

15. Communicating the decision

a Decision will be communicated by the Member Secretary in writing

b. Suggestions for modifications, if any, should be sent by IEC

c Reasons for rejection should be informed to the researchers

d. The schedule plan of ongoing review by the IEC should be communicated to the PL

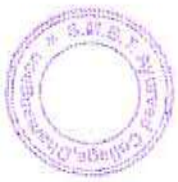
16. Follow up procedures

a. Reports should be submitted at prescribed intervals for review.

b. Final report should be submitted at the end of study.

c. All SAES and the interventions undertaken should be intimated.

d. Protocol deviation, if any, should be informed with adequate justifications.



e. Any amendment to the protocol should be resubmitted for renewed approval

f Any new information related to the study should be communicated.

g Premature termination of study should be notified with reasons along with

summary of the data obtained so far.

h. Change of investigators/ sites should be informed

17. Record keeping and Archiving

a. Curriculum Vitae (CV) of all members of IEC.

b. Copy of all study protocols with enclosed documents, progress reports, and

c. Minutes of all meetings duly signed by the Chairperson.

d. Copy of all existing relevant national and international guidelines on research ethics and laws along with amendments

e. Copy of all correspondence with members, researchers and other regulatory bodies.

f Final report of the approved projects.

g All documents should be archived for prescribed period.

18. Updating IEC members

a. All relevant new guidelines should be brought to the attention of the members.

b. Members should be encouraged to attend national and international training programs in research ethics for maintaining quality in ethical review and be aware of the latest developments in this area identified.

COMPOSITION IEC

Chairperson

The IEC Chairperson should be a highly respected individual from outside SMBT Ayurved college and Hospital, fully capable of managing the IEC and the matters brought before it, with fairness and impartiality.

The task of making the IEC a respected part of the institutional community will fall primarily on the shoulders of this individual. The IEC must be perceived to be fair and impartial, immune from pressure of administration, the investigators whose protocols are brought before it, or other professional and non-professional sources.

The IEC Chairperson will respect the diverse backgrounds, perspectives, and sources of expertise of all IEC members, especially the contributions of the non-scientists, and must have the ability to foster respect among the IEC members.

The Chairperson shall ensure active participation of all members (particularly non-affiliated, non-medical/ non- technical members) in all discussions and deliberations.

The Chairperson shall ratify minutes of the previous meetings, handle complaints against researchers and EC members, conflict of interest issues and requests for use of EC data etc.

Member Secretary

The Member Secretary will be a staff member of SMBT Ayurved College and Hospital, committed to the task of coordinating and managing the activities of the committee. He/she will be responsible for scheduling the meetings, describing the agenda and ensuring that the function of the committee is conducted as per the norms and policies described in this SOPs.

Specific roles of Member Secretary (As per ICMR Guidelines 2017)

- Member Secretary will be responsible for ensure training of EC secretariat and ECmembers
- Ensure SOPs are updated as and when required
- Ensure adherence of EC functioning to the SOPs
- Prepare for and respond to audits and inspections
- Ensure completeness of documentation at the time of receipt and timely inclusion inagenda for EC review.
- Assess the need for expedited review/ exemption from review or full review

Basic Medical Scientist:

- To provide scientist aspects of the study: Investigator's brochure, safety of drug, Pharmacodynamics and pharmacokinetics of drug, lab procedures, study design, sample size, use of biological samples,
- To see: preclinical data and whether protocol adequately addresses issue of all this matter or not, Qualification of PI and GCP training certificate, Details of SAEs and reporting time limit from PI, All ethics issues and other procedures involved inthe study

Clinician:

- Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics
- Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report)
- Review medical care, facility and appropriateness of the principal investigator, provision for medical car, management and compensation.
- Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.

Social Scientists/philosopher/ethicist/theologian:

- Ethical review of the proposal, ICD along with the translations.
- Assess impact on community involvement, socio–cultural context, religious orphilosophical context, if any
- Serve as a patient/participant/ societal / community representative and bring inethical and societal concerns.

Legal experts:

- Ethical review of the proposal, ICD along with translations, MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol specific other permissions, such as, stem cell committee for stem cell research, HMSC for international collaboration, compliance with guidelines etc.
- Interpret and inform EC members about new regulations if any
- To review Seven incidence of SAE included or not, Adequacy of amount
- To see whether any clause is violating the norm, Confidentiality, dispute resolution, Updated with regulatory requirements and interpretation of the same, Insurance policy: it should cover the participants for injury due to all clauses mentioned in Rule 122DAB, Validity, Countries for which the policy provides cover and Liability limit – per person and total
- Indemnity: it should Covers the liability of investigator and sponsor and Could be part of CTA or separate document
- To see informed consent document

Layperson:

- Ethical review of the proposal, ICD along with translation(s).
- Evaluate benefits and risks from the participant's perspective and opine whetherbenefits justify the risks.
- Serve as a patient/participant/ community representative and bring in ethical andsocietal concerns.
- Assess on societal aspects if any
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Quorum Requirements

- All research projects for approval by the full board of the IEC shall be reviewed at convened meetings at which a majority of the members of the IEC are present. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting. The presence of the following five (5) members is required to form part of the quorum without which a meeting cannot be convened and a decision regarding the project cannot be taken. These 5 members should have the following representation:
  a) basic medical scientists (preferably one clinical pharmacologist);
  b) Clinicians
  c) legal expert;
  d) social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian or similar person;
  e) lay person from the community;

In addition to the above, the quorum must fulfill following criteria-

i. A quorum should include at least one member whose primary area of expertise is in a non-scientific area, a clinician, and at least one member who is independent of SMBT Ayurved College and Hospital site and has no immediate family member affiliated to SMBT Ayurved College and Hospital

ii. No quorum should consist entirely of members of one profession or one gender.

iii. When an alternate member attends a meeting as a substitute for a regular member,the alternate member's participation counts toward the quorum requirements. Alternate members will serve in the same representative capacity as the member for whom they substitute.

In the absence of a Member Secretary of IEC for scheduled IEC meeting, another member of the IEC will be nominated by the Chairperson for that meeting to coordinate and manage the activities of the IEC for that meeting.

Member Secretary/ IEC Chair shall review disclosures to determine whether a conflict of interest exists and to determine appropriate management of the conflict of interest.

1. POLICY OF COMMUNICATIONS WITH DIFFERENT STAKE HOLDERS:

1.1. Purpose:

This SOP defines IEC communication with different stakeholder as per regulatory mandate and specifications. IEC communicates with following mentioned stakeholders as per regulatory mandate and specifications:

o Principal Investigator /study team designee
o DCGI
o Dean of the Institute
o Sponsor
o Study Participants

IEC receives letters from different stakeholder submitted or sent to IEC Secretariat and maintain them in record. IEC may mention outward number for letters sent to all concerned stakeholders and records of the same also are kept.

1.2. Principal Investigator:

IEC writes or e-mails to Principal Investigator regarding following mentioned communications but not limited to, whenever deemed necessary.

o Study Project Initial Dossier and Amendments, Approval/Dis-Approval letter*/ Query Letters
o Reply to Serious Adverse Event notification
o Opinion on EC analysis and compensation of Study injury/Death
o Response to Protocol deviation/Violation/Waiver
o Response to Continue review/study completion report
o Study termination letter.

* **Communicating the decision:** The IEC, SMBT Ayurved College & Hospital would issue an opinion letter to communicate the decision taken on any project following prescribed format of approval letter as per recommendation of New Drugs and Clinical Trials Rules, 2019. This opinion letter would be issued by the Member Secretary to convey the decision of the IEC to the Principal Investigator and must include the following information mention turnaround time 21 days:

o The name of the Project (Same as the Project title)
o List of documents reviewed by the IEC, including the revised version of documents if any. List of members present at the meeting.
o Members who did not participate in the decision making process.
o The date and time of meeting.
o The decision of the IEC,
o A note to PI to strictly adhere to SOP of IEC, GCP and latest regulatory requirements plus submission progress updates/deviations as and when it occurs while implementing the sanctioned project.
o An IEC may decide to reverse its positive decision on a study in the event of receiving information that may adversely affect the benefit / risk ratio.

1.3. DCGI:

IEC writes to DCGI or emails regarding following mentioned communications but not limited to, whenever deemed necessary

o Opinion on SAE Analysis and Compensation of Study injury/death if applicable
o Study Termination letter

o Issues with Investigators or different stake holders involved
o Recommendations on DCGI Approved and other studies (If necessary)
o Ethics Committee Registration Communications

2. POLICY OF COMMUNICATIONS WITH DIFFERENT STAKE HOLDERS:

2.1. Purpose:

This SOP defines IEC communication with different stakeholder as per regulatory mandate and specifications. IEC communicates with following mentioned stakeholders as per regulatory mandate and specifications:

o Principal Investigator /study team designee
o DCGI
o Dean of the Institute
o Sponsor
o Study Participants

IEC receives letters from different stakeholder submitted or sent to IEC Secretariat and maintain them in record. IEC may mention outward number for letters sent to all concerned stakeholders and records of the same also are kept.

2.2. Principal Investigator:

IEC writes or e-mails to Principal Investigator regarding following mentioned communications but not limited to, whenever deemed necessary.

o Study Project Initial Dossier and Amendments, Approval/Dis-Approval letter*/ Query Letters
o Reply to Serious Adverse Event notification
o Opinion on EC analysis and compensation of Study injury/Death
o Response to Protocol deviation/Violation/Waiver
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o Members who did not participate in the decision making process.
o The date and time of meeting.
o The decision of the IEC,
o A note to PI to strictly adhere to SOP of IEC, GCP and latest regulatory requirements plus submission progress updates/deviations as and when it occurs while implementing the sanctioned project.
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IEC writes to DCGI or emails regarding following mentioned communications but not limitedto, whenever deemed necessary

- o Opinion on SAE Analysis and Compensation of Study injury/death if applicable
- o Study Termination letter
- o Issues with Investigators or different stake holders involved
- o Recommendations on DCGI Approved and other studies (If necessary)
- o Ethics Committee Registration Communications

VULNERABLE POPULATION SOP

The Declaration of Helsinki states that 'Medical research involving a underprivileged or vulnerable population or community is only justified if the research is responsive to the health needs and priorities of that population or community and if there is a reasonable likelihood that this population or community stands to benefit from the results of the research.'

- **Purpose**
  The purpose of this SOP is to describe how the IEC will ensure that the rights and interests of vulnerable population are safeguarded. The EC will ensure that individuals or communities included for research are selected in such a way that the burdens and benefits of the research are equally distributed.

- **Scope**
  This SOP applies to the process by which the EC will protect the rights and interests of vulnerable population. Additional protection will be ensured depending upon the risk of harm and the likelihood of benefit.

- **Responsibility**
  It is the responsibility of the EC members to identify study proposals including vulnerable population and ensure that these are considered for full board. The EC will ensure that measures for safeguarding rights and interests of vulnerable participants are mentioned in theface sheet, study proposal, Participant /Assent Information Sheet/ and informed consent/assent form. They have the responsibility to ensure that the vulnerable population is not exploited and they will guide the investigators to design protocols and describe the process of informed consent in such a manner that this will be done.

- **Flow chart-**

No.	Activity	Responsibility
1	Receive the submitted documents ↓	IEC Secretariat
2	Determine protocols including vulnerable population ↓	IEC members and Chairperson
3	Review of protocol by appropriate reviewes and assess whethertheir inclusion is justified	IEC members andChairperson
4	Ensure measures for protecting rights and interests of vulnerable population are described in the face sheet ↓	IEC members and Chairperson
5	Review the Participant /Assent Information Sheet/ and Informed Consent/Assent form	IEC members and Chairperson

- **Detailed instructions**

  - **Determine protocols including vulnerable population**
    Project proposals presented before the Ethics Committee Meeting which includes vulnerablepopulation: It is the responsibility of the EC to see whether the inclusion of vulnerable populations in the study is justifiable or the population is just being exploited to generate
    clinical data. In such cases, appropriate reviewers will assess the risk and ensure measures for protecting their rights. Review of risk assessment will be documented in IEC minutes

  - **Vulnerable groups:** Effort may be made to ensure that individuals or communities invited for research be selected in such a way that the burdens and benefits of the research are equally distributed. **(ANNEX 1.1, AF/EC/1.1/06/V2.0 See section C, Q 6 a & b)**

    - Research on genetics should not lead to racial inequalities;
    - Persons who are economically or socially disadvantaged should not be used to benefit those who are better off than them;
    - Rights and welfare of mentally challenged and mentally differently able persons who areincapable of giving informed consent or those with behavioural disorders must beprotected. Appropriate proxy consent from the legal guardian should be taken after the person is well informed about the study, need for participation, risks and benefitsinvolved and the privacy and confidentiality procedures. The entire consent process should be properly documented;
    - Adequate justification is required for the involvement of participants such as prisoners, students, subordinates, employees, service personnel etc. who have reduced autonomy asresearch participants, since the consent provided may be under duress or various other compelling reasons.
    - Persons who are terminally ill, have incurable disease and mental illness and cognitively impaired and physically disabled.
    - Pregnant and lactating women
    - Children (<18 years)
    - Tribal and marginalized communities
    - Refugee, migrants, homeless, persons or populations in conflict zones, riots areas or disaster situations;

    Suffering from stigmatizing or rare diseases etc

5.2.1 Consideration issues and protection of specific vulnerable groups:

i. ***Children*** **:**

Before undertaking research/trial in children the investigator must ensure that –

a. Children will not be involved in research that could be carried out equally well with adults;
b. The purpose of the research is to obtain knowledge relevant to health needs of children. For clinical evaluation of a new drug the study in children should always be carried out after the phase III clinical trials in adults. It can be studied earlier only if the drug has a therapeutic value in a primary disease of the children;
c. A parent or legal guardian of each child has given consent;
d. The assent of the child should be obtained to the extent of the child's capabilities such as in the case of mature minors from the age of 7 (seven) years up to the age of 12 (twelve) years (verbal assent along with parental/ LAR consent) & from the age of 12 (twelve) years up to the age of 18 (eighteen) years (written assent along with parental/ LAR consent).

e. Research should be conducted in settings in which the child and parent can obtain adequate Medical and psychological support;

f. Interventions intended to provide direct diagnostic, therapeutic or preventive benefit for the individual child participant must be justified in relation to anticipated risks involved in the study and anticipated benefits to society;

g. The child's refusal to participate in research must always be respected unless there is no medically acceptable alternative to the therapy provided/ tested, provided the consent has been obtained from parents / guardian;

h. Interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual child participant as any available alternative interventions;

i. The risk presented by interventions not intended to benefit the individual child participant is low when compared to the importance of the knowledge that is to be gained.

ii. Pregnant or nursing women:

Pregnant or nursing women should in no circumstances be the participant of any researchunless the research carries no more than minimal risk to the foetus or nursing infant and theobject of the research is to obtain new knowledge about the foetus, pregnancy and lactation. As a general rule, pregnant or nursing women should not be participants of any clinical trialexcept such trials as are designed to protect or advance the health of pregnant or nursingwomen or foetuses or nursing infants, and for which women who are not pregnant or nursingwould not be suitable participants.

a. The justification of participation of these women in clinical trials would be that theyshould not be deprived arbitrarily of the opportunity to benefit from investigations, drugs, vaccines or other agents that promise therapeutic or preventive benefits.
   Example of such trials are,
   - To test the efficacy and safety of a drug for reducing perinatal transmission of HIV infection from mother to child,
   - Trials for detecting foetal abnormalities and for conditions associated with or aggravated by pregnancy etc.
   - Women should not be encouraged to discontinue nursing for the sake of participation in research and in case she decides to do so, harm of cessation of breast-feeding to the nursing child should be properly assessed except in those studies where breast feeding is harmful to the infant. Compensation in terms of supplying supplementary food such as milk formula should be considered in such instances.

b. **Research related to termination of pregnancy:** Pregnant women who desire to undergoMedical Termination of Pregnancy (MTP) could be made participants for such research as per The Medical Termination of Pregnancy Act, GOI, 1971.

c. **Research related to pre-natal diagnostic techniques:** In pregnant women such research should be limited to detect the foetal abnormalities or genetic disorders as per the Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, GOI, 1994 and not for sex determination of the foetus.

iii. An audio-video recording of the informed consent process in case of vulnerable participants in clinical trials of New Chemical Entity or New Molecular Entity including procedure providing information to the participants and his understanding of such consent, shall be maintained by the investigator for record. The Ethics

committee may direct the Principal Investigator for consent to take participants permission for studies involving vulnerablepopulation.

- **Glossary Vulnerability**

- The Council for International Organizations of Medical Sciences **(CIOMS)** defines **vulnerability** as "Substantial incapacity to protect one's own interests owing to such impediments as lack of capability to give informed consent, lack of alternative means of obtaining medical care or other expensive necessities, or being a junior or subordinatemember of a hierarchical group."
- **Vulnerable (research) participants:** Vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests. Individuals whose willingness to volunteer in a research study may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate may also be considered vulnerable. (WHO)

Legally Authorized Representative (LAR)

- A LAR is an individual or judicial or other body authorized under applicable law to consenton behalf of a prospective participant to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure as per research protocol.

- **References**

1. Ethical Guidelines for Biomedical Research on Human Participants , ICMR , 2006
2. E6 Good Clinical Practice: Consolidated Guidance, April 1996, ICH –GCP
3. WHO Standards and Operational Guidance for Ethics Review of Health-RelatedResearch with Human Participants , 2011
4. Training curriculum for ethics in clinical research - www.fhi.org
5. SOPs Ethics Committee for Research on Human Participants – Seth GS Medical College and KEM Hospital, Mumbai Reference: SOP-20 reviewing proposal involvingvulnerable population
6. Order from Director General of Health Services (DGHS), Ministry of Health and FamilyWelfare, Office of Drugs Controller General (India), Gazette of Indian New Delhi, dated31st July 2015 No.489.
7. National Ethical Guidelines for Medical and Health Research Involving Human participants, ICMR 2017
8. National Ethical Guidelines for Biomedical Research Involving Children, ICMR 2017

POLICY REGARDING TRAINING OF NEW AND EXISTING MEMBER

1. **Purpose**

The purpose of this section is to inform the existing member and new member of Ethics committee why training is necessary and how the members should seek to occasionally attend training or workshop programs to up-date themselves on the progress of technology, information and ethics.

New IEC members are required to undergo a training program on joining the Committee. It is the responsibility of the IEC Secretariat to give copy of the SOPs of the IEC, ICMR guidelines to the IEC members for reference and use.

2. **Scope:**

The SOP applies to all personnel of the IEC.

3. **Responsibility:**

It is the responsibility of the IEC members to have them educated and trained periodically.

4. **Flow chart:**

Sl.No.	Activity	Responsibility
1	Topics for training ↓	IEC members / staff
2	How to get trained ↓	IEC members / staff
3	Keeping the training record	IEC members /staff

5. **Detailed instructions:**

Topics for training:

- Ethics committee members should have knowledge of Good Clinical Practice (GCP) including Schedule Y amended in 2019
- Declaration of Helsinki and other International guidelines like CIOMS,

Ethical Issues:

- Ethical Guidelines for Biomedical Research on Human Participants, ICMR-2017
- E6 Good Clinical Practice: Consolidated Guidance, April 1996.
- WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, 2011
- Forum for Ethical Review Committees in Asia and the Western Pacifica SOPs 2006
- New Drugs and Clinical Trial rules, 2019

An interchange of ideas, information and experiences with overseas institutions and organizations related to research ethics will be attempted. Efforts would be made to collect information on overseas trends and to attend international specialist meetings organized for the exchange of experience and information.

5.1 How to get trained

- IEC conducts formal training to all the members on the recent amendments and guidelines

5.2 Keeping the training records

- Fill in the form to record the training/workshop/conference activities in chronological order.
- Make a copy of the form.
- Keep the original form (Attendance list) as records with signed and dated.
- Give the copy to the administrative staff to keep in the IEC member training record file.

6. Glossary:

Conference: A meeting of individuals or representatives of various organizations for the purpose of discussing and/or acting on topics of common interest.

Meeting: Deliberations between at least two (2) persons where such deliberations determine or result in the joint conduct or disposition of business.

Workshop: A group of people engaged in study or work on a creative project or subject

7. References:

- ✓ International Conference on Harmonization of technical requirements for pharmaceuticals for human use(ICH)-2016.
- ✓ Forum for Ethical Review Committees in Asia and the Western Pacific SOPs 2006
- ✓ WMA Declaration of Helsinki-Ethical principal for medical Research involving human subjects-2013
- ✓ Ethical Guidelines for Biomedical Research on Human Participants, ICMR-2017
- ✓ Standard and operational guidance for ethics review of health related research with human participants-2011
- ✓ New Drugs and Clinical Trial Rules, 2019

ANNEXURE: 01

AF/IEC/01/04/V-8.0

TRAINING RECORD FORM

Name:

Department Name / Affiliation:

Staff / Membership since: Status:

Education Background:

Professional Qualification

1. Legal expert
2. Basic science Scientist
3. Basic medical scientist
4. Clinician
5. Social worker
6. Lay person
7. Any other Work Experience

Sl.No	Courses/ Workshops/ Conferences/Meetings attended	Organized by	Venue	Dates	Source of Funding
1					
2					