INSTITUTIONAL ETHICS COMMITTEE FOR BIOMEDICAL AND HEALTH RESEARCH (IECBHR), MEDICAL COLLEGE & SSG HOSPITAL, BARODA

STANDARD OPERATING PROCEDURE

VERSION - 2.0 AMENDMENT - 2

RELEASE DATE: 01-01-2025

SSGH

Name of Ethics Committee	Institutional Ethics Committee for Biomedical and Health Research (IECBHR), Medical College, Baroda
Registration Number	EC/NEW/INST/2022/2679
Address of the Ethics Committee	Dr. Sangita Patel, Department of Community Medicine, Third Floor, New Teaching Block, Medical College Baroda, Anandpura, Vadodara-390001
Contact Details of the Ethics Committee	Email ID: IECBHR2mcb@gmail.com Contact No. Of Institute: +91265 2421594 Mobile No. Of Member secretary:9825552478 Fax No. Of Institute: +91265 2421056
Updated Standard Operating Procedure (SOP) is available at the Official Website of Medical College Baroda	www.medicalcollegebaroda.edu.in

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INTRODUCTION:

The need for evaluating research has been emphasized under the general principles of precaution and risk minimization. An appropriately constituted Ethics Committee must clear all proposals for biomedical research involving human subjects to safeguard the welfare and rights of participants. The Ethics Committee is entrusted not only with the initial review of the proposed research protocols prior to the initiation of the projects, but also with the continuing responsibility of regular monitoring of the ethical compliance of the approved proposals until completion. Such ongoing reviews will be in accordance with the Declaration of Helsinki and all national and international guidelines for biomedical research involving human subjects.

OBJECTIVE:

The objective of this standard operating procedure is to contribute to ensure the effective functioning of the Institutional Ethics Committee for Health Research (IECBHR) Medical College Baroda and S.S.G. Hospital to achieve a competent and consistent ethical review mechanism for health and biomedical research proposals dealt by the committee as prescribed by the Ethical Guidelines for Biomedical Research on Human Subjects, Indian Council of Medical Research (ICMR).

IECBHR will review and approve all types of research proposals involving human participants with a view to safeguarding the dignity, rights, safety, and well-being of research participants. The goal of research, however important would never be permitted to override the health and wellbeing of the research subjects. Independence and competence will be the two hall-marks of the IECBHR.

The IECBHR will take care of all cardinal principles of research ethics viz. Autonomy, Beneficence, Non-maleficence and Justice in planning, conduct and reporting of the proposed research. For this purpose, it will look into the aspects of the informed consent process, care and protection of research participants, risk-benefit ratio, distribution of burden and benefit, and provisions for appropriate compensations whenever required. The committee will also examine compliance with all regulatory requirements, applicable guidelines and laws.

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1. AUTHORITY FOR IECBHR CONSTITUTION

The Dean, Medical College Baroda, will be the appointing authority under which the Institutional Ethics Committee for Biomedical and Health Research [IECBHR], Medical College Baroda, is constituted. The formation letter from The Dean, Medical College, Baroda will clearly specify the terms of reference for the independent functioning of the Institutional Ethics Committee, which will be done while taking care of existing regulations. The IECBHR will be established by the Dean, Medical College, Baroda. The Chairperson will suggest names of potential members, but the final decision will remain with the Head of the Institute.

The Terms of Reference (TOR) would include:

- Statement on Independence of the committee
- Core value of the committee
- Scope of the committee
- Appointment of Chairperson, Member Secretary and other members, including subject experts, when required
- Communication with regulatory authorities
- Preparation of Standard Operating Procedure for effective functioning of the committee

2. IECBHR'S INDEPENDENCE AND COMPETENCE IN FUNCTIONING AND DECISION MAKING

IECBHR will be multidisciplinary and multi-sectorial in composition. Independence and competence will be its two hallmarks. The Chairperson of the Committee will be from outside the institution to maintain its independence. The Member Secretary will be appointed from amongst the members. Other members will be a mix of medical/non-medical, scientific, and non-scientific persons, including laypersons, to reflect different viewpoints. The lay person will be from outside the institute. There will be adequate representation of age, gender, community, field, etc., in the committee to safeguard the interests and welfare of all sections of the community/society. Members will be required to be aware of local, social, and cultural norms, as these are the most critical social control mechanisms. If needed, subject experts may be invited to offer their views. (The membership of affiliate and non-affiliate members will be balanced to maintain a 50% representation from each group)

3. SOP DEVELOPMENT, REVIEW, AND REVISION PROCEDURE

The purpose of this Standard Operating Procedure (SOP) is to define the process for writing, reviewing, distributing, and amending SOPs of IECBHR. The SOPs provide clear instructions for the committee's related activities to be conducted in accordance with existing Indian regulations and national and international ethical guidelines. The Chairperson of the IECBHR will appoint an SOP team (Member Secretary and two or more members) to formulate a new

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SOP or to revise existing SOPs. The SOP team shall do this by following the standard procedures and formats while drafting or editing any SOP of the IECBHR.

Member Secretary of the IECBHR will coordinate activities of writing, reviewing, distributing, and amending SOPs. It shall:

- Ensure that all the IECBHR members have access to the SOPs
- Ensure that all the IECBHR members are working according to current version of SOP
- Maintain a file of all current and past SOPs

SOP team will then:

- Assess the request(s) for SOP/s revision in consultation with the Member Secretary and Chairperson
- Propose new/ modified SOP/s as needed
- Draft the SOP/s in consultation with the IECBHR members
- Review the draft SOP
- Submit the draft for approval to the Chairperson
- Get it released by the Appointing Authority

Identifying the need for new or amendments of the current SOP:

- Any member of the IECBHR who feels the requirement of a revision or notices an inconsistency/ discrepancy/ has any suggestions on how to improve the existing SOPs or requests to design an entirely new SOP can put forth their request by writing to the IECBHR Chairperson.
- The Chairperson will inform all the IECBHR members about this request at a regular full-board IECBHR meeting.
- If the IECBHR members agree to the request, an appropriate SOP team will be appointed by the Chairperson. The SOP team will be assigned the task of proceeding with the revision/formulation of the SOP.
- If the IECBHR members do not agree to the amendment, no further action will be taken.
- The Chairperson will inform the member of the IECBHR who requested modification of the SOP regarding the Committee's decision.

Writing and reviewing a new/ revised SOP:

- Each SOP will be given a title that is self-explanatory and easily understood. A unique number will be assigned to each SOP item.
- Each page of the SOP will bear the footer, which will have the page number, the effective date, i.e., the date of release of the SOP by the Appointing Authority, and the SOP version. The header will bear the name of the committee, the name of the Institute, and the SOP title.

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- The draft SOP written by one or more members of the SOP team will be reviewed by the remaining members of the SOP team [sent either in hard copy or by email].
- After incorporating the suggestions put forth by the SOP team members, a copy of the revised draft SOP will be sent to the Member Secretary, who will circulate it to all the IEC members.
- A new version will then be brought forth, subject to the nature of change; if there is a minor administrative addition/ deletion or change, an amendment will be added instead of coming out with a new version. But if the Committee is of the opinion that a new version needs to be brought out, considering the importance of changes, instead of an amendment, a new version shall be brought forth.

Implementing, distribution, and filing of SOPs:

- The approved SOP will be implemented from the effective date.
- One complete original set of the current SOP will be filed in the SOP Master file.
- The approved SOP will be notified to the Registering Authority and will also be uploaded on the institute's website.
- Only one copy of the earlier version will be filed in the file entitled 'Past SOPs of the IECBHR'.

Revision interval

- The IEC members will review the SOPs at least once every 2-3 years.

4. COMPOSITION OF ETHICS COMMITTEE AND ROLE OF MEMBERS:

The members in the ethical committee will not be less than seven, maximum being 15. A minimum of five persons will be required to compose a quorum [this would include a clinician, basic medical scientist, legal expert, lay person and social worker] along with chairperson and member secretary.

A subcommittee [s] may be delegated to function independently by ensuring consistent ethical framework for competent review and evaluation of ethical aspects of research proposals related to regulatory requirements arising out of adverse events (AE) or serious adverse events (SAE) as and when they occur. Similarly, expedited reviews may be delegated to a panel of committee members as and when submitted and required. The Composition of the Committee will be as follows:

- The Chairperson [mandatorily from outside the institution as per regulatory requirements as well as for maintenance of its independence]
- Member Secretary [From within the institution]
- Legal expert
- Social scientist/ representative of non-governmental voluntary agency/ Philosopher/ Ethicist/ Theologian

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- Lay person from the community
- 1 - 7 members from different departments/ specialties/ disciplines etc.
    - Basic medical scientists
    - Clinicians
    - Subject Expert and representatives of different potential participant groups [as invited members] as and when the need arises.

The committee shall consist of at least 50% of its members who are not affiliated with Medical College Baroda.

Quorum Requirements for EC Meetings

1. A minimum of five members present in the meeting room.
2. The quorum should include both medical, non-medical, and technical and/or non-technical members.
3. Minimum one non-affiliated member should be part of the quorum.
4. Preferably, the lay person should be part of the quorum.
5. The quorum for reviewing regulatory clinical trials should be in accordance with current CDSCO requirements.
6. No decision is valid without the fulfilment of the quorum.

   In the absence of the chairperson, one senior committee member from outside of the institute will chair the meeting.

Roles and responsibilities of members

Each IECBHR Member at the time of appointment will be provided with a copy of SOP, defining his/ her roles and responsibilities. These will be as follows:

1. **The Chairperson**:
    a. Appointment of members
    b. Formation of committee for review/ new version of IECBHR SOPs
    c. Conduct of meeting and be accountable for the independent and efficient functioning of the committee
    d. Ensure active participation by all the members [particularly non-affiliated, non-medical/non-technical in all discussions and deliberations
    e. Appoint another member as Chairperson, in his/ her absence
    f. Approval of minutes of meeting
    g. Member Secretary will sign documents like minutes of meetings, certificates, and other relevant documents on behalf of IECBHR. In the absence of the Member Secretary, the Chairperson shall sign the mentioned documents.
    h. Ensure that any conflict of interest is well taken care of

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i. Seek COI declaration from members and ensure quorum and fair decision making
j. Handle complaints against researchers, EC members, conflict of interest issues, and requests for use of EC data, etc.

2. **Member Secretary**:
   a. Manage the administrative work of IECBHR
   b. Call for proposals; assess need for full committee/ expedite review
   c. Review and check submitted proposals for completeness
   d. Propose and circulate the agenda for meetings
   e. Ensure an adequate number of studies in a single meeting
   f. Review and reporting of Serious Adverse Event (SAE)
   g. Review protocol deviations
   h. Communication with various stakeholders [researchers, regulatory bodies, etc.]
   i. Archiving of all IECBHR documents
   j. Monitor conduct of trials and their progress
   k. Prepare for audits
   l. Prepare meetings and agenda for subcommittees
   m. Preparing minutes of meeting
   n. Sign documents like minutes of meetings, certificates, and other relevant documents on behalf of IECBHR
   o. Review of Standard Operating Procedures (SOP)
   p. Preparation of annual reports
   q. Updating of new rules and regulations
   r. Arrange for capacity building among IECBHR members
   s. Arrange for subject experts when required

   In the absence of the Member Secretary (or when a Conflict of Interest is declared by him/her), a Joint Member Secretary shall be elected from within the affiliated members of the ethics committee. The elected Joint Member Secretary shall carry out the duties of the Member Secretary (administrative work)

3. **Lay Person**:
   a. Ethical review of the proposal, ICD, along with translation(s).
   b. Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks.
   c. Serve as a patient/ participant/ community representative and bring in ethical and societal concerns.
   d. Assess on societal aspects, if any
   e. Review of compensation processes

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f. Review of post-trial benefits
g. Review of non-trial related injuries
h. Issues with vulnerability
i. Monitoring of the ongoing research project

4. **Social Scientist**:
   a. Ethical review of the proposal, ICD, along with the translations
   b. Assess impact on community involvement, socio-cultural context, religious or philosophical context, if any, serve as a patient/ participant/ societal/ community representative and bring in ethical and societal concerns.
   c. Review of compensation processes
   d. Analysis of risks and benefits, review of post-trial benefits
   e. Review of non-trial related injuries
   f. Issues with vulnerability
   g. Monitoring of ongoing research projects

5. **Lawyer**:
   a. 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 the stem cell committee for stem cell research, HMSC for international collaboration, compliance with guidelines, etc.
   b. Interpret and inform EC members about new regulations, if any
   c. Review of compensation processes
   d. Compliance with current National Laws
   e. Analysis of risks and benefits
   f. Review of post-trial benefits
   g. Issues with vulnerability
   h. Monitoring of ongoing research projects.

6. **Basic Scientist**:
   a. Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology, and statistics, continuing review process, SAE, protocol deviation, progress, and completion report
   b. For clinical trials, a pharmacologist to review the drug safety and pharmacodynamics [Investigator's brochure]
   c. Analysis of risks and benefits
   d. Review of post-trial benefits
   e. Review of non-trial related injuries

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f. Issues with vulnerability
g. Monitoring of ongoing research projects

7. **Clinician:**
   a. Scientific review of protocols, including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study, and statistics
   b. Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report)
   c. Review medical care, facility, and appropriateness of the principal investigator, provision for medical care, management, and compensation
   d. Thorough review of protocol, investigator's brochure (if applicable), and all other protocol details and submitted documents
   e. Review of informed consent process
   f. Analysis of risks and benefits
   g. Review of post-trial benefits
   h. Review of non-trial related injuries
   i. Issues with vulnerability
   j. Monitoring of ongoing research projects

Dissolving the Committee

- At any point in time, should IECBHR cease to exist, the Committee is automatically dissolved.

5. PROCEDURE FOR INDUCTION, RESIGNATION, REPLACEMENT, OR REMOVAL OF MEMBERS

The Appointing Authority will appoint the members in consultation with existing members of IECBHR. Members will be appointed based on their competencies and integrity and may be drawn from any public or private institution.

Once confirmed for an appointment, the letter of appointment will include the date of appointment and the length of tenure.

At the time of joining, the member[s] will provide a copy of their Curriculum vitae, Medical Registration Certificate [wherever applicable], highest qualification, and Good Clinical Practices Training Certificate to the Committee.

Each new member will sign a confidentiality agreement and conflict of interest upon appointment, stating that all matters of which he/she becomes aware during the course of his/her work on the IECBHR will be kept confidential and that any conflicts of interest, which exist or may arise during his/her tenure on the IEC, will be declared. The member will retain a copy of the same.

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Every member will individually submit a Conflict-of-Interest Declaration prior to review of a research project involving himself/ herself and will not be part of the discussion and decision-making process of the full committee.

Upon appointment, members will be provided with the following documentation:

1. IECBHR Standard Operating Procedures (SOP)
2. Up-to-date list of members' names and contact information
3. Roles and responsibilities of each member
4. Any previous reports on the IEC's activities or relevant information.

Training of Ethics Committee members in applicable rules and regulations and Ethics Committee SOPs

The Member Secretary or an IECBHR member will provide introductory training in Research Ethics, GCP, and SOPs to the new member.

A newly inducted member should submit a certificate of training within 6 months by attending the required training at workshops, etc.

All members, including the Chairperson and Member Secretary, will be encouraged to receive continued training by participating in a workshop, conference, and/ or re-training program related to research ethics, as a delegate, faculty, facilitator, etc.

The IECBHR itself will conduct workshops on ethics in clinical research, GCP, SOPs preparation, or changing regulations or guidelines at least once a year to impart training and update the IECBHR members and Institutional faculty members.

These workshops shall also fulfil the need to fill gaps in current IECBHR members' knowledge as determined from regular self-assessments or issues raised during review of research protocols at full committee meetings or whenever new guidelines or regulations come into force.

The IECBHR may nominate and/or sponsor the expenses of (as applicable) an IECBHR member or prospective members for attending a conference, continuing education session, workshop, and/ or training program, etc., outside the institution.

The duration of the appointment will usually be for a period of 2 years. At the end of 2 years, as the case may be, the committee may be reconstituted or half of its members replaced. A member can also be replaced:

1. In the event of his/ her death/ retirement/ resignation from the organization

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2. In particular circumstances, like for any action not commensurate with the responsibilities laid down in the guidelines, deemed unfit for a member

3. If he/ she fails to attend three consecutive meetings of the IEC, without prior intimation, unless exceptional circumstances exist

4. If a member fails to attend at least two-thirds of all scheduled IEC meetings in each year, barring exceptional circumstances.

The Chairman will notify the member of such lapse of membership in writing, recommending his/ her replacement to the Appointing Authority.

Any member can tender resignation [with one month's notice or until a suitable replacement is arranged] from the Committee with proper reasons; the resignation will be sent to the Appointing Authority, routed through the Chairperson/Deputy Chairperson [as per the circumstances].

In case of vacancy arising due to death/ resignation/ termination of a member, necessary efforts will be made to fill the vacancy of the former member as early as possible.

All members, old and new, will attend training sessions at regular intervals [new members to attend within 1 year of appointment]. IECBHR will cover the costs of attending training and education sessions.

All the members will be well versed in their roles and responsibilities. The Member Secretary will arrange for the evaluation of IEC members' education and training of IEC members every six months via an online questionnaire. This will be to ensure that all members are updated with the SOP, current regulatory guidelines, and acceptable ethical standards.

6. ELIGIBILITY CRITERIA AS PRINCIPAL INVESTIGATOR:

IECBHR will review and approve regulated research proposals/ trials involving human participants that conform to safeguard the dignity, rights, safety, and well-being of all actual and potential research participants. IECBHR will take care that all the cardinal principles of ethics, viz. Autonomy, Beneficence, Non-malfeasance, and Justice are taken care of in planning, conducting, and reporting of the proposed research.

For company-sponsored clinical trials, the eligibility criteria for the Principal Investigator will be as follows:

- Professor, Associate Professor, and Assistant Professor, Tutor with a minimum of 5 years of academic experience
- They shall submit a short current CV and Medical Council Registration Certificate.

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If principal investigator not affiliated to the institute

For consideration of the research study (sponsored/ non-sponsored) when the Principal Investigator is not affiliated with the Institute (Government Medical College, Baroda and SSG Hospital, Vadodara)

1. One or more Co-investigators are essential from the institute. Without a Co-investigator from the Institute, the study will not be considered for review by the ethics committee.

2. Approval from the Head of the Department or the head of the institution of the Non-Affiliated Principal Investigator is a must before submission of the study to the ethics committee.

3. Permission from the Head of the institution of Medical College, Baroda, and S.S.G. Hospital is required before submission of the study.

4. Material transfer agreement as per ICMR guidelines has to be carried out before the study can be submitted to the IECBHR, whenever applicable or as directed by the ethics committee.

5. The MOU between the Department of Non-Affiliated Principal Investigator and the Head of the Institution of Medical College, Baroda, and S.S.G. Hospital, Vadodara, needs to be carried out before submission to the ethics committee.

6. Ethics committee fees of 20,000 INR to be drawn in a cheque in case of a sponsored research study and 5000 INR in case of a non-sponsored research protocol, to be submitted at the time of protocol submission.

7. The payment of fees does not by any means confirm the approval of the study.

8. The research study wherein subjects are at risk requires insurance of the required amount.

9. Once the study is given permission, a periodic progress report needs to be submitted to the ethics committee every 6 months, and the ethics committee has the right to investigate the progress of the study anytime during or after the study is over.

10. In case of legal matters involving the study, only the Principal Investigator will remain legally responsible for the legal matter at any time from the start of the study.

11. In case the study is being categorised as under the privilege of the patient, reimbursement needs to be given. If the subject needs to travel for the study, Travel Allowance (TA) and Dearness Allowance (DA) of the subject's requirement needs to be given.

12. Whenever required, audio-video consenting with the Co-investigator is essential as part of the study.

13. Declaration of Conflict of Interest (COI) is a must along with protocol submission.

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14. Amendments suggested in the protocol after the ethics committee review must be communicated to the committee, and an approval letter of the amendment must be sent by the Member Secretary.

15. The above matter should be acceptable to both Principal Investigator and Co-investigator before submission of the protocol, which must be signed by both of them, along with their signatures on this matter draft.

7. APPLICATION PROCEDURES

Submission of a new protocol for review

- All proposals should be submitted to the secretariat in the prescribed application form (Annexure VII) and expedited review form, if applicable, along with the declaration by all investigators.
- All relevant documents should be attached to the application form.
- For a thorough and complete review, all research proposals should be submitted with the following documents
    - Title of the project
    - Name of the PI and Co-I with designation *(e.g. in academic research guide with MD/MS Degree remains PI)*
    - Name of the institute/ hospital/ field area where research will be conducted
    - Departmental presentation letter/ scientific review committee presentation letter.
    - Approval of the Head of the Department
    - Protocol of the proposed research as per format given in the Annexure I
    - Ethical issues in the study and plans to address these issues.
    - Proposal should be submitted in prescribed format with all relevant enclosures mentioned in the check list of form like case report forms, questionnaires, follow up cards etc
    - Informed consent process, including patient information sheet and informed consent form in local language(s)
    - For any drug/ device trial, all relevant pre-clinical animal data and clinical trial data from other centres within the country/ countries, if available
    - Curriculum vitae of all the investigators
    - Any regulatory clearances required
    - Source of funding and financial requirements for the project
    - Other financial issues, including those related to insurance
    - An agreement to report Serious Adverse Events (SAE) to IECBHR (if applicable)

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- Statement of conflicts of interest, if any
- Agreement to comply with the relevant national and international guidelines applicable
- A statement describing any compensation for participation (including expenses and access to medical care) to be given to research participants; a description of the indemnity arrangements, 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) in the protocol made on that account. The reasons for negative decisions should be provided
- Plans for publication of results, "positive or negative," while maintaining the privacy and confidentiality of the study participants
- CTRI Registration number, where applicable
- Any other information relevant to the study

- The academic proposals after verification by the secretariat shall be sent by investigator electronically (in a single file PDF format only) to all members and secretariat along with one hard copy to the secretariat at least 7 days before the scheduled meeting
- Investigator shall also submit two hard copies and a soft copy (CD/ DVD/ Pen drive/ External hard drive) to the secretariat.
- Proposals along with the application and documents in the prescribed format should be duly signed by the Principal Investigator (PI) and Co-investigators/ Collaborators.
- The date of the meeting will be intimated to the researcher to remain present to offer clarifications if necessary.
- The decision will be communicated in writing. If a revision is to be made, the revised documents in the required number of copies should be submitted within the stipulated period of time as specified in the communication, on or before the next meeting.

Submission of amendments to the Protocol

- Amended protocol shall be submitted in two hard copies and one soft copy (CD/ DVD/ Pen drive/ External hard drive) to the secretariat with the following:
- Amended protocol
- Version change history
- Amendment history for protocol
- Amendment history for ICF
- Additional documents that require approval
- Submission letter

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Submission of Additional/ Revised documents

- One copy of all documents should be sent to the secretariat

Change in PI

- In case of transfer of the PI working on an ongoing project approved by IECBHR, it is the duty of the PI to make alternate arrangements of the PI and inform the IECBHR.

Participation of principal investigator (PI) in IECBHR meeting

- The Secretary shall notify all PIs of the meeting date and time at least four days before. The secretary shall also inform all PIs about their proposal's place in agenda. Co-Investigator (CoI) may attend on the PI's behalf if necessary.
- The PI/Co-I may be invited into the meeting room during consideration of his or her proposal
- The PI/Co-I may be invited to make a 6 to 8-minute presentation on the proposal under consideration. After the presentation, the PI shall remain in the meeting to answer any questions, concerns, and suggestions from members
- After the question-and-answer session, PI/Co-I and any other persons with a potential conflict of interest with the proposal shall leave the meeting during the decision/ voting period

8. PROCEDURE FOR COMMUNICATION WITH IECBHR

- All communication should be done to the secretariat office.
- Secretariat office address:
  IECBHR Office,
  Demo Room No 3, Third floor, Department of Community Medicine
  New Teaching Block, Medical College Baroda,
  Anandpura, Vadodara, Gujarat
- Email: IECBHR2mcb@gmail.com
- Secretariat office timing: 10 a.m. to 5 p.m.
- All communications to be done through the EC coordinator if appointed.
- In an emergency, the Member Secretary may be contacted on his/her mobile.

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9. REVIEW OF PROTOCOLS (ELEMENTS OF REVIEW)

The purpose of this SOP is to describe what and how the IECBHR members will review a new research study protocol, at a formal meeting, use of basic principles of research ethics, Autonomy, no harm, Beneficence, and Justice, keeping in mind.

The mandate of the IECBHR will be to review those research proposals that:

1. Involve participants taken from S.S.G. Hospital, Baroda*

2. Are undertaken at S.S.G. Hospital and Medical College Baroda*

3. Carried out by the faculty of S.S.G. Hospital and Medical College, Baroda

4. Are submitted by an Institute affiliated with Medical College and S.S.G. Hospital, Baroda.

*Participants can be involved and undertaken at the community level also, such as Schools, Health centres, Private Clinics, Companies, Industries, Rural areas, Urban areas, Corporations, etc, especially for the Community Medicine department and other departments, also depending on study objectives.

Each review will be based on the Statement of General Principles as per the ICMR Ethical Guidelines for Biomedical Research on Human Participants, 2017.

1. **Principles of essentiality**, whereby after a due consideration of all alternatives in the light of the existing knowledge, the use of human participants is considered to be essential for the proposed research. This should be duly vetted by an ethics committee independent of the proposed research.

2. **Principles of voluntariness**, whereby respect for the right of the participant to agree or not to agree to participate in research or to withdraw from research at any time is paramount. The informed consent process ensures that participants' rights are safeguarded.

3. **Principles of non-exploitation**, whereby research participants are equitably selected so that the benefits and burdens of the research are distributed fairly and without arbitrariness or discrimination. Sufficient safeguards to protect vulnerable groups should be ensured.

4. **Principle of social responsibility**, whereby the research is planned and conducted so as to avoid the creation or deepening of social and historical divisions or in any way disturb social harmony in community relationships.

5. **Principles of ensuring privacy and confidentiality**, whereby to maintain the privacy of the potential participants, her/ his identity and records are kept confidential and access is limited to only those authorized. However, under certain circumstances (suicidal ideation, homicidal tendency, HIV positive status, when required by the court of law, etc), privacy of information

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can be breached in consultation with the EC for valid scientific or legal reasons, as the right to life of an individual supersedes the right to privacy of the research participants.

6. **Principles of risk minimization**, whereby due care is taken by all stakeholders (including but not limited to researchers, ECs, sponsors, regulators) at all stages of the research to ensure that the risks are minimized and appropriate care and compensation is given if any harm occurs.

7. **Principles of professional competence**, whereby the research is planned, conducted, evaluated, and monitored throughout by persons who are competent and have the appropriate and relevant qualification, experience, and/or training.

8. **Principles of maximization of benefit**, whereby due care is taken to design and conduct the research in such a way as to directly or indirectly maximize the benefits to the research participants and/or to society.

9. **Principles of institutional arrangements**, whereby institutions where the research is being conducted have policies for appropriate research governance and take the responsibility to facilitate research by providing required infrastructure, manpower, funds, and training opportunities.

10. **Principles of accountability and transparency**, whereby the research plan and outcomes emanating from the research are brought into the public domain through registries, reports, and scientific and other publications while safeguarding the right to privacy of the participants. Stakeholders involved in research should disclose any existing conflicts of interest and manage them appropriately. The study should be conducted in a fair, honest, impartial, and transparent manner to guarantee accountability. Related records, data, and notes should be retained for the required period for possible external scrutiny/ audit.

11. **Principles of totality of responsibility**, whereby all stakeholders involved in research are responsible for their actions. The professional, social, and moral responsibilities that comply with ethical guidelines and related regulations are binding on all stakeholders directly or indirectly.

12. **Principles of environmental protection**, whereby researchers are accountable for ensuring protection of the environment and resources at all stages of research, in compliance with existing guidelines and regulations.

During the review process, the IECBHR will consider the following elements of a given research proposal:

The protocol should be submitted as prescribed. The format of the same shall be downloaded in the format from the website https://www.medicalcollegebaroda.edu.in/.

The copies of duly signed research protocol are to be submitted to the committee as follows:

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One soft copy sent through mail to the official mail id IECBHR2mcb@gmail.com

Two hard copies with appropriate reference studies (NA in case of new research question)

1. Scientific design and conduct of the study
2. Examination of predictable risks/harms and potential benefits with communication to the study participants
3. Recruitment strategies
4. Procedure for independent selection of subjects in methodology including inclusion/ exclusion, withdrawal, removal criteria and other issues like advertisement details etc.
5. Protection of subject rights and responsibilities
6. Issues related to protocol deviation and violation
7. Management of research related injuries, serious adverse events
8. Payment for participation and Compensation provisions
9. Justification for placebo in control arm, if any
10. Availability of products after the study, if applicable
11. Informed Consent Process [includes participant information sheet, informed consent form in local languages, along with AV recording protocols [where necessary]; Requirement of assent if indicated.
12. Protection of privacy and confidentiality
13. Involvement of the community, wherever required
14. Plans for data analysis and reporting
15. Adherence to all regulatory requirements and applicable guidelines changing from time to time [including CDSCO, GOI, ICMR, etc.]
16. Competence of investigators, research, and supporting staff
17. Facilities and infrastructure of study sites
18. Criteria for withdrawal of patients, suspending or terminating the study
19. Mechanism declared for trial participant to contact IECBHR, if the need arises
20. Justification for waiver of informed consent

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21. Protection of vulnerable population [as stated later]

22. Community need and social values: Outcome of the planned results should be relevant to the health problem of the society.

Rights and responsibilities of the participant

In order to ensure that rights and responsibilities are protected, IECBHR shall review Informed Consent Document to see that participant is well informed. Apart from this, IECBHR shall regularly monitor the ongoing trial to oversee the protection of the rights and responsibilities of the participant.

Rights of participants in research

Participants should know about the trial that:
✓ Every research/ trial is approved by a local Institutional Ethics Committee made up of scientists, doctors, advocates, and community members.
✓ These committees ensure that trial participants are exposed to the minimum possible risks in relation to the expected benefits.
✓ Details about the Institutional Ethics Committee and participants are free to approach it for any grievance related to the clinical trial.
✓ Rights of Participants of research/ clinical trials are protected under the law.
✓ The participant has the right to know everything that is going to happen in a study.
✓ The potential participant has the right to refuse to take part in research.
✓ Participant is also free to withdraw from the study at any time without giving any reason.
✓ During the trial, the privacy of participants and the confidentiality of their data are maintained.
✓ If new information is discovered during a study, you will be informed about the same.
✓ The informed consent process is one of the key aspects of protecting research participants, and the decision to volunteer for a study is individual and free from undue influences.

Responsibilities of participants in research

✓ To adhere to taking the trial medication according to the prescribed dosages and schedule.
✓ To undergo periodic investigations/follow-up as prescribed in the trial protocol on schedule.
✓ To immediately report any observation/ untoward event (possible side effect) during the trial.

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Voluntariness and prior intimation with regard to the participant's involvement and withdrawal from the trial

IECBHR shall ensure that no participant is forced to enter into a clinical trial. The informed consent document shall clearly indicate the voluntariness of the trial, and any refusal shall not affect the ongoing medical treatment.

Information and comprehension of participants regarding (initial and ongoing) the associated risks and benefits of the trial

To ensure the same, IECBHR shall maintain a favourable balance of benefits and risks, evaluate plans to minimize risks and discomfort, and assess the merit of the research before approving it. As a part of continuing review at an appropriate interval and focused review based on notifications of SAEs at the study site or other study sites when notified, EC will also assess any altered risks in the study.

Protection of confidentiality and privacy of participants

The researcher should safeguard the confidentiality of research-related data of participants and the community. Data of individual participants/community may be disclosed in certain circumstances with the permission of the EC, such as specific orders of a court of law, threat to a person's or community's life, public health risk that would supersede personal rights to privacy, serious adverse events (SAEs) that are required to be communicated to an appropriate regulatory authority, etc.

Monitoring to ensure equitable selection of subjects, with special attention to vulnerable and high-risk subjects

Efforts must be made to ensure that individuals or communities invited for research are selected in such a way that the benefits and burdens of research are equitably distributed. Vulnerable individuals/groups should not be included in research solely to benefit others who are better off than themselves.

Compensation for participation in the trial

Payment for participation: Participants (Comparator/Control groups) shall be reimbursed for expenses incurred in connection with their participation in research, including inconvenience, time spent, and other incidental costs, in either cash or kind. Participants will not be required to pay for any research-related costs beyond routine clinical care, including investigations, patient workup, interventions, or associated treatment.

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When the LAR gives consent on behalf of a participant, payment shall not constitute an undue inducement and will be carefully reviewed by the IECBHR. IECBHR will look for documents verifying that the participant actually got the reimbursement.

Compensation for research-related harm: Research participants who suffer direct physical, psychological, social, legal, or economic harm as a result of their participation are entitled, after due assessment, to financial or other assistance to compensate them equitably for any temporary or permanent impairment or disability. In case of death, participants' dependents will be entitled to monetary compensation. IECBHR shall review the research proposal as a built-in mechanism for mitigating research-related harm.

10. FUNCTIONING OF THE COMMITTEE

Meetings of IECBHR shall be held on scheduled intervals as prescribed (Minimum once every two months). Additional sessions will be held as and when necessary, especially for reported Serious Adverse Events and Expedite Reviews. Last date for receipt of new research proposals shall ordinarily be 3 weeks before the scheduled meeting.
2 hard copies and 1 soft copy in email need to be submitted to the IECBHR Office. All investigators need to declare, at the time of submitting their new project, the status of their ongoing approved projects. After the MS review of the submitted documents, he/she shall forward the project to all members. About 10 days shall ordinarily be given for each member to review the project. In case a subject expert is needed, it shall be identified from the already available pool of experts [within/outside the institution], and the documents of the project shall even be forwarded to them. Primary reviewers may be identified for reviewing specific components of a given research proposal. After the initial review of the project PI/Co-Investigator will be required to remain present during the meeting or will be invited to offer clarifications on any queries the members may have. Decisions will be taken by consensus after discussions, and voting will be done if necessary. If a decision is reached by voting, specific comments of minority votes shall specifically be included in the minutes of the meeting. The decisions of the meeting shall be recorded as minutes of the meeting. It shall then be circulated via email to all members for suggestions or corrections, with replies due within a stipulated time frame. On receiving replies from all members, MS shall then finalize the minutes of the meeting and submit them to the Chairperson for signature. These minutes of the meeting shall be archived as a separate file and confirmed during the next meeting.

11. CONDUCT OF FULL COMMITTEE/ BOARD MEETING

Once the agenda is prepared, it will be intimated to the investigators and IEC members online or by email. It will include the time and place of the meeting. No proposal will be considered for

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approval unless the Principal Investigator or Co-investigator attends the meeting. After review by the committee members, the PI will be given an opportunity to provide clarification on any queries the members may have.

Members who are unable to attend a meeting can contribute before the meeting by submitting online comments/suggestions to the Member Secretary. If required, minutes of the meeting may include such written comments.

A meeting will be considered valid only if the quorum is fulfilled. This will be maintained throughout the meeting and at the time of decision-making. If a member has declared a conflict of interest for any research proposal, the Chairperson shall take it in writing before the beginning of the meeting and record it in the minutes of the meeting. The member who has declared a Conflict of Interest will be asked to withdraw from the EC meeting (leave the room) while the research proposal is being discussed, unless he/she is an investigator. If the IEC Member is an investigator, he/she shall be present only for the review process. At the time of discussion amongst members and final decision, the concerned member shall leave the meeting. This will be minuted and the quorum rechecked.

Meetings will be scheduled for an allocated time. If the issues are not completed within the allocated time, the IECBHR may either continue the meeting until all agenda items have been considered or schedule an additional meeting. If an additional meeting is called, it will be held within 14 working days.

The IECBHR meetings will be conducted to ensure confidentiality and open discussion among members and the investigator[s]. Each member will be allowed to put forward their views on the research project, especially laypeople. All such suggestions shall be taken care of to be incorporated into the suggestion letter to be given to the Principal Investigator. In case a member differs from the views of other Committee Members, his view/opinion will be recorded explicitly in the minutes of the meeting. Final decision, if required, may be taken through a voting process.

Conduct of meeting

- The chairperson shall lead all meetings of the IECBHR.
- If, for reasons beyond control, the chairperson is not available, the committee will decide on a chairperson for that particular meeting who will be from outside of the institute.
- In the case where the Member Secretary is unsuccessful in routing the materials to committee members, the Member Secretary shall at least notify the member(s) of the non-occurrence of the meeting, and shall arrange for alternative means of material

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distribution. Whenever possible, the Member Secretary shall distribute the materials electronically.

- The Member Secretary shall notify all committee members and applicants of any changes in meeting time, date, or agenda as soon as they are discovered.

Meeting Procedure

- The chairperson or a delegated member of the committee shall call the meeting to order only when a quorum of members is present. If the quorum is incomplete, the meeting shall be rescheduled.
- If the meeting is to review a new submitted protocol, the Principal Investigator of that protocol may be invited when deliberating on the protocol to answer questions that shall be raised by the committee but must go out when decisions are made on the protocol.
- The chairperson shall follow the agenda for the progress of the meeting. The meeting shall most likely follow the following order
- Confirmation of minutes of the previous meetings
- Matters arising from previous minutes
- Discussion of new agendas
- Action items (voting on protocols, acceptance of serious adverse events, Periodic and annual reports, and final reports)
- Other matters
- The meeting of IECBHR will be held monthly (every 1 month) and as and when needed.

Meeting Minutes

- During committee meetings, all deliberations shall be recorded in writing or electronically.
- The minutes shall include a list of attendees, actions taken by the committee, the decision or vote on those actions, including the number of members voting for, against, and abstaining, the basis for requiring changes in or disapproving research, and a written summary of the discussion of issues and their resolution.
- The secretary shall also include a summary of each considered protocol in the minutes.
- The secretary shall circulate the minutes with a copy of the next meeting's agenda to all committee members at least four days before the date of the subsequent meeting.
- All committee members shall review the minutes for accuracy and completeness.
- The committee members shall make recommendations to the minutes at the next committee meeting.

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- The chairperson shall confirm the accuracy and completeness and sign the minutes during the next meeting.
- The secretary shall archive the official minutes with the meeting's agenda and all relevant attachments.

12. INDEPENDENT CONSULTANTS

IECBHR may call upon subject experts as independent consultants to provide a special review of selected research protocols, if needed. These experts may be specialists in ethical or legal aspects, specific diseases or methodologies, or represent particular communities, patient groups, or special interest groups, e.g., Cancer patients, HIV/AIDS-positive persons, or ethnic minorities. They are required to provide their specialized views but do not participate in decision-making, which will be made by the members of the IECBHR. They will have to submit the necessary documents, viz. CV, MRC, if related, and sign the confidential agreement before giving the documents for review.

13. PROCESS OF REVIEW

Review of informed consent document, assent form (as applicable), and translations

- The process used for obtaining informed consent
- The adequacy, completeness, and understandability of the information in the ICF
- Contents of the participation information sheet, including the local language translations
- Back translations of the informed consent document in English, wherever required
- Provision for audio-visual recording of the consent process, if applicable
- Review of consent waiver or verbal/oral consent request, if asked for

Evaluation of recruitment strategies

Recruitment strategies will be evaluated to ensure equitable inclusion of participants without skewing towards any particular patient population based on socio-economic class, gender, or literacy. Specific emphasis will be placed on the following aspects of recruitment strategies:

1. Full information is to be conveyed to potential research participants.
2. Inclusion and Exclusion criteria for research participants.
3. Students or staff recruitment in research.
4. Healthy volunteers.
5. Information contained in the advertisement and mode of its communication.
6. Compensation is being provided for travel as well as loss of daily wages on a case-by-case basis.

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Evaluation of proposals involving special groups and vulnerable populations

The Ethics Committee will evaluate the specific context-dependent characteristics that may place study participants at increased risk of harm or wrongdoing. The Ethics Committee will ensure special protections for groups deemed vulnerable.

The Ethics Committee will enable the participation of vulnerable individuals by protecting their rights and interests through social safeguards and protections. The Member Secretary/ the Chairperson will be responsible for ensuring that reviews of these groups are appropriate to protect the reviews of such studies. The Ethics Committee may involve subject experts when required for selected reviews.

Conduct of research on vulnerable population

- Vulnerable subjects: A vulnerable category of subjects includes members of a group with hierarchical structure (e.g. prisoners, armed forces personnel, staff and students of medical, nursing, and pharmacy academic institutions), patients with incurable diseases, unemployed or impoverished persons, patients in emergencies, ethnic minority groups, homeless persons, nomads, refugees, minors, or others incapable of personally giving consent.
- Review Procedure
  - Conducting trials on vulnerable populations can never be given exemption from review and cannot be passed through expedited review.
  - All research that involves vulnerable populations and special groups should be subjected to full review by all members.
  - Audio-visual consent is mandatory for regulatory trials involving vulnerable populations.

Elements for review of research involving vulnerable subjects

- Strategic issues include inclusion and exclusion criteria for selecting and recruiting participants, informed consent, willingness to volunteer, coercion and undue influence, and confidentiality of data.
- The IHEC must carefully consider group characteristics, such as economic, social, physical, and environmental conditions, to ensure that the research incorporates additional safeguards for vulnerable subjects.
- Investigators must not over-select or exclude certain groups based on perceived limitations or complexities associated with those groups. For example, it is not appropriate to target staff and students as research subjects merely because they are a readily available "captive" population.

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- Research should comply with ICMR guidelines, Schedule Y, and other local statutory guidelines, if any.
- Just as in providing medical care, research studies that plan to involve any potentially vulnerable populations must have adequate procedures to assess and ensure each subject's capacity, understanding, and informed consent and assent.
- In certain instances, it may be possible for researchers to enhance understanding for potentially vulnerable subjects. Examples include:
    - Depute someone not involved in the research to obtain consent, such as a consent monitor, a subject advocate, or an interpreter for hearing-impaired subjects.
    - A translator of informed consent forms into the subject's language and reading the consent form to the subject slowly, ensuring understanding paragraph by paragraph.
- The IHEC may require additional safeguards to protect potentially vulnerable populations. For instance:
    - The IHEC may direct the investigator to submit each signed informed consent form to the IHEC.
    - Someone from the IHEC may oversee the consent process.
    - A waiting period of a few days to establish initial contact and allow time for family discussions and questions.

Children Involved as Subjects in Research

- Children are persons who have not attained the legal age for consent to treatments or procedures involved in the research under the applicable jurisdiction in which the research will be conducted
- The proposed research must fall within one of two categories
    - Research not involving greater than minimal risk
    - Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.
- It is the general position of IHEC that children will not be included in research in one of the following categories:
    - Research involving greater than minimal risk but likely to yield knowledge that can be generalized about the subject's disorder or condition.
    - Research not otherwise approvable, which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health and welfare of children.
- A specific explanation in the protocol must be provided for the enrolment of children.

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Parental Permission

- Permission of one parent is sufficient for research involving less than minimal risk to children. Permission of both parents is required for any research involving more than minimal risk to children. IHEC will not allow the inclusion of any children in clinical trials where parental permission is not possible (for example, neglected or abused children). No consent waiver will be given.
- Assent of the Child
  - Assent must be obtained when the child is capable of giving it. The IHEC should consider the age, maturity, and psychological state of the child. The assent form should be tailored for the child's level of understanding. For young children, especially, it should be a simple, age-appropriate, one-page document.
  - The IHEC may determine that the assent of the child is not necessary if all three of the following conditions are satisfied:
    - The research offers a possible direct benefit to the child.
    - The benefit is important to the health or well-being of the child.
    - The benefit is available only in the context of the research.
  - IHEC must take great care in approving research where the child is suffering from a life-threatening illness with little chance of therapeutic benefit.
  - IHEC must also be cautious in allowing parents to overrule a child's dissent when experimental therapy has little or no reasonable expectation of benefit.

Research on Pregnant Women, Fetuses, and Human In Vitro Fertilization

- Research involving pregnant women and fetuses should involve the least possible risk. The IHEC must document specific findings to minimize the potential for risk or harm to the fetus, and must also give additional attention to the conditions for obtaining informed consent. The IHEC must be familiar with the requirements of the following conditions
  - Research involving pregnant women.
  - Research involving the fetus in utero.
  - Research involving the fetus ex utero.
  - Research involving dead fetuses, fetal material, or placenta.
- Special explanation in the protocol must be required for the enrollment of these groups.
- Pregnant women should not be involved in research where the "purpose of the activity is to meet the health needs of the mother." A purpose of treating the "health needs" alone of the pregnant woman is not ethical when the benefits to her are greatly outweighed by the risks to fetus and offspring.
- Where the purpose of clinical research involving a pregnant woman is not to meet her health needs, she may participate only "if the risk to the fetus is minimal."

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- Research can only be permitted with the fetus as a subject when "the purpose of the activity is to meet the health needs of the particular fetus and the fetus will be placed at risk only to the minimum extent necessary to meet such needs."
- Non-therapeutic research is not permitted on the fetus.
- A subject expert should have been called for the research involving pregnant women and fetus.

Research Involving Students and Staff of Medical College Baroda

- "Student" refers to any individual enrolled at Medical College Baroda, including those in training as Residents, Fellows, or Postdoctoral trainees. This also includes individuals enrolled at a training facility other than Medical College Baroda, a training program, or a work program.
- "Staff" includes all Medical College Baroda and Medical College Baroda General Hospital employees, including faculty and outsourced contractual employees.
- Medical College Baroda and Medical College Baroda General Hospital students and staff have the same rights as any other potential research participants, irrespective of the degree of risk, provided all of the following conditions exist:
    - The research must not provide any academic or occupational advantage to participating students or staff over non-participants. Researchers must not impose any educational or occupational penalty on students or staff who choose not to volunteer.
    - Students and staff must not be systematically treated differently from non-student or non-staff subjects in the research project.
    - Due to the potential for perceived or real coercion to participate, students and staff (especially those under the direct supervision of the Principal Investigator (PI) or co-investigators) must be reviewed by the Head of the Institute.

Research Involving Decisionally-Impaired Subjects

- Decisionally-impaired individuals are those with a diminished capacity for judgment and reasoning due to psychiatric, organic, developmental, or other disorders that affect cognitive or emotional functions. Other individuals, who may be considered decisionally-impaired, with limited decision-making ability, are individuals under the influence or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps
- As with all subjects, the IHEC must carefully consider selection issues, privacy, confidentiality, coercion, undue influence, and risk-benefit analysis. IHEC should consider additional safeguards to protect these individuals.

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- A specific explanation in the research protocol must be provided for enrolling these groups.
- The proposed research must fall into one of two categories:
  - Research not involving greater than minimal risk.
  - Research involving greater than minimal risk, but presenting the prospect of direct benefit to the individual subjects.
- It is the general position of IHEC that individuals with decisional impairment will not be enrolled in research in one of the following categories
  - Research involving greater than minimal risk, but likely to yield knowledge that can be generalized about the subject's disorder or condition
  - Research not otherwise approvable, which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health and welfare of the individual
- If the research subject is unable to consent, the individual's assent, and particularly their dissent, should be considered. The process for determining whether an individual is capable of providing assent must be included in the research protocol.
- If the research subject cannot give their consent and has not expressed dissent, then a surrogate decision-maker must be found to consent on the subject's behalf. Consent from one of the family members: competent spouse, competent parent, or adult child (in order of preference) should be taken in this situation

Research on Ethnic Minority Groups, Homeless Persons, Nomads, and Refugees

- As with all subjects, IHEC must carefully consider selection issues, privacy, confidentiality, coercion, undue influence, and risk-benefit analysis. The IHEC should consider additional safeguards to protect these subjects
- A specific explanation in the research protocol must be provided for the enrollment of these subjects.
- The proposed research must fall into one of two categories:
  - Research not involving greater than minimal risk.
  - Research involving greater than minimal risk, but presenting the prospect of direct benefit to the individual subjects.
- It is the general position of IHEC that ethnic minority groups, homeless persons, nomads, and refugees will not be enrolled in research in one of the following categories:
  - Research involving greater than minimal risk, but likely to yield knowledge that can be generalized about the subject's disorder or condition.
  - Research not otherwise approvable, which presents an opportunity to understand, prevent, or alleviate a serious health or welfare issue.

Research Involving Prisoners and Armed Forces Personnel

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- It is the general position of IHEC that prisoners and armed forces personnel should not be involved in research.

Evaluation of the budget with regard to indemnity, compensation, roles, and responsibilities

IECBHR will review the source and means of compensation for study-related injury. Plans for payment for participation, reimbursement of incurred costs (such as travel or lost wages), incidental expenses, and other inconveniences will be reviewed. After the approval from IECBHR, the Sponsor/CRO will submit the Clinical Trial Agreement (CTA)/ Memorandum of Understanding and Indemnity Agreement Document, which will be signed by the sponsor and the Medical Superintendent of the hospital, with the counter-signature of the PI. All CTAs shall be evaluated to confirm the required inclusions/ exclusions. The PI will start the drug trial only after the agreement is fully executed.

Periodic review of the Trial

IECBHR will review the ongoing research at a six-month interval (or more often, if deemed necessary, depending on the level of risk). It will ensure that the progress report, safety report[s], and final reports are submitted at regular intervals.

Progress reports:

- ✓ PI will be required to submit a progress report every six months after the IECBHR approval. The progress report consists of the number of patients screened, randomized, dropouts, or withdrawals if any.

SUSAR and CIOMS Reports:

- ✓ IECBHR expects to be regularly updated with SUSAR and CIOMS reports of ongoing trials indicating adverse events or newly identified risk factors at other sites or any relevant published data in reference to the investigational drug.

Safety reporting:

- ✓ A Serious Adverse Event (SAE) occurring to a research participant will be reported to the IECBHR as per existing regulatory requirements.

Final reports:

- ✓ The IECBHR will receive a final report as soon as the research is completed.
- ✓ It would include information on whether the study achieved its objectives, the main findings, and arrangements for publication or dissemination of the research, including any feedback to participants.

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14. EXPEDITED REVIEW PROCESS

- All revised proposals, unless specifically required to go to the main committee, will be examined in a meeting of selected members identified by the chairperson to expedite decision-making.
- Expedited review may also be taken up in cases of nationally relevant proposals requiring urgent review.
- The proposals involve no more than minimal risk to research participants.
- An expedited review may be conducted only if the protocols involve:
    - Revised proposals previously approved through full review by the IHEC or continuing review of approved proposals where there is no additional risk or activity is limited to data analysis or health record research.
    - Urgent amendments to approved protocols for safety reasons
    - Anonymous surveys and retrospective studies.
    - Urgent proposal of national interest
    - Research on interventions in emergency situations, i.e., epidemic
    - Research on Disaster Management
    - Analysis of stored pathological specimens/paraffin blocks without personal identifiers.
    - Research activities that involve only procedures listed in one or more of the following categories:
        - Clinical studies of drugs and medical devices are only conducted when:
            - Research is on already approved drugs except when:
                - Study of drug interaction
                - Conducting a trial on vulnerable populations
            - Adverse Events (AE) or unexpected Adverse Drug Reaction (ADR) of minor nature is reported
        - Research involving clinical materials (data, documents, records, or specimens) that have been collected for non-research (clinical) purposes.
    - Other documents which would be considered for expedited review include but are not limited to:
        - Minor deviations from originally approved research during the period of approval (usually one-year duration).
        - Change in the name or address of the sponsor.
        - Change in contact details of Principal Investigator (PI) and IHEC.
        - Change in PI or handover of trials or projects.
        - Inclusion or deletion of names of Co-Investigators.
        - Request for change in PI, Co-I, or any member involved in the research.
        - Minor amendments in the protocol or case record form.

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- Minor corrections in the budget.
- Other administrative changes in the investigator's brochure, informed consent form, etc.

15. REVIEW OF SERIOUS ADVERSE EVENT REPORTS

- **Purpose**
  - The purpose of this SOP is to highlight the procedure for the review of serious adverse event reports (SAEs) for all the research projects and clinical trials approved by IECBHR, Medical College Baroda.
- **Scope**
  - This guideline is applicable to all the research projects and clinical trials approved by IECBHR, Medical College Baroda.
- **Responsibility**

Chairperson:

  - Ensure all reported SAEs are discussed during the EC meeting.
  - Opinion to DCGI on SAE compensation in a timely manner.
  - Ensure appropriate management of SAE by the researcher/applicant.
  - Ensure subjects or their nominees are receiving compensation and medical management as applicable.
  - Ensure all reporting timelines are met; if not, then appropriate justification should be documented.
  - Ensure causal relationships are established for each SAE by IECBHR, Medical College, Baroda.

Member Secretary/ EC coordinator:

  - Ensure all relevant data for SAEs are submitted to IECBHR, Medical College Baroda.
  - Ensure SAEs are communicated with the Chairperson and Other members as applicable.
  - Filing of SAE records at IECBHR, Medical College Baroda office.
  - To send a compensation opinion letter to DCGI for each SAE reported.
  - Communication with the researcher/applicant in case need for further information related to SAE

SAE review subcommittee

- The SAE review subcommittee shall consist of two clinician members and basic medical scientists. The Member Secretary/Joint member secretary shall be a member of this subcommittee to facilitate its smooth functioning and coordinate with the Chairperson. The presence of one clinician and one Basic Medical Scientist (Pharmacologist) is a must

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to conduct the review of SAE. The SAE subcommittee may invite the investigator to provide any clarifications.

- This subcommittee shall review all trial-related documents, source documents, SAE reports by principal investigator, SAE reports by sponsor, and medical management-related documents. It will suggest the relation of causality with trial medications and required compensations to the Chairperson for its submission to CDSCO. The recommendations of the SAE review subcommittee and the report to CDSCO shall be ratified in the next IECBHR full committee meeting.

Handling of serious adverse event:

- The researcher/investigator is responsible for reporting all SAEs to the IECBHR, Medical College, Baroda, within 24 hours of knowledge. Reporting of SAEs may be done via email (including on non-working days).
- Sponsor(applicant) and Investigator, after due analysis, will send detailed SAE reports to IECBHR, Medical College, Baroda, in the reporting format of CDSCO within 14 calendar days of occurrence.
- IECBHR, Medical College Baroda will send its recommendation on compensation for SAE to the DGGI within 30 calendar days of occurrence.
- The financial compensation will be over and above any expenses incurred on the medical management of the subject.
- The Chairperson may call for an IECBHR meeting to discuss the handling and management of reported SAE. The investigator may be called in to the meeting to offer clarification.
- The chairperson of the committee will have the right to temporarily suspend any research activities in the purview of the committee if untoward or unexpected adverse events occur. If this occurs, the full committee must re-evaluate the proposal at its next meeting and decide whether to continue the study.

Compensation for research-related harm:

- Sponsor shall provide the compensation as defined by CDSCO.

Compensation receipt by research participants:

- IECBHR, Medical College, Baroda should ensure that receipt of payment by the subjects is in a timely manner.
- Site should notify the payment order from the competent authority and the subject's acknowledgement of the compensation given to the subject.
- In case of death or disability, IECBHR, Medical College Baroda should ensure that compensation is given to the subject's nominee (i.e., nominee as per details provided under the Informed consent form.

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16. FOLLOW-UP PROCEDURES

- The schedule for periodical review of ongoing approved projects will be communicated to the PI at least two weeks before
- All SAEs and the interventions undertaken should be intimated
- Annual Status Reports for periodical review should be submitted in the prescribed format (Annexure IV)
- Protocol deviation, if any, should be reported with justifications
- Any amendment to the protocol should be submitted for approval
- Change of investigators should be notified
- Premature termination of the study should be notified in the given format (Annexure V)
- Final closure report should be submitted at the end of the study in the given format (Annexure VI)

17. PROCEDURE FOR AMENDMENTS

- Any proposed changes to approved projects will require to be reported by the PI to the IECBHR_for review. Such requests will outline the nature of the proposed changes, reasons for the changes, and an assessment of any ethical implications arising from the request on the conduct of the research. All amended documents will have the changes highlighted and contain revised version numbers and dates.
- Expedited Review of requests for minor amendments and urgent amendments to approved protocols for safety reasons may be undertaken by the Member Secretary between scheduled meetings at the discretion of the Chairperson [as above], which will be ratified at the next IECBHR meeting.
- The IECBHR will review all other requests for amendments at its next scheduled Full Committee meeting, provided the request has been received by the Member Secretary by the agenda closing date.
- The decision of the IECBHR will be communicated in writing to the PI, advising whether the proposed amendment and/or request for extension has been given ethical approval within 15 working days of the meeting at which the request was considered [this may be the Full Committee meeting or Expedited Review Meeting].
- Notification of the approval of amendments and extensions will be conveyed in writing in the standard format.
- If the IEC determines that further information, clarification or modification is required for the consideration of the request for amendment or extension, the correspondence to the investigator will clearly articulate the reasons for this determination, and will clearly set out the information that is required.

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- All received and approved requests for amendments and extensions will be recorded, and the status of the project will be updated in the IEC's data of received and reviewed applications.
- In cases of re-consenting or use of newly updated consent forms, IECBHR shall ask for submission of a copy of the re-consented document or a copy of the newly updated consent form.

18. DECISION MAKING

- All decisions will be taken in meetings and not by the circulation of project proposals.
- Members will discuss the various issues before arriving at a consensus.
- A member should withdraw from the meeting during the decision procedure where a conflict of interest arises, and this should be indicated to the chairperson prior to the application and recorded in the minutes (Annexure VIII).
- Decisions will be made only in meetings where the quorum is complete.
- Only members can make the decision. The expert consultants will only offer their opinions.
- Decisions shall be arrived at through consensus. When a consensus is not possible, the IHEC shall vote, and the majority decision shall prevail.
- There should be a provision of a dissent note by the members.
- Decision will be to approve, reject, or revise the proposals. Specific suggestions for modifications and reasons for rejection will be given to the PI/applicant.
- In cases of conditional decisions, clear suggestions for revision will be given.
- Modified proposals may be reviewed by an expedited review by identified members.
- Procedure for appeal by the researcher will be clearly defined.
- The decision will be recorded in the minutes of the meeting, and the Chairperson's approval will be taken in writing.
- All present members should submit their opinion in writing for all the submitted proposals in the voting sheet. (Annexure VIII).
- Declaration of Conflict of Interest in each voting sheet is to be clearly marked, and this is also used as a policy to monitor or prevent conflicts of Interest. (Annexure VIII).
- The decision will be made by members only, and invitees will have no right to make a decision or vote.
- The Head of the Institute (Dean) or the Head of the hospital (Superintendent) will have no right of vote or participate in decision-making.

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19. COMMUNICATION OF DECISIONS OF THE INSTITUTIONAL ETHICS COMMITTEE

After the review meeting, the IECBHR will report the committee's decision in writing to the Principal Investigator (PI) once all members approve the minutes.

- Letter of suggestions - for revision with minor modifications/amendments
- Approval with or without mandatory regulatory instructions [as the case may be]
- Approval will be given after examination by the Member Secretary or expedited review, as the case may be.
- Revision with major modifications for resubmission
- This will be placed before the full committee for reconsideration for approval, or not approved (or termination/revocation of permission if applicable)
- Disapproval/revocation of permission

Clearly defined reasons will be given for not approving/ terminating/ revoking of permission. Suppose the requested information is not received from the applicant within three months of the issue of the suggestion letter. In that case, the project may be dismissed, and the applicant will be required to resubmit the project at a later date as a fresh application.

Once compliance with the suggestions of the reviewed proposals is received, it will be the discretion of the Member Secretary to have the re-submission reviewed by one/ more members of IECBHR without convening a Full Committee/Board Meeting.

Upon receipt of the IEC members' comments, approval may be granted for the concerned research project, subject to their comments.

In all cases, IECBHR will notify the PI of the ethical approval of a project only when all outstanding requests for further information, clarification, or modification have been satisfactorily resolved.

If the IECBHR determines that a project is ethically unacceptable or that approval needs to be revoked, the notification of the IEC's decision will include the grounds for the decision while communicating it to the PI. The status of the projects will be regularly updated in the IECBHR's data of received and reviewed applications for record purposes.

Communication from IECBHR to the Investigator regarding the decision on the proposal will ordinarily be made within 15 working days after review of the application by the full

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committee/ in cases of Exempt from Full Committee/ in cases of Expedite Reviews/ in cases of case reports or case series.

20. PROTOCOL DEVIATION/ NON-COMPLIANCE/ VIOLATION REVIEW END MANAGEMENT

Purpose

To provide instructions for taking action(s) when investigator(s)/trial site(s) fail(s) to: follow the procedures written in the approved protocol and comply with national and/or international guidelines, statutory provisions, institutional guidelines, or rules or procedures for the conduct of human research;

Scope

This guideline is applicable to all the research projects and clinical trials approved by IECBHR, Medical College Baroda.

Responsibility

Chairperson:

- To ensure appropriate corrective and preventive action for non-compliance reported.
- To ensure corrective actions are informed to the Researcher as applicable.
- For cause visit/unplanned visit to the study site for review of actions taken by the researcher for non-compliance reported.

Member Secretary/ EC coordinator:

- Documentation of corrective and preventive action for non-compliance reported.
- Communication Researcher/investigator for IECBHR, Medical College, Baroda, opinion or feedback on non-compliance reported.
- To document the facility, report for the site visit conducted by IECBHR, Medical College, Baroda.
- Filing of records at IECBHR, Medical College Baroda office.

Detection of Protocol Deviation/ Non-Compliance/ Violation

Protocol Deviation/Non-Compliance/Violation may be detected in one of the following ways (but not limited to those listed below):

- The Principal Investigator (PI) himself/herself may forward protocol deviation/non-compliance/violation reports to inform the IECBHR, Medical College Baroda

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- Protocol deviation/ non-compliance/ violation detected by IECBHR, Medical College Baroda member.
    a. after due enquiry of the PI/study site or
    b. during monitoring of the project at the trial site or
    c. during scrutinizing annual/ periodic reports/ SAE reports/ any other communication received from the Investigator/ trial site.
- Allegation of protocol deviation/ non-compliance/ violation reported to the IECBHR, Medical College Baroda:
  Communication/ complaint/ information received from a research participant who has been enrolled or any individual who has been approached for enrollment.
- Any report/ communication brought to the notice of the Member Secretary/ Chairperson of IECBHR, Medical College, Baroda.

Management of Protocol Deviation/ Non-Compliance / Violation

- Upon receipt/notice of non-compliance, its impact (i.e., impact of non-compliance on patient rights, safety, and well-being) shall be assessed by the Member Secretary in consultation with the Chairperson. This discussion can be in person or by phone.
    - Followed by the seriousness of the violation/non-compliance decision shall be taken to
    - Call an expedited meeting of members or
    - Can be discussed telephonically with other relevant members or
    - Notification to IECBHR, Medical College Baroda is sufficient, and no further action is expected from PI/Site.
- If reported/observed non-compliance is related to SAE or AE, then clinician members must be mandatorily contacted to take their opinion. If it is related to legal and social aspects, then respective IECBHR, Medical College Baroda members must be contacted for their opinion.
- In case an expedited meeting is required, the Member Secretary plans an unscheduled meeting for discussion on reported non-compliance with available members; however, ensuring quorum is not necessary. Members related to the type of non-compliance should be part of the meeting. During the meeting, non-compliance and its management shall be discussed in detail. If IECBHR, Medical College Baroda, requires further information related to non-compliance, it shall be asked from the PI/Site. The recommendation/suggestion shall be given via a recommendation or observation letter to the PI.
- If required, IECBHR members can plan for a cause assessment visit at the study site.
- Discussion during the meeting shall be documented in the form of minutes of the meeting, and the chairperson will approve the same.

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- The PI shall follow up to get responses on the submitted suggestion or observation letter.
- If an unscheduled meeting is not required for non-compliance observed at the site during monitoring, then it shall be notified and discussed in the subsequent regular meeting of the ethics committee.
- If non-compliance is identified during a member's facility visit to the study site, it shall be discussed with an authorized signatory available at the site, and an appropriate response shall be obtained. The member must convey this information to the Member Secretary or the Chairperson (by telephone or during a meeting, depending on the seriousness of the non-compliance).
- IECBHR, Medical College Baroda should maintain a record of all such non-compliance notifications or reports from the study site, along with actions suggested and taken by the study site.

IECBHR, Medical College Baroda, Decision Making and Action

- Direct the PI to ensure that deviations/non-compliances/violations do not occur in the future and that IECBHR recommendations are followed.
- Reasonable time shall be given to the PI to respond to IECBHR, Medical College Baroda's observation.
- Enlist measures that the PI would undertake to ensure that deviations/non-compliance/violations do not occur in the future.
- Call for additional information.
- Suspend the study until additional information is made available and scrutinized based on the seriousness of non-compliance.
- Inform the Institutional Head/Dean/Medical Superintendent.
- Revoke approval of the current study.
- Inform DCGI or other relevant regulatory authorities.
- Refuse to review subsequent applications from an investigator cited for non-compliance for a specified duration of time.
- Any other action considered appropriate by the IECBHR for safeguarding the interests of the research participants in the current trial or future trials.
- **Note:** All IECBHR, Medical College Baroda records (minutes of meetings, decisions, etc.) shall be archived as per the archiving procedure.

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21. MONITORING OF ONGOING PROJECT

The Committee will monitor approved projects to ensure compliance with the approved protocol. In doing so, it can call for and discuss information on any relevant aspect(s) of the project with the investigator(s) at any time. In particular, the Committee may require investigators to provide interim reports on stipulated dates and a final report at completion of the study. Continuing approval of the research is subject to the PI submitting an interim report by the specified date [if required].

1. The Committee will require the following information in the report:

- ✓ Progress to date, outcome/ results, and publications/ presentations in the case of completed
- ✓ research
- ✓ Maintenance, security, confidentiality, and integrity of records and data
- ✓ Compliance with the approved protocol
- ✓ Compliance with any conditions of approval
- ✓ Changes to the protocol or conduct of the research
- ✓ Changes to the personnel of the PI/other investigators and
- ✓ Serious Adverse Events or complaints relating to the project

2. The Committee may adopt any additional appropriate mechanism(s) for monitoring, as deemed necessary, such as: random inspections of research sites, data, and signed consent forms; interviews, with the prior consent of research participants, etc, to ensure:

- ✓ Participant's right, safety, and well-being in the project
- ✓ Adequacy and continuity of the informed consent process
- ✓ Any cause assessment needed for non-compliance(s)
- ✓ Opportunities are identified for any improvements and their appropriate actions

3. For the same, the Committee may identify a few members to oversee respective projects. These members, after their visit, will be required to submit their report, which includes:

- ✓ If investigational product accountability is adequately controlled
- ✓ Verify that the PI follows approved protocols and approved amendments
- ✓ Whether all SAEs are appropriately reported within the time as per the current regulations
- ✓ Documentation of project files
- ✓ Any unreported protocol deviation or violation
- ✓ Adequacy and continuity of the informed consent process

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4. The Committee will require, as a condition of approval of each project, that investigators immediately report anything which might warrant review of ethical approval of the protocol, including:

- ✓ Proposed changes in the protocol
- ✓ Any unforeseen events that might affect the continued ethical acceptability of the project,
- ✓ New information from other published or unpublished studies which may have an impact on the continued ethical acceptability of the trial, or which may indicate the need for amendments to the trial protocol.

5. The Committee also requires, as a condition of approval of each project, that investigators inform the IECBHR, giving reasons, if the research project is discontinued before the expected date of completion, and that the investigators comply with the approved protocol.

6. Where the Committee is satisfied that circumstances have arisen such that a research project is not being or cannot be conducted in accordance with the approved protocol, it may withdraw its approval. In such circumstances, the Committee will inform the PI and the Head of the Institute that the research project will be discontinued, suspended, or any other necessary steps will be taken.

7. In determining the frequency and type of monitoring required for approved projects, the Committee will consider the degree of risk to participants in the research project, depending upon the individual project.

8. The Committee will ensure that adequate information about the rights and responsibilities of research participants is displayed at relevant sites, too.

9. All such activities undertaken by the Committee for monitoring shall be documented and recorded in a separate file in the IECBHR Office. It may also keep soft copies of random Audio-Visual Informed Consent Processes in the IECBHR Office.

22. FINANCIAL DEALINGS BY IECBHR

Incomes and Expenditures towards the functioning of the committee

1. Standard fees will be charged for the review of research proposals submitted by the investigators to IECBHR.
2. Research proposal review fees is to be deposited in favour of 'INSTITUITIONAL ETHICS COMMMITTEE FOR BIOMEDICAL AND HEALTH RESEARCH VADODARA" having PAN No: AABTI0810K, payable at AXIS BANK, Sayajigunj, Vadodara (Account no. 921020029483983).

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3. No member is expected to receive any remuneration, in either cash or kind, from any investigator or industry involved in the research proposal to be reviewed. Conflict(s) of Interest, if any, will be declared prior to review as mentioned earlier, and if required, depending upon the Conflict of Interest, will not be part of the decision-making during the review process.
4. The IECBHR will bear expenses towards the conduct of the meeting(s).

Management of IECBHR funds

Management of cash flow is in the hands of the Member Secretary with prior approval from the Chairperson and EC. The fund of IECBHR can be utilized for below activities:

1. Office development of IECBHR
2. As an honorarium payment to the IECBHR staff
3. To purchase equipment (LCD projector, Printer, Laptop, Hard disc etc) and logistics (register, stationery) for the IECBHR office
4. To organize a conference on ethics
5. To attend ethics/research-related national or international conference/CME/training
6. For the provision of refreshments to the members during the meeting
7. To look after other expenses like postal handling, courier charges etc.,
8. Any other activity that IECBHR members feel is necessary for the development of IECBHR

- If the PG student submits the protocol in the first year of residency the applicant fee is Rs.3000 (Incl. TDS) per protocol and if delayed fine increases every monthly by Rs.500. If the cheque submitted for protocol submission bounces, it is to be noted that the applicant has to pay double the amount (Rs.3000 + Rs.3000). Only after the clearance of the next cheque, the certificate of approval will be issued. If the study is funded, the applicant's fee will be Rs. 15,000.
- When PI is from an outside institute, fees of Rs. 20,000 for sponsored research and Rs. 5000 for non-sponsored research are to be submitted.
- On receiving a successful payment, the PI shall be issued a receipt of payment.
- It does not ensure that approval shall be definitely granted. Any protocol rejected shall be reviewed; no fee will be refunded.

Honorarium to the members

The honorarium issued by the committee to its members shall be issued in the form of a cheque only and not in cash, and the details of the same are as follows:

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Sr. No.	Members	Honorarium/protocol*
1.	Chair-person of Ethics Committee	₹ 200
2.	Member secretary of Ethics Committee	₹ 200
3.	Chair-person of Committee (LRAC)	₹ 200
4.	Member Secretary of Scientific Committee (LRAC)	₹ 200
5.	Other members (lay person, clinician, legal expert, NGO, social worker etc	₹ 150
6.	Clerk	₹ 100
7.	Servant	₹ 50

*If the study is funded from our institute with an applicant fee of Rs. 15,000, the Honorarium will be 5 times the above-mentioned honorarium.

*When PI is from an outside institute with fees of Rs. 20,000 for sponsored research, the Honorarium will be 6 times the above-mentioned honorarium.

If the committee feels the need of a clinical expert's opinion, he/she will be given an honorarium of ₹. 1000 (per visit). Reimbursement of travelling expense (₹. 500) for attending the IECBHR meetings will be given to persons not affiliated with Medical College, Baroda.

23. ADMINISTRATIVE OFFICE OF IECBHR

- It shall be the duty of the Appointing Authority to provide a separate office and record room for the regular functioning of the committee.
- A separate room within the institution shall be identified for meeting(s) of the committee.
- Office of the IECBHR shall be well equipped with tables, chairs, a computer, a printer, a telephone, an internet facility, shredders, and steel lockable cupboards for its efficient functioning. Any additional requirements shall also be fulfilled as needed.
- Preferably, a separate room shall be provided to facilitate the archival and retrieval of documents. Regular pest control measures shall be undertaken in accordance with regulatory requirements, with ensured fire safety measures. Steel lockable cupboards shall be used to store the documents.

Communication with IECBHR office

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- Any new project shall be submitted to the IECBHR office. This includes application, protocol, and informed consent documents in English and in vernacular languages.
- Apart from PI, all communications to all other stakeholders [Appointing authority/ Regulatory Authority], etc. shall be made via email/ hard copy.
- Principal Investigator shall be required to update/ communicate IECBHR for any amendments, adverse events, serious adverse events, 1st recruitment in a new trial, sponsor's site visit report, interim/ yearly updates, compliance with monitoring visits, etc., in one hard copy.

24. RECORD KEEPING AND ARCHIVAL

- All efforts will be made to keep the records under lock and key for maintaining security, integrity, and confidentiality using lockable cupboards
- Access to the keys of locked cupboards will be available only to authorized persons.
- One hard copy of all the research projects [including amendments, SAE reports, etc.] will be maintained.
- The physical records will contain a copy of the application, any relevant correspondence between the applicant, other stakeholders, and the Committee, other material used to inform potential research participants, and all approved documents.
- All documents of the IECBHR, including applications, membership, minutes of meetings, and correspondence, will be kept confidential in accordance with applicable rules/ guidelines.
- Apart from the above, archival would also include monitoring reports, copies of communication with other stakeholders, self-assessment documents, and any other relevant communication/ record depicting IECBHR work.
- All relevant records about research projects will be held for at least a period of 5 years, from the time of closure of the research project, to allow for future reference and in compliance with regulatory requirements [period to vary depending on prevalent regulatory requirements].
- To ensure confidentiality, all documents provided to IECBHR members, which are no longer required, will be disposed of securely.

25. PERIODIC SELF-ASSESSMENT

- Every time a new committee is constituted/ re-constituted, the members will undergo initial training on ethics in clinical research, good clinical practices, and SOPs. One training every year at a minimum should be acquired by each member as part of a continuous development program.

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- All in-house trainings will be followed by an evaluation of their effectiveness with a test. As indicated by the results, retraining shall be undertaken for members found deficient. Apart from this, the Member Secretary will be responsible for the assessment of all IECBHR members with a self-assessment exercise at least once a year. During such an exercise, if the performance is not found satisfactory, the member will be subjected to training again and re-evaluated.
- Adequate steps will be taken to ensure continuous training of the members to evaluate the working of the Ethics Committee as a whole unit.
- Based on the assessment report, corrective measures [if any are suggested] will be implemented, depending upon their feasibility.

26. ANNUAL REPORT

The Member Secretary will make a yearly activity report for submission to the Head of the Institute that will include the following elements:

- ✓ Number and dates of the IECBHR meetings of the full committee
- ✓ Membership changes
- ✓ Number of SAE subcommittees and any other subcommittees (as applicable)
- ✓ Number and type of proposals (Pharma/ Government sponsored/ Registry/ investigator-initiated collaborations with foreign universities or international organizations) reviewed in a year, status of each study proposal, whether completed/ ongoing /terminated
- ✓ Number of approvals for full board review/expedited review with decisions
- ✓ Brief details about workshops, training programmes, and other activities undertaken by the IECBHR and those attended by IECBHR members
- ✓ Monitoring reports [if any relevant]
- ✓ Self-assessment report(s)
- ✓ Yearly audit of income and expenditure
- ✓ Any other relevant matter/ suggestions
- ✓ Ethics Committee Members

27. SUMMARY:

All investigators (e.g. PG Guide and Student) of S.S.G. Hospital and Medical College Baroda, Vadodara have to comply with the Standard Operating Procedure (SOP) during Protocol Submission, Protocol Review Meeting, Research Execution, and Publication Phase.

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The protocol submitted will pass through the Scientific committee (Local Research Committee) meeting first; once approved, it will be sent for ethics committee meeting approval (with a gap of 2 weeks in between).

- As per the updated ICMR Ethical Guideline for Biomedical Research (Version Year 2017), all HODs and Investigators/ Students involved in any academic research/Clinical Trial have to ensure compliance with the Ethical Guideline for Biomedical Research during all academic research protocol preparation, conduct of research, and publication/s.
- IECBHR is entrusted not only with the initial review of the proposed research protocols before initiation of the projects, but also has a continuing responsibility of regular monitoring for the compliance of the ethics of the approved proposals till completion.
- Data and findings of PG Research and/or Academic Research can be demanded anytime by the IECBHR.
- On completion of PG Research/ Academic Research, a complete study report with data (e.g., softcopy of dissertation on a CD/DVD) needs to be submitted to the Central Library of Medical College, Baroda, while maintaining confidentiality of Patient Identity.
- If any Serious Adverse Drug Reaction Event (SAE) is identified during research, it needs to be informed to IECBHR by filling up Suspected Adverse Drug Reaction Reporting Form of PPI (Pharmacovigilance Program of India) for voluntary reporting of Adverse Drug reaction by Healthcare Professionals for Serious AEFI Case notification Form and It's Copy may be submitted to ADR Monitoring Centre at Pharmacology Department.
- The protocol is to be presented at the respective departments, and approval from the head of the department is mandatory for submission of the protocol to IECBHR/LRAC (Local Research Advisory Committee).
- Rules of the M.S. University of Baroda and NMC guidelines for MD/MS will be applicable for Final Eligibility to appear in PG Examination.
- In any case of Plagiarism, deviation from the ICMR Ethical Guideline for Biomedical Research (Version Year 2017) or deviation from the approved protocol will be identified, and it shall be seriously considered.
- For submitting a research protocol to the IECBHR, a participant has to pay a standard fee of Rs. 3000 per protocol. The payment is to be made in the form of a cheque. If the cheque submitted for protocol submission bounces, it is to be noted that the applicant has to pay double the amount (Rs. 3000 + Rs. 3000). Only after the clearance of the next cheque, the certificate of approval will be issued. If the study is funded, applicant fee will be RS. 15000.
- All PG students (admission year 2025 onwards) will have to complete registration and submission of assignments of the online research course (BCBR) by the end of their 1st year. If the PG student submits the protocol in the first year of residency, the applicant fee is Rs. 3000 per protocol, and if delayed, the fine increases every month by Rs. 500.

INSTITUTIONAL ETHICS COMMITTEE FOR BIOMEDICAL AND HEALTH RESEARCH,VADODARA

INSTITUTIONAL ETHICS COMMITTEE FOR BIOMEDICAL AND HEALTH RESEARCH,VADODARA

✓ ETHICS COMMITTEE (IECBHR) MEMBERS

NAME	CONTACT NUMBER	EMAIL ID
Dr. Sandeep Shah	9824060693	sandeephshah@hotmail.com
Dr. Sangita Patel	9586835623	sangita-psm@yahoo.co.in
Dr. Archana Gandhi	9376224817	draug20@gmail.com
Dr. Neeta Kanani	9825321811	neetakanani2003@gmail.com
Dr. Sameer Kacheriwala	9898930339	dr.samir_k@yahoo.com
Dr. Rinki Shah	9879544027	rhs2252011@yahoo.com
Ms. Jayna Bhavin	9428800188	jayana2683@yahoo.co.in
Mr. Sameer Parmar	9426376848	samir.p.msw@gmail.com
Mrs. Shubhangi Puranik	8866491750	shubhangigandhi@yahoo.com
Ms. Smita Maniar	9825041649	smita.maniar@deepakfoundation.org
Ms. Shruti Kantawala	9898516439	Shruti.kantawala-fn@msubaroda.ac.in

✓ SCIENTIFIC COMMITTEE (LRAC) MEMBERS

NAME	CONTACT NUMBER	EMAIL ID
Dr. Jivraj Damor	7622852275	jivrajdamor45@gmail.com
Dr. Kalpita Shringarpure	9824673141	kshringarpure@gmail.com
Dr. R N Daveshvar	9427322493	med.sup.ssgh@gmail.com
Dr. Sangita Patel	9586835623	sangita-psm@yahoo.co.in
Dr. Jaya Pathak	9824211723	docjayap@gmail.com
Dr. Maitri Shah	9426370499	maitrishah.gynec@gmail.com
Dr. Niyati Trivedi	9998961097	dr.natrivedi@gmail.com
Dr. Sejal Thakkar	9824097310	drsejal@dermat.co.in
Dr. Kavita Lalchandani	9274586809	lalchandanikavita@yahoo.in
Dr. Rahul Gupta	9824403936	docot.rahul25@gmail.com

INSTITUTIONAL ETHICS COMMITTEE FOR BIOMEDICAL AND HEALTH RESEARCH.VADODARA

INSTITUTIONAL ETHICS COMMITTEE FOR BIOMEDICAL AND HEALTH RESEARCH.VADODARA

ANNEXURES

ANNEXURE I - IECBHR MEMBER CV TEMPLATE

CURRICULUM VITAE:

NAME:

QUALIFICATION

CONTACT NUMBER:

EMAIL:

Role in IECBHR: **Date:**

Educational Qualification:

Professional Affiliations:

Personal Information

Birth Date/Age:

Sex:

Nationality:

Residential Address:

Research and Training Experience relating to IECBHR Committee:

Self-Declaration:

I do here by declare that the information given in this record is true to do the best of my knowledge and belief.

Signature with Date: _____ Place: Vadodara

INSTITUTIONAL ETHICS COMMITTEE FOR BIOMEDICAL AND HEALTH RESEARCH,VADODARA

INSTITUTIONAL ETHICS COMMITTEE FOR BIOMEDICAL AND HEALTH RESEARCH,VADODARA

ANNEXURE II - IECBHR MEMBER APPOINTMENT LETTER TEMPLATE

APPOINTMENT LETTER

Letter Ref. No.: Date:

From,

The CHAIRPERSON-IECBHR,

Medical College Baroda and S.S.G Hospital

Raopura, Vadodara

To,

Sub: Appointment as a _____ Member of Institutional Ethics Committee for Biomedical and Health Research (IECBHR)

Dear Sir/Madam,

On behalf of Medical College Baroda and S.S.G. Hospital, Vadodara, I hereby appoint you as _____ Member of Institutional Ethics Committee for Biomedical and Health Research (IECBHR) of this institute for the period of __/__/____ to __/__/____. Kindly send your written acceptance letter in the given format along with your short curriculum vitae.

Yours sincerely,

Signature:

Name:

Seal:

INSTITUTIONAL ETHICS COMMITTEE FOR BIOMEDICAL AND HEALTH RESEARCH, VADODARA

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ANNEXURE III - IECBHR MEMBER ACCEPTANCE LETTER TEMPLATE

Date:

To,

The CHAIRPERSON IECBHR,

Medical College Baroda and S.S.G. Hospital,

Raopura, Vadodara

Sub: Consent to be a Member of IECBHR

Dear Sir/Madam,

I give my consent to become a _____ Member of Institutional Ethics Committee for Biomedical and Health Research (IECBHR) of Medical College Baroda and S.S.G. Hospital, Vadodara. I shall regularly participate in the IECBHR meeting to review and give my unbiased opinion regarding the ethical issues.

I shall not keep any literature or study related document with me after the discussion and final review.

I shall maintain all the research project related information confidential and shall not reveal the same to anyone other than project related personnel. I herewith enclose my CV.

Thanking you,

Yours sincerely,

Signature:

Date:

Name:

Mobile No.:

Email:

INSTITUTIONAL ETHICS COMMITTEE FOR BIOMEDICAL AND HEALTH RESEARCH,VADODARA

INSTITUTIONAL ETHICS COMMITTEE FOR BIOMEDICAL AND HEALTH RESEARCH,VADODARA

ANNEXURE IV- DECLARATION OF CONFLICT OF INTEREST and CONFIDENTIALITY

Date:

To,

The CHAIRPERSON- IECBHR,

Medical College Baroda and S.S.G. Hospital,

Raopura, Vadodara

Sub: Confidentiality/ Conflict of Interest Agreement

Dear Sir,

Hereby, I declare my conflict of interest and confidentiality

I shall not keep any literature or study related document of IECBHR of Medical College Baroda and S.S.G. Hospital, Vadodara, with me after the discussion and final review.

I shall maintain all the research related information of IECBHR of Medical College and Hospital, Vadodara; confidential and shall not reveal the same to anyone other than project related personnel.

Conflict of Interest:

I do not have any Conflict of Interests.

Attestation:

I attest that my answers are true, that I have disclosed all conflicts of interest in accordance with IECBHR conflicts of interest policy and will not bias, or in any way impact the integrity of, my work.

Thanking you,

Yours sincerely,

Signature:

Date:

Name:

INSTITUTIONAL ETHICS COMMITTEE FOR BIOMEDICAL AND HEALTH RESEARCH,VADODARA

INSTITUTIONAL ETHICS COMMITTEE FOR BIOMEDICAL AND HEALTH RESEARCH,VADODARA

Sir Sayajirao General Hospital
સર સયાજીરાવ જનરલ હોસ્પિટલ
SSGH

ANNEXURE V - AGENDA TEMPLATE

Date:

AGENDA OF IECBHR MEETING

An IECBHR meeting (Meeting Number) is scheduled on (Date) at (Venue) from (Time) onwards.

Agenda 1:	Leave of absence if any
Agenda 2:	Confirmation of minutes of the previous meetings and matters arising from previous minutes.
Agenda 3:	Discussion of new protocol submission/Amendment of previously approved protocol and action items (voting on protocols, deliberations on serious adverse events, periodic and annual reports, and final reports)
Agenda 4:	Anything else with the permission of the CHAIRPERSON.

Signature

Member Secretary

IECBHR

INSTITUTIONAL ETHICS COMMITTEE FOR BIOMEDICAL AND HEALTH RESEARCH,VADODARA

INSTITUTIONAL ETHICS COMMITTEE FOR BIOMEDICAL AND HEALTH RESEARCH,VADODARA

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ANNEXURE VI - MTNUTES OF MEETING TEMPLATE

Date:

MINUTES OF IECBHR MEETING (meeting number and date)

The following members of the committee were present in the meeting

1.
2.
3.

Agenda 1:	Leave of absence if any
Agenda 2:	Confirmation of minutes of the previous meetings and matters arising from previous minutes ***Passed and seconded by***
Agenda 3:	Discussion of new protocol submission/ Amendment of previously approved protocol and action items (voting on protocols, acceptance of serious adverse events periodic and annual reports, and final reports) ***1.*** ***2.*** ***3.***
Agenda 4:	Anything else with the permission of the CHAIRPERSON. ***Comments:***

Signature

Chairperson/Member Secretary

IECBHR

INSTITUTIONAL ETHICS COMMITTEE FOR BIOMEDICAL AND HEALTH RESEARCH,VADODARA

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ANNEXURE VII - VOTING SHEET TEMPLATE

Voting Sheet

IECBHR Meeting No.: Date:
Title:
IECBHR No.: Protocol No.: PI:

Name of Member	Role of Member	COI* Yes/No	Vote Approved/Rejected/Not applicable/Revision		Signature Date
Dr. Sandeep Shah	Chairperson	☐ Y ☐ N	☐ Approved ☐ Revision	☐ Rejected ☐ Not applicable	
Dr. Sangita Patel	Member Secretary	☐ Y ☐ N	☐ Approved ☐ Revision	☐ Rejected ☐ Not applicable	
Dr. Archana Gandhi	Clinician	☐ Y ☐ N	☐ Approved ☐ Revision	☐ Rejected ☐ Not applicable	
Dr. Neeta Kanani	Researcher	☐ Y ☐ N	☐ Approved ☐ Revision	☐ Rejected ☐ Not applicable	
Dr. Rinki Shah	Clinician	☐ Y ☐ N	☐ Approved ☐ Revision	☐ Rejected ☐ Not applicable	
Dr. Sameer Kacheriwala	Clinician	☐ Y ☐ N	☐ Approved ☐ Revision	☐ Rejected ☐ Not applicable	
Ms Jayna Bhavin	Legal Expert	☐ Y ☐ N	☐ Approved ☐ Revision	☐ Rejected ☐ Not applicable	
Mr. Sameer Parmar	Social Scientist	☐ Y ☐ N	☐ Approved ☐ Revision	☐ Rejected ☐ Not applicable	
Mrs. Shubhangi Puranik	Layperson	☐ Y ☐ N	☐ Approved ☐ Revision	☐ Rejected ☐ Not applicable	
Ms. Smita Maniar	NGO Representative	☐ Y ☐ N	☐ Approved ☐ Revision	☐ Rejected ☐ Not applicable	
Ms. Shruti Kantawala	Food and Nutritionist	☐ Y ☐ N	☐ Approved ☐ Revision	☐ Rejected ☐ Not applicable	

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COI*- Conflict of Interest to be declared before the start of meeting and member to leave the meeting during decision making.

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