



NATIONAL ASSESSMENT AND ACCREDITATION PROJECT (NAAC)

1. Title of the committee : Institutional Ethical Committee and Intellectual Property Right Cell

2. Details of committee members:

Sr. No.	Name	Designation in committee
1	Dr. P. U. Vaishnav	Chairperson
2	Dr. B.H.Shelat,	Member secretary (Co-Chairperson)
3	Mrs. Paras Savaliya	Member secretariat
4	Mr. Virendra Jain,	Member secretariat
5	Dr. Sachin Shukla,	Basic medical scientist
6	Dr. S. G. Parekh	Statistician
7	Shree Umesh Dhagat	Legal experts
8	Shree Pranav Dhagat	One representative
9	Shree Anup Desai	Philosopher/ theologian/ ethicist
10	Shree Prashantbhai Bhatt	Lay person
11	Mrs. Arpita Vaidhya Mrs. Dhara vyas Mr. Kailash Nagar	Member

Details Of IPR Cell Members :

Sr. No.	Name	Designation in committee
1	Dr. P. U. Vaishnav	Chairperson
2	Dr. B.H.Shelat,	Vice Chairperson
3	Mrs. Paras Savaliya	Member secretary
4	Mr. Virendra Jain	Coordinator
5	Shree Umesh Dhagat	Legal experts
6	Dr. S. G. Parekh	Statistician
7	Shree Prashantbhai Bhatt	Layman person/Community Representative
8	Dr. Sachin Shukla, Mrs. Arpita Vaidhya Mrs. Dhara vyas Mr. Kailash Nagar	Member



3. GUIDING PRINCIPLES OF IEC

- If the serious events are a result of breach of protocol (Intervention), the committee may recommend disciplinary action against those who are responsible while allowing the continuation of the study without changes in the protocol.
- If the research intervention has a reasonable possibility of being the cause of the serious events in question, the study must be put on hold with a systematic reversal, safeguarding the health and well-being of the subject while the cause is being determined. After the cause is identified, the study may continue with appropriate changes in the study protocol or the committee may recommend termination as appropriate.
- If statistical significance of endpoints has been reached and meaningful inferences can be drawn, termination of the study should be considered.
- If the cause of events cannot be ascertained and the seriousness of adverse events is such that continuation of the study may pose a significant threat to life or may cause permanent disability, the committee is obliged to recommend termination.
- If the sponsor and the Investigators desire termination, the same may be recommended noting the specific reasons for termination as provided by them.

4. ROLES AND RESPONSIBILITIES OF THE IEC AND ITS MEMBERS

The Committee shall:

- Provide independent and competent review of all ethical aspects of research proposals.
- Review research proposals submitted to it within a reasonable time and document its views in writing to the applicant(s).
- To assist in the development and education of a research community responsive to local health care requirements.
- Safeguard the dignity, rights, safety, and well-being of all study participants and communities paying special attention to investigations that may involve vulnerable participants.
- Request the Investigator(s) to explain any aspect of the study that may require



- Personal appearance at its Committee meeting.
- Provide guidance to the Investigator on all aspects of the welfare and safety of research participants.
- Ensure scientific soundness of the proposed research.
- Make available acceptable standard format accepted by the committee for submissions of research proposals.

GENERAL ROLE OF All MEMBERS

- The members' (including Chairperson and Secretary) primary responsibilities will be determining the scientific and ethical validity of the research and the protection of the safety, rights and confidentiality of the research subjects.
- Participate in the IEC meeting.
- Review and discuss research proposals assigned for evaluation.
- Review progress reports and monitor ongoing studies.
- Monitor site for adverse events and recommend appropriate action(s).
- Maintain confidentiality of the documents and deliberations of the IEC meetings.
- Declare conflict of interest, if any - Such disclosure shall be sufficiently detailed and timely to allow the IEC Administration to transfer the project to another IEC member or allow time for an alternate member to attend the IEC meeting to meet quorum.
- The IEC member/consultant shall evaluate whether a conflict of interest exists, and he/ she shall disclose any identified conflicts to the IEC at the next IEC meeting. If an IEC member discovers that he/she has a conflict of interest during the conduct of a study over which the IEC provides oversight, the IEC member/consultant shall report the conflict to the IEC. Other IEC members shall cooperate with the IEC and other officials in their review of the conflicts of interest issues and shall comply with all requirements of the IEC.
- Carry out work delegated by the Chairperson, Co-Chairperson and/or Member Secretary.
- Participate in continuing education activities on ethics and research.



- Provide information and documents related to training obtained in ethics and research to the IEC secretariat.

ROLE OF CHAIRPERSON

- Chair the meetings
- Facilitate and participate in IEC educational activities
- Keep abreast of regulations and policies governing IEC review of research and the conduct of human subjects research
- Appoint IEC members

ROLE OF SECRETARY AND THE SECRETARIAT

- Organization of an effective and efficient tracking procedure for each proposal received.
- Preparation, maintenance and distribution of study files.
- Organization of regular IEC meetings.
- Preparation of the agenda and the minutes of the meetings.
- Maintenance of the IEC records and archives.
- Communication with IEC members and Investigators.
- Arrangement of trainings/workshops for personnel and IEC members.
- Receipt of IEC processing fees.
- Maintain financial records which includes details of IEC fee for their services, honorarium payment to members and other expenses incurred.
- Prepare for financial audits and maintain the financial audit reports.
- Organizing the preparation, review, revision and distribution of SOPs
- Providing the necessary administrative support for IEC related activities to the Chairperson of the Committee.
- Correspondence with Chairperson and IEC members, with Investigator and with Regulatory Authority.



ROLE OF IEC SECRETARIAT

- Organizing an effective and efficient tracking procedure for each proposal received.
- Preparing, maintaining and distributing study files.
- Providing necessary administrative support for IEC related activities to the Member Secretary, IEC.
- Receiving IEC processing fees and issuing official receipts for the same.
- Making the pre and post arrangements of IEC meetings.
- Filing study related documents i.e., Archiving and maintaining the study files.
- Preparation for accreditation, audits
- Participate in the development, revision and subsequent implementation of SOPs.

5. OPERATIONAL MECHANISM PROCEDURE FOR MEETING

- Meetings shall be scheduled approximately twice a year based on the load of the proposals. Exact meeting date shall be notified at least 3 weeks in advance so that all members can make themselves available for the purpose.
- The Secretary shall be the convener with responsibility for organizing the meetings, maintaining the records, laying out the agenda and communicating with all concerned for the meeting. He/she shall prepare the minutes of the meetings after incorporating the comments of all the members and get it approved by the Chairperson before communicating decision of the IEC to the Investigators.

The meetings must demonstrate and document the following deliberations:

- The presence of full quorum
- Declaration of conflict of interest
- Confirmation of Last meeting's Minute



- Details of risk-benefit assessment decision of review (initial, continue review) of study
- Any changes requested
- Non-compliance
- Monitoring sites, reports and Corrective and Preventive Action (CAPA) plan
- Any other relevant discussions/updates.

PLAN OF ACTIVITIES (BEFORE MEETING)

- IEC Secretary prepares the agenda a week prior to the IEC meeting and circulates the agenda via email
- Schedule studies on the agenda. The number of items is based on available expertise (members and consultants), urgency, order of submission to the IEC and IEC workload.
- Secretary prior to the meeting will identify IEC members who may have a conflict of interest due to their participation as key personnel on a current or proposed research project.
- An IEC member who has a conflict of interest with regard to a research project that will be reviewed at a convened IEC meeting must notify the IEC office of the conflict prior to the meeting.
- Once the IEC office receives notice of refuse, the IEC Secretary will seek an alternate IEC member to join the meeting for the review of that project if necessary to meet quorum.
- The copies of the protocols/documents shall be sent to the IEC members by either electronic mail (in case of electronic submission of protocols) or by courier of hard copies and CD (soft copy) preferably 10 days in advance of the scheduled meeting.

QUORUM REQUIREMENTS

- All research projects for approval by the full board of the IEC shall be reviewed at convened meetings at which a majority of the members of the IEC are present.
- The presence of the following five (5) members is required to form part of the quorum without which a meeting cannot be convened and a decision regarding



the project cannot be taken. (Schedule Y) For review of each protocol, the quorum of Ethics Committee should be at least one members from the following representations:

- 1) Basic medical scientists, 2) Clinician, 3) Legal expert, 4) Lay person from the Community 5) Social scientist or representative of NGO or Philosopher or ethicist or theologian or similar person

CONDUCT OF MEETING

- At the beginning of each convened IEC meeting, the IEC Chair or designee will ask the members if anyone has a financial or non-financial conflict of interest with regard to any of the research projects that will be reviewed at the meeting. The IEC Chair or designee will announce that members with a conflict of interest must excuse themselves from deliberation and decision on that research protocol. Regular meetings shall be held at least quarterly.
- Research involving vulnerable populations (vulnerable to coercion or undue influence) will be placed on the agenda only when at least one individual (IEC member or independent consultant) who is knowledgeable about or experienced in working with the population will participate in the meeting (or an independent consultant has been obtained). If expertise with a specific vulnerable population is needed but not available from the IEC members, an expert member will be obtained or the item will be scheduled for a later meeting when expertise is available.
- Secretariat shall obtain signatures on Confidentiality, Conflict of Interest, Agreement, Attendance etc.
- Chairperson will initiate the meeting and Secretary shall discuss the minutes of the previous meeting of IEC as well as major issues/policies discussed in minutes of the other IEC and present the agenda for the current meeting
- The IEC shall inform Investigators to attend the full board meeting related to their studies, and clarify doubts, if any
- IEC completes the adequate review of the research studies submitted. The committees will review new studies, amendments, annual /continuing review of ongoing studies, any other documents and assess final reports of all research activities through a scheduled agenda



- The decisions shall only be made at meetings where a quorum is present.
- Only IEC members who attend the meeting will participate in the decision. Decisions will be arrived at through consensus/unanimous opinion amongst the members of IEC.
- The decision-making is thus concerned with the process of deliberating and finalizing a decision. IEC will approve when all participating members will give consensus and quorum will be present, without quorum the decision cannot be made.

AFTER THE MEETING

- The Secretary shall compile the proceedings of IEC meeting. The minutes of the meeting will be compiled and sent to Chairperson for review within 7 working days.
- Once finalized, the IEC meeting will be signed by Member Secretary and Chairperson and shall be circulated to all IEC members within 15 days.
- The minutes of the IEC meeting will be ratified in the subsequent IEC meeting
- Secretary shall email the minutes of the meeting (MoM) to IEC members after obtaining approval from the chairperson.
- Place the original version of the minutes in the minutes file and copy of the minutes shall be filed in the corresponding research protocol file.
- A copy of decision letter along with all project related correspondence shall be placed in the appropriate project files and communicated to investigators
- The Secretary shall communicate IEC decisions to the Investigators in writing.

6. REVIEW OF POLICY

- The chairperson is authorized to make recommendations to the committee about changes in the policy.
- The policy will be reviewed every 2 years
- Functional modalities of IPR cell



- The cell functions autonomously from the premises of IEC.
- Twice a year meetings are held for IPR related issues.
- The IPR cell acts as the interface between the Principal investigator (PI) and the copyright attorney.
- IPR awareness Workshops/ Conferences/ Short term Courses are organized annually.

7. LIST OF RECORDS TO BE MAINTAINED IN COMMITTEE

- Meetings register of IEC and IPR Cell: Agenda and minutes of the meeting and its ATR.
- Rule and regulation/Policy/Circulars file
- Report file :
 - List of thesis submitted in Library (Departmental research and PG Students research project)
 - IPR Cell activity reports

Mrs. Paras Savaliya

Member secretariat
IEC and IPR Cell
Date: 27th August 2018

PRINCIPAL