EO- 484547/2018/CP

ALL INDIA INSTITUTE OF MEDICAL SCIENCES

Ansari Nagar, New Delhi-29

No.F.20-29/2013-Estt. I (Committee)

Dated the: 09 AUG 2018

MEMORANDUM

Subject: Constituting of Sub-Committee to assist Institute Ethics Committee for monitiorning of Adverse Events in clinical trials - Reg.

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The Director, AIIMS is pleased to re-constitute the Sub Committee for monitiorning of Adverse Events in clinical trials to assist Institute Ethics Committee consisting of the following members:

(i)	Dr. Y. K. Gupta Ex. Prof. & Head, Department of Pharmacology, AIIMS, New Delhi	-	Chairman
(ii)	Dr. Sunesh Kumar, Professor, Deptt. of Obsterterics & Gynecology, AIIMS, New Delhi	-	Member
(iii)	Dr. C. S. Yadav, Profesor, Department of Orthopedics	-	Member
(iv)	Dr. Rakesh Yadav, Professor, Department of Cardiology	-	Member
(v)	Dr. Achal Srivastava, Professor, Department of Neurology	-	Member
(vi)	Dr. Vinod Ahuja, Professor, Department of Gastroenterology & Assoc. Dean (Research)	-	Member
(vii)	Dr. Sameer Bakhshi, Professor, Department of Medical-Oncology	-	Member
(viii)	Dr. Rajesh Khadgawat, Professor, Department of Endocrinology	-	Member
(ix)	Dr. Rakesh Lodha Professor, Department of Peadiatrics	-	Member
(x)	Dr. Vijay Prakash Mathur, Professor, Department of Pediatric Dentistry	-	Member
(xi)	Dr. Naresh Gupta, Professor, Deptt. of Medicine Maulana Azad Medical College, New Delhi	-	Member
(xii)	Dr. Lalit Gupta, Professor, Deptt. of Pharmacology Lady Harding Medical College, New Delhi	-	Member
(xiii)	Dr. Sudhir Sarangi, Assistant Professor, Department of Pharmacology	-	Member
(xiv)	Dr. Piyush Ranjan, Assistant Professor, Department of Medicine	-	Member
(xv)	Dr. Pooja Gupta, Assistant Professor, Department of Pharmacology	-	Member Secretary

- The tennure/terms of this committee is two years or till further order.
- External members of Ethics Sub-Committee will be paid honorarium for attendance at the meeting as admissible under the rules
- A copy of National Ethical Guidelines for Biomedical and Health Research involving Human Participants issued by ICMR, New Delhi is enclosed herewith for the committee for reference.

(B.S.GILL)
ADMINISTRATIVE OFFICER

Encl. As above:

Distribution: As above

CC::

1. All Chief of Centres/ Head of Departments
2. The PPS to Director/PS to Dean (Acad)/Research/Exam/Assoc. Dean (Acad/Research/Exam) Registrar/MS/DD(A)/CAO, AIIMS, New Delhi
3. The Computer Facility - with a request to upload this on official website of the Institute

Sh. Pawan Kumar for n.a. please.
10/08/18

09/08/18

New Guidelines

NATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL AND HEALTH RESEARCH INVOLVING HUMAN PARTICIPANTS

INDIAN COUNCIL OF MEDICAL RESEARCH
NEW DELHI
2017

INTRODUCTION

The code of conduct for physicians was well laid out in traditional Indian systems of medicine and do no harm was the underlying universal principle besides other principles applicable to the prevalent culture and the class systems of the society. The Indian Council of Medical Research (ICMR) issued the Policy Statement on Ethical Considerations Involved in Research on Human Subjects in 1980.[1] Due to rapid advances in biomedical science and technology, new ethical dimensions emerged which necessitated further updation of these guidelines. Subsequently the Ethical Guidelines for Biomedical Research on Human Subjects was released in 2000,[2] followed by the revised Ethical Guidelines for Biomedical Research on Human Participants in 2006.[3] In the meantime, the Central Drugs Standard Control Organization (CDSCO) also released the Indian Good Clinical Practice Guidelines (2001)[4] for clinical trials and revised Schedule Y of the Drugs and Cosmetics Act, 1940, in the year 2005[5] with several amendments in the Rules under Drugs and Cosmetics Act in the year 2013. ICMR and the Department of Biotechnology (DBT) jointly brought out Guidelines for Stem Cell Research and Therapy in 2007 and a further revision in 2013 which is now revised as National Guidelines for Stem Cell Research, 2017.[6]

The Nuremberg Code of 1947[7] was the first international treatise on the ethics of research involving human beings and highlighted the essentiality of obtaining voluntary consent. In 1964, the World Medical Association formulated guidelines on conducting research on humans, known as the Declaration of Helsinki. This has undergone seven revisions with the latest version being issued in October 2013 at Fortaleza, Brazil.[8]

In 1979, the Belmont Report released by the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research in the United States of America (USA), for the first time enunciated the three basic ethical principles for research involving human subjects: respect for persons, beneficence and justice.[9] The Department of Health and Human Services (DHHS), USA, released the Federal Policy for the Protection of Human Subjects as the 'Common Rule' in 1991 (revised in 2017).[10] The International Conference on Harmonization (ICH) brought out the Good Clinical Practice Guidelines E6 (R1) in 1996[11] revised as E6 (R2) in 2016.[12] The National Bioethics Advisory Commission, USA (2001),[13] the Council for International Organizations of Medical Sciences (CIOMS), Geneva (2002 revised in 2016),[14,15] and the Nuffield Council of Bioethics, United Kingdom (2002)[16] released recommendations/guidelines relevant

to research in developing countries. UNESCO's Universal Declaration on Bioethics and Human Rights (2005)[17] and other international instruments on human rights further defined the Universal Codes of Ethics to be adopted by the member countries The revised ICMR ethical guidelines have adapted important guidance points from these international guidelines keeping in mind the diverse socio-cultural milieu of our country.

The socio-cultural ethos in India and its varying standards of healthcare pose unique challenges to the application of universal ethical principles to biomedical and health research. The last decade has seen emerging ethical issues necessitating further revision of the earlier guidelines and preparation of the current National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017. These guidelines have covered some newer areas like public health research, social and behavioural sciences research for health and responsible conduct of research, and research during humanitarian emergencies and disasters while a few other specialized areas like informed consent process, biological materials, biobanking and datasets and vulnerability have been expanded into separate sections.

Scope

These guidelines are applicable to all biomedical, social and behavioural science research for health conducted in India involving human participants, their biological material and data. The purpose of such research should be:

i. directed towards enhancing knowledge about the human condition while maintaining sensitivity to the Indian cultural, social and natural environment;

ii. conducted under conditions such that no person or persons become mere means for the betterment of others and that human beings who are participating in any biomedical and/or health research or scientific experimentation are dealt with in a manner conducive to and consistent with their dignity and well-being, under conditions of professional fair treatment and transparency; and

iii. subjected to a regime of evaluation at all stages of the research, such as design, conduct and reporting of the results thereof.

STATEMENT OF GENERAL PRINCIPLES

1.0 Research on human participants pertains to a broad range of scientific enquiry aimed at developing generalizable knowledge that improves health, increases understanding of disease and is ethically justified by its social value. Every research has some inherent risks and probabilities of harm or inconvenience to participants/communities. Therefore, protection of participants should be built into the design of the study. Do no harm (non-maleficence) has been the underlying universal principle guiding health care in all systems of medicine around the world. While conducting biomedical and health research, the four basic ethical principles namely; respect for persons (autonomy), beneficence, non-maleficence and justice have been enunciated for protecting the dignity, rights, safety and well-being of research participants. These four basic principles have been expanded into 12 general principles described below, and are to be applied to all biomedical, social and behavioural science research for health involving human participants, their biological material and data.

1.1 General Principles

1.1.1 Principle of essentiality whereby after due consideration of all alternatives in the light of 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 (EC) independent of the proposed research.

1.1.2 Principle 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.

1.1.3 Principle 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.

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

1.1.5 Principle of ensuring privacy and confidentiality whereby to maintain privacy of the potential participant, 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 court of law etc.) privacy of the information 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 participant.

1.1.6 **Principle 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.

1.1.7 **Principle 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.

1.1.8 **Principle 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 the society.

1.1.9 **Principle 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.

1.1.10 **Principle of transparency and accountability** 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 conflict of interest and manage it appropriately. The research 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.

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

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

ETHICAL REVIEW PROCEDURES

4.0 It is necessary for all research proposals on biomedical, social and behavioural science research for health involving human participants, their biological material and data to be reviewed and approved by an appropriately constituted EC to safeguard the dignity, rights, safety and well-being of all research participants. ECs are entrusted with the initial review of research proposals prior to their initiation, and also have a continuing responsibility to regularly monitor the approved research to ensure ethical compliance during the conduct of research. The EC should be competent and independent in its functioning.

4.0.1 The institution is responsible for establishing an EC to ensure an appropriate and sustainable system for quality ethical review and monitoring.

4.0.2 The institution is responsible for providing logistical support, such as infrastructure, staff, space, funds, adequate support and protected time for the Member Secretary to run the EC functions.

4.0.3 The EC is responsible for scientific and ethical review of research proposals. Although ECs may obtain documentation from a prior scientific review, they must determine that the research methods are scientifically sound, and should examine the ethical implications of the chosen research design or strategy.

4.0.4 All types of biomedical and health research (whether clinical, basic science, policy, implementation, epidemiological, behavioural, public health research, etc) must be reviewed by an EC before it is conducted.

4.1 Terms of reference (TOR) for ECs

4.1.1 The TOR for the EC and its members should be clearly specified by the institution in the EC SOPs (Annex 1 for the List of SOPs).

4.1.2 Every EC should have written SOPs according to which the committee should function. The EC can refer to ICMR guidelines in preparing the SOPs for all biomedical and health research and to CDSCO guidelines for drug and device trials under the purview of the licensing authority. The SOPs should be updated periodically to reflect changing requirements. A copy of the latest version of SOPs should be made available to each member and they should be trained on the SOPs. The SOPs must be available in the secretariat of the EC as both hard and soft copies.

4.1.3 The scope, tenure and renewal policy of the EC should be stated.

4.1.4 Members of the EC should not have any known record of misconduct.

4.1.5 The EC should be registered with the relevant regulatory authorities, for example, ECs approving clinical trials under the ambit of Drugs and Cosmetics Actshould be registered with CDSCO.

4.2 Special situations

4.2.1 Institutions can have one or more than one EC. They can have multiple ECs to review large numbers of research proposals. Each EC can function as a stand-alone committee which should follow all the SOPs and TORs of that institution.

4.2.2 An institution that does not have its own EC (user institution) may utilize the services of the EC of another institution (host institution) preferably in the adjoining/nearby area. Relevant requirements must be fulfilled before they do so. See Box 4.1 for further details.

Box 4.1 Utilizing the services of an EC of another institution

The following requirements must be fulfilled by institutions that use the services of an EC from another institution:

- The two institutions (host and user) should enter into an MoU for utilizing the services of the EC of the host institution or the user institution should provide a 'No Objection Certificate' and agree to be overseen by the EC of the host institution.
- The EC of the host institution should have access to all research records including the source documents and research participants for continuing review of the implemented project, including site visits.
- The EC of the host institution can undertake site monitoring and will have all the rights and responsibilities related to ethical review of the projects submitted by the user institutions.

4.2.3 For multicentric biomedical and health research, all participating sites may decide to utilize the services of one common EC from a participating site identified as designated main EC for the purpose of primary review. This EC should be located in India and registered with the relevant authority. However, the local site requirements, such as informed consent process, research implementation and its monitoring, etc. may be performed by the local EC. This would require good communication and coordination between the researchers and EC secretariats of participating sites. For clinical trials under the Drugs and Cosmetics Act, the requirements as stated by CDSCO must be followed. See section 4.10 for further details.

4.2.4 Stem cell proposals should be reviewed and approved by the institutional committee

for stem cell research (IC-SCR) before being submitted to the EC for consideration, in accordance with the National Guidelines for Stem Cell Research (2017).

4.2.5 Independent ECs (Ind EC) that function outside institutions can be used by researchers who have no institutional attachments. For these committees, the following essential conditions should be met:

- The Ind EC must be established as a registered legal entity, governed by individuals who are not members of the proposed EC and who will oversee and monitor the functioning of the Ind EC.
- It should function according to SOPs that follow the national guidelines for functioning of ECs.
- It should not accept research proposals from investigators affiliated to institutions that have their own ECs unless there is an MoU.
- It will have rights and responsibilities related to the projects submitted to it.
- It should have access to all research records, including the source documents and research participants.
- It should undertake continuing review of the implemented project including site visits.
- It should familiarize itself with local socio-cultural norms that may help to ensure protection of rights and wellbeing of research participants.

4.2.6 Institutions could have subcommittees such as the SAE subcommittee or expedited review committee. These should be part of the main committee and comprise Chairperson/ Member Secretary and one to two appropriate designated members of the main EC as defined in the SOPs. These subcommittees can report to the concerned main EC.

4.2.7 Institutions could have separate committee for SAE in which one or two members of EC could be included to facilitate continuity of EC activity and its report should be reviewed by main EC.

4.3 Composition of an EC

4.3.1 ECs should be multi-disciplinary and multi-sectoral.

4.3.2 There should be adequate representation of age and gender.

4.3.3 Preferably 50% of the members should be non-affiliated or from outside the institution.

4.3.4 The number of members in an EC should preferably be between seven and 15 and a minimum of five members should be present to meet the quorum requirements.

4.3.5 The EC should have a balance between medical and non-medical members/technical and non-technical members, depending upon the needs of the institution.

The composition, affiliations, qualifications, member specific roles and responsibilities are given in Table 4.1.

Table 4.1 Composition, affiliations, qualifications, member specific roles and responsibilities of an EC

S. No.	Members of EC	Definition/description
1.	**Chairperson/ Vice Chairperson** (optional) Non-affiliated Qualifications - A well-respected person from any background with prior experience of having served/ serving in an EC	• Conduct EC meetings and be accountable for independent and efficient functioning of the committee • Ensure active participation of all members (particularly non-affiliated, non-medical/ non- technical) in all discussions and deliberations • Ratify minutes of the previous meetings • In case of anticipated absence of both Chairperson and Vice Chairperson at a planned meeting, the Chairperson should nominate a committee member as Acting Chairperson or the members present may elect an Acting Chairperson on the day of the meeting. The Acting Chairperson should be a non-affiliated person and will have all the powers of the Chairperson for that meeting. • Seek COI declaration from members and ensure quorum and fair decision making. • Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data, etc.
2.	**Member Secretary/ Alternate Member Secretary** (optional) Affiliated Qualifications - • Should be a staff member of the institution • Should have knowledge and experience in clinical research and ethics, be motivated and have good communication skills	• Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review • Schedule EC meetings, prepare the agenda and minutes • Organize EC documentation, communication and archiving • Ensure training of EC secretariat and EC members • Ensure SOPs are updated as and when required • Ensure adherence of EC functioning to the SOPs • Prepare for and respond to audits and inspections • Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for EC review. • Assess the need for expedited review/ exemption from review or full review.

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	• Should be able to devote adequate time to this activity which should be protected by the institution	• Assess the need to obtain prior scientific review, invite independent consultant, patient or community representatives. • Ensure quorum during the meeting and record discussions and decisions
3.	**Basic Medical Scientist(s)** Affiliated/ non-affiliated Qualifications - • Non-medical or medical person with qualifications in basic medical sciences • In case of EC reviewing clinical trials with drugs, the basic medical scientist should preferably be a pharmacologist	• Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report • For clinical trials, pharmacologist to review the drug safety and pharmacodynamics.
4.	**Clinician(s)** Affiliated/ non-affiliated Qualifications - • Should be individual/s with recognized medical qualification, expertise and training	• Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics • Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report) • Review medical care, facility and appropriateness of the principal investigator, provision for medical car, management and compensation. • Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.
5.	**Legal expert/s** Affiliated/ non-affiliated Qualifications - • Should have a basic degree in Law from a recognized university, with experience • Desirable: Training in medical law.	• Ethical review of the proposal, ICD along with translations, MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol specific other permissions, such as, stem cell committee for stem cell research, HMSC for international collaboration, compliance with guidelines etc. • Interpret and inform EC members about new regulations if any

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6. **Social scientist/ philosopher/ ethicist/theologian** Affiliated/ non-affiliated Qualifications - • Should be an individual with social/ behavioural science/ philosophy/ religious qualification and training and/or expertise and be sensitive to local cultural and moral values. Can be from an NGO involved in health-related activities	• Ethical review of the proposal, ICD along with the translations. • Assess impact on community involvement, socio-cultural context, religious or philosophical context, if any • Serve as a patient/participant/ societal / community representative and bring in ethical and societal concerns.	4.3.7 4.3.8 4.3.9
7. **Lay person(s)** Non-affiliated Qualifications - • Literate person from the public or community • Has not pursued a medical science/ health-related career in the last 5 years • May be a representative of the community from which the participants are to be drawn • Is aware of the local language, cultural and moral values of the community • Desirable: involved in social and community welfare activities	• Ethical review of the proposal, ICD along with translation(s). • Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks. • Serve as a patient/participant/ community representative and bring in ethical and societal concerns. • Assess on societal aspects if any.	4.3.10 4.3.11 4.3.12

4.3.6 The quorum should be as specified in Box 4.2.

Box 4.2 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 or technical or/and 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 fulfilment of the quorum.

**Medical members are clinicians with appropriate medical qualifications. Technical members are persons with qualifications related to a particular branch in which the study is conducted, for example social sciences.*

4.4

4.4.1

4.4.2

4.4.3

4.4.4

4.3.7 So as to maintain independence, the head of the institution should not be part of the EC but should act as an appellate authority to appoint the committee or to handle disputes.

4.3.8 The Chairperson and Member Secretary could have dual roles in the ethics committee. They could fulfil a role based on their qualifications (such as that of clinician, legal expert, basic scientist, social scientist, lay person etc.) in addition to taking on the role of Chairperson or Member Secretary.

4.3.9 The EC can also have a set of alternate members who can be invited as members with decision-making powers to meet the quorum requirements. These members have the same TORs as regular members and can attend meetings in the absence of regular members.

4.3.10 The EC can maintain a panel of subject experts who are consulted for their subject expertise, for instance, a paediatrician for research in children, a cardiologist for research on heart disorders, etc. They may be invited to attend the meeting to give an expert opinion on a specific proposal but will not have decision making power/voting rights.

4.3.11 The EC may invite subject experts as independent consultants or include a representative from a specific patient group as a member of the EC or special invitee, for opinion on a specific proposal, for example HIV, genetic disorders, or cancer, with appropriate decision making power.

4.3.12 As far as possible a separate scientific committee should priorly also review proposal before it is referred to EC. EC can raise scientific queries besides ethical ones as both good science and ethics are important to ensure quality of research and participant protection.

4.4 Terms of reference for EC members

4.4.1 The head of the institution should appoint all EC members, including the Chairperson.

4.4.2 The appointment letter issued to all members should specify the TORs. The letter issued by the head of the institution should include, at the minimum, the following:

- Role and responsibility of the member in the committee
- Duration of appointment
- Conditions of appointment

4.4.3 Generally, the term of EC membership may be 2–3 years. The duration could be extended as specified in the SOPs. A defined percentage of EC members could be changed on a regular basis.

4.4.4 EC members may be given a reasonable honorarium for attendance at the meeting.

4.4.5 Members to be appointed on the EC should be willing to fulfil the EC requirements as given in Box 4.3.

Box 4.3 Requirements for EC members

Every EC member must:

1. provide a recent signed CV and training certificates on human research protection and good clinical practice (GCP) guidelines, if applicable;
2. either be trained in human research protection and/or GCP at the time of induction into the EC, or must undergo training and submit training certificates within 6 months of appointment (or as per institutional policy);
3. be willing to undergo training or update their skills/knowledge during their tenure as an EC member;
4. be aware of relevant guidelines and regulations;
5. read, understand, accept and follow the COI policy of the EC and declare it, if applicable, at the appropriate time;
6. sign a confidentiality and conflict of interest agreement/s;
7. be willing to place her/his full name, profession and affiliation to the EC in the public domain; and
8. be committed and understanding to the need for research and for imparting protection to research participants in research.

4.5 Criteria for selection of members of an EC

4.5.1 Members should be selected in their personal capacities based on their qualifications, experience, interest, commitment and willingness to volunteer the required time and effort for the EC. See Table 4.1 for further details.

4.5.2 Members are appointed to the EC for a particular role. They cannot substitute for the role of any other member who is absent for a meeting. The role of Chairperson/ Member Secretary is an additional activity to their primary responsibility based on their qualifications. Hence, if the Chairperson is a lawyer, she or he can serve as both the lawyer and the Chairperson.

4.5.3 These criteria should be specified in SOPs.

4.6 Training

4.6.1 Members should be trained in human research protection, EC functions and SOPs, and should be conversant with ethical guidelines, GCP guidelines (if applicable) and relevant regulations of the country.

4.6.2 EC members should undergo initial and continuing training in human research protection, applicable EC SOPs and related regulatory requirements. All trainings should be documented.

4.6.3 Any change in the relevant guidelines or regulatory requirements should be brought to the attention of all EC members.

4.6.4 EC members should be aware of local, social and cultural norms and emerging ethical issues.

4.7 Roles and responsibilities of the EC

4.7.1 The basic responsibility of an EC is to ensure protection of the dignity, rights, safety and well-being of the research participants.

4.7.2 The EC must ensure ethical conduct of research by the investigator team.

4.7.3 The EC is responsible for declaration of conflicts of interest to the Chairperson, if any, at each meeting and ensuring these are recorded in the minutes.

4.7.4 The EC should perform its function through competent initial and continuing review of all scientific, ethical, medical and social aspects of research proposals received by it in an objective, timely and independent manner by attending meetings, participation in discussion and deliberations.

4.7.5 The EC must ensure that universal ethical values and international scientific standards are followed in terms of local community values and customs.

4.7.6 The EC should assist in the development and education of the research community in the given institute (including researchers, clinicians, students and others), responsive to local healthcare requirements.

4.7.7 Responsibilities of members should be clearly defined (details in Table 4.1). The SOPs should be given to EC members at the time of their appointment.

4.7.8 The Secretariat should support the Member Secretary and Alternate Member Secretary (if applicable) in all their functions and should be trained in documentation and filing procedures under confidentiality agreement.

4.7.9 The EC should ensure that privacy of the individual and confidentiality of data including the documents of EC meetings is protected.

4.7.10 The EC reviews progress reports, final reports and AE/SAE and gives needful suggestions regarding care of the participants and risk minimization procedures, if applicable.

4.7.11 The EC should recommend appropriate compensation for research related injury, wherever required.

4.7.12 The EC should carry out monitoring visits at study sites as and when needed.

4.7.13 The EC should participate in continuing education activities in research ethics and get updated on relevant guidelines and regulations.

4.7.14 The EC may see that conduct of same/similar research by different investigators from same institution is harmonized. 'Me too' research (replicative) should not to be encouraged and submission of same research to different funding agencies should not be accepted.

4.8 Submission and review procedures

4.8.1 Researchers should submit research proposals as soft or hard copies to the Secretariat for review in the prescribed format and required documents as per EC SOPs. The EC should prepare a checklist for the required documents as given in Box 4.4 (a) and 4.4 (b). This list is subject to modifications, depending on the type of research, EC SOPs and institutional policies.

Box 4.4 (a) Details of documents to be submitted for EC review

1. Cover letter to the Member Secretary
2. Type of review requested
3. Application form for initial review
4. The correct version of the informed consent document (ICD) in English and the local language(s). Translation and back translation certificates (if applicable)
5. Case record form/questionnaire
6. Recruitment procedures: advertisement, notices (if applicable)
7. Patient instruction card, diary, etc. (if applicable)
8. Investigator's brochure (as applicable for drug/biologicals/device trials)
9. Details of funding agency/sponsor and fund allocation (if applicable)
10. Brief curriculum vitae of all the study researchers
11. A statement on COI, if any
12. GCP training certificate (preferably within 5 years) of investigators (clinical trials)
13. Any other research ethics/other training evidence, if applicable as per EC SOP
14. List of ongoing research studies undertaken by the principal investigator (if applicable)
15. Undertaking with signatures of investigators
16. Regulatory permissions (as applicable)
17. Relevant administrative approvals (such as HMSC approval for International trials)
18. Institutional Committee for Stem Cell Research (IC-SCR) approval (if applicable)
19. MoU in case of studies involving collaboration with other institutions (if applicable)
20. Clinical trial agreement between the sponsors, investigator and the head of the institution(s) (if applicable)

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21. Documentation of clinical trial registration (preferable)
22. Insurance policy (it is preferable to have the policy and not only the insurance certificate)for study participants indicating conditions of coverage, date of commencement and date of expiry of coverage of risk (if applicable)
23. Indemnity policy, clearly indicating the conditions of coverage, date of commencement and date of expiry of coverage of risk (if applicable)
24. Any additional document(s), as required by EC (such as other EC clearances for multicentric studies)
25. Protocol

Box 4.4 (b) Details of documents to be included in the protocol

The protocol should including the following:

1. the face page carrying the title of the proposal with signatures of the investigators;
2. brief summary/ lay summary;
3. background with rationale of why a human study is needed to answer the research question;
4. justification of inclusion/exclusion of vulnerable populations;
5. clear research objectives and end points (if applicable);
6. eligibility criteria and participant recruitment procedures;
7. detailed description of the methodology of the proposed research, including sample size (with justification), type of study design (observational, experimental, pilot, randomized, blinded, etc.), types of data collection, intended intervention, dosages of drugs, route of administration, duration of treatment and details of invasive procedures, if any;
8. duration of the study;
9. justification for placebo, benefit–risk assessment, plans to withdraw. If standard therapies are to be withheld, justification for the same;
10. procedure for seeking and obtaining informed consent with a sample of the patient/participant information sheet and informed consent forms in English and local languages. AV recording if applicable; informed consent for stored samples;
11. plan for statistical analysis of the study;
12. plan to maintain the privacy and confidentiality of the study participants;
13. for research involving more than minimal risk, an account of management of risk or injury;
14. proposed compensation, reimbursement of incidental expenses and management of research related injury/illness during and after research period;
15. provision of ancillary care for unrelated illness during the duration of research;
16. an account of storage and maintenance of all data collected during the trial; and
17. plans for publication of results – positive or negative – while maintaining confidentiality of personal information/ identity.
18. ethical considerations and safeguards for protection of participants.

Table 4.2 Types of review

S. No.	Types of review	
1	**Exemption from review**	Proposals with less than minimal risk where there are no linked identifiers, for example, • research conducted on data available in the public domain for systematic reviews or meta-analysis; • observation of public behaviour when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person; • quality control and quality assurance audits in the institution; • comparison of instructional techniques, curricula, or classroom management methods; • consumer acceptance studies related to taste and food quality; and • public health programmes by Govt agencies such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers).
2	**Expedited review**	Proposals that pose no more than minimal risk may undergo expedited review, for example; • research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples; • research involving clinical documentation materials that are non-identifiable (data, documents, records); • modification or amendment to an approved protocol including administrative changes or correction of typographical errors and change in researcher(s); • revised proposals previously approved through expedited review, full review or continuing review of approved proposals; • minor deviations from originally approved research causing no risk or minimal risk; • progress/annual reports where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee; and • for multicentre research where a designated main EC among the participating sites has reviewed and approved the study, a local EC may conduct only an expedited review for site specific requirements in addition to the full committee common review. • research during emergencies and disasters (See Section 12 for further details).

(Contd.)

3 **Full committee review** All research proposals presenting more than minimal risk that are not covered under exempt or expedited review should be subjected to full committee review, some examples are;

- research involving vulnerable populations, even if the risk is minimal;
- research with minor increase over minimal risk (see Table 2.1 for further details);
- studies involving deception of participants (see section 5.11 for further details);
- research proposals that have received exemption from review, or have undergone expedited review/undergone subcommittee review should be ratified by the full committee, which has the right to reverse/or modify any decision taken by the subcommittee or expedited committee;
- amendments of proposals/related documents (including but not limited to informed consent documents, investigator's brochure, advertisements, recruitment methods, etc.) involving an altered risk;
- major deviations and violations in the protocol;
- any new information that emerges during the course of the research for deciding whether or not to terminate the study in view of the altered benefit–risk assessment;
- research during emergencies and disasters either through an expedited review/ scheduled or unscheduled full committee meetings. This may be decided by Member Secretary depending on the urgency and need;
- prior approval of research on predictable emergencies or disasters before the actual crisis occurs for implementation later when the actual emergency or disaster occurs.

4.8.2 The Member Secretary/Secretariat shall screen the proposals for their completeness and depending on the risk involved categorize them into three types, namely, exemption from review, expedited review, and full committee review. See Tables 2.1 for risk categorization and 4.2 for further details regarding types of review.

4.8.3 A researcher cannot decide that her/his proposal falls in the exempted, expedited or full review category. All research proposals must be submitted to the EC. The decision on the type of review required rests with the EC and will be decided on a case-to-case basis. Researchers can approach the EC with appropriate justification for the proposal to be considered as exempt, expedited or if waiver of consent is requested.

4.8.4 Expedited review can be conducted by Chairperson, Member Secretary and one or two designated members or as specified in SOPs.

4.8.5 Approval granted through expedited review and the decisions of the SAE subcommittee must be ratified at the next full committee meeting.

4.8.6 EC members should be given enough time (at least 1 week) to review the proposal and related documents, except in the case of expedited review.

4.8.7 All EC members should review all proposals. However, the EC may adopt different procedures for review of proposals in accordance with their SOPs.

4.8.8 The EC may adopt a system for pre-meeting peer review by subject experts and obtain clarifications from the researchers prior to the meeting in order to save time and make the review more efficient during the full committee meeting, especially in institutions where there are no separate scientific review committees.

4.8.9 The EC may have a system of appointing primary and secondary reviewers. The Member Secretary should identify the primary and secondary reviewers for reviewing the scientific content and the ethical aspects in the proposal as well as the informed consent document, depending upon their individual expertise.

4.8.10 The Member Secretary may identify subject experts to review the proposal as per need. These experts may be invited to the EC meeting or join via video/tele conference but will not participate in final decision making.

4.8.11 The EC should meet regularly, adopt best practices, try to reduce turnaround time or have procedures in place for early decision making so that research is not delayed.

4.8.12 The designated (primary and secondary) reviewers and subject experts should conduct the initial review of the study protocol and study related documents as per the pre-defined study assessment form and for factors as described in Table 4.3.

Table 4.3 Ethical issues related to reviewing a protocol

1	**Social values**	• The basic requirement for health research to be ethically permissible is that it must have anticipated social value. The outcome of the research should be relevant to the health problems of society. All stakeholders, including sponsors, researchers and ECs must ensure that the planned research has social value.
2	**Scientific design and conduct of the study**	• Valid scientific methods are essential to make the research ethically viable as poor science can expose research participants or communities to risks without any possibility of benefit.

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		• Although ECs may obtain documentation from a prior scientific review, they should also determine that the research methods are scientifically sound, and should examine the ethical implications of the chosen research design or strategy. • The EC can raise scientific concerns (even if the study has prior approval of a scientific committee) if it may affect quality of research and or safety of research participants.
3	**Benefit-risk assessment**	• The benefits accruing from the planned research either to the participants or to the community or society in general must justify the risks inherent in the research. • Risks may be physical, psychological, economic, social or legal and harm may occur either at an individual level or at the family, community or societal level. It is necessary to first look at the intervention under investigation and assess its potential harm and benefits and then consider the aggregate of harm and benefits of the study as a whole. • The EC should review plans for risk management, including withdrawal criteria with rescue medication or procedures. • The EC should give advice regarding minimization of risk/ discomfort wherever applicable. • Adequate provisions must be made for monitoring and auditing the conduct of the research, including the constitution of a Data and Safety Monitoring Board (DSMB) if applicable (for example in clinical trials)
4	**Selection of the study population and recruitment of research participants**	• Recruitment should be voluntary and non-coercive. Participants should be fairly selected as per inclusion and exclusion criteria. However, selection of participants should be distributive such that a particular population or tribe or economic group is not coerced to participate or benefit. • Participants should be able to opt out at any time without their routine care being affected. • No individual or group of persons must bear the burden of participation in research without accruing any direct or indirect benefits. • Vulnerable groups may be recruited after proper justification is provided.
5	**Payment for participation**	• Plans for payment for participation, reimbursement of incurred costs, such as travel or lost wages, incidental expenses and other inconveniences should be reviewed.

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		• There is a need to determine that payments are not so large as to encourage prospective participants to participate in the research without due consideration of the risks or against their better judgement. No undue inducement must be offered.
6	**Protection of research participants' privacy and confidentiality**	• ECs should examine the processes that are put in place to safeguard participants' privacy and confidentiality. • Research records to be filed separately than routine clinical records such as in a hospital setting.
7	**Community considerations**	• The EC should ensure that due respect is given to the community, their interests are protected and the research addresses the community's needs. • The proposed research should not lead to any stigma or discrimination. Harm, if any, should be minimized. • Plans for communication of results to the community at the end of the study should be carefully reviewed. • It is important to examine how the benefits of the research will be disseminated to the community.
8	**Qualifications of researchers and adequacy assessment of study sites**	• The EC should look at the suitability of qualifications and experience of the PI to conduct the proposed research along with adequacy of site facilities for participants.
9	**Disclosure or declaration of potential COI**	• The EC should review any declaration of COI by a researcher and suggest ways to manage these. • The EC should manage COI within the EC and members with COI should leave the room at the time of decision making in a particular study.
10	**Plans for medical management and compensation for study related injury**	• The proposed plan for tackling any medical injuries or emergencies should be reviewed. • Source and means for compensation for study related injury should be ascertained.
11	**Review of the informed consent process**	The informed consent process must be reviewed keeping in mind the following: • the process used for obtaining informed consent, including the identification of those responsible for obtaining consent and the procedures adopted for vulnerable populations; • the adequacy, completeness and understandability of the information to be given to the research participants, and when appropriate, their LARs;

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- contents of the patient/participation information sheet including the local language translations (See section 5 for further details);
- back translations of the informed consent document in English, wherever required;
- provision for audio-visual recording of consent process, if applicable, as per relevant regulations; and
- if consent waiver or verbal/oral consent request has been asked for, this should be reviewed by assessing whether the protocol meets the criteria. See section 5 for further details.

4.9 Full committee meeting

4.9.1 All proposals that are determined to undergo full committee review must be deliberated and the decision about the proposal taken at a full committee meeting.

4.9.2 ECs should conduct regular full committee meetings to deliberate proposals in accordance with a pre-decided schedule, as described in the SOPs.

4.9.3 A meeting will be considered valid only if the quorum is fulfilled. This should be maintained throughout the meeting and at the time of decision making.

4.9.4 If a member has declared a COI for a proposal then this should be submitted in writing to the Chairperson before beginning the meeting and should be recorded in the minutes.

4.9.5 The member who has declared COI should withdraw from the EC meeting (leave the room) while the research proposal is being discussed upon. This should be minuted and the quorum rechecked.

4.9.6 A list of absentee members as well as members leaving or entering in-between the meeting should be recorded.

4.9.7 Proposals should be taken up item-wise, as given in the agenda.

4.9.8 No of proposals reviewed in a meeting should justify that there is ample time devoted for review of each proposal. If there are more number of proposals for consideration per meeting either meetings may be more frequent or more EC's to be constituted as per requirement of the institution.

4.9.9 Time allotted for the meeting should be reasonable to allow ample discussion on each agenda item.

4.9.10 The minutes of the previous meeting and list of protocols that were exempt from review or underwent expedited review should be ratified.

4.9.11 The researcher may be called in to present a proposal or provide clarifications on the study protocol that has been submitted for review but should not be present at the time of decision making.

4.9.12 The primary and secondary reviewers can brief the members about the study proposal and review carried out as per EC SOPs.

4.9.13 The comments of an independent consultant (if applicable) could be presented by the Member Secretary or subject experts could be invited to offer their views, but they should not participate in the decision-making process. However, her/his opinion must be recorded.

4.9.14 Representative(s) of the study group population can be invited during deliberations to offer their viewpoint but should not participate in the decision-making process.

4.9.15 The EC may utilize electronic methods such as video/conference calls for connecting with other subject experts/independent consultants during the meeting.

4.9.16 All members of the EC (including the Chairperson and the Member Secretary) present in the room have the right to vote/express their decision and should exercise this right.

4.9.17 The decision must be taken either by a broad consensus or majority vote (as per SOP) and should be recorded. Any negative opinion should be recorded with reasons.

4.9.18 The decisions may be as shown in Box 4.5.

Box 4.5 Types of decisions by EC

An EC can give one of the following decisions:

- approved – with or without suggestions or comments;
- revision with minor modifications/amendments – approval is 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/revoking of permission if applicable) – clearly defined reasons must be given for not approving/terminating/revoking of permission.

4.9.19 Approval may be granted for the entire duration of the proposed research or can be subject to annual review depending on the type of study. The EC should review the annual report (counted from the day of approval or date of actual start of the study) for continuation as per SOP.

4.9.20 Depending on the risk involved, the progress of the proposal may be monitored annually or at shorter intervals (quarterly, half yearly) as per EC decision. Approval may be continued if progress is satisfactory

4.9.21 An EC may decide to reverse its positive decision on a study if it receives information that may adversely affect the benefit-risk assessment.

4.9.22 The Member Secretary (assisted by the Secretariat) should record the discussions and prepare the minutes which should be circulated to all the members for comments before final approval by the Chairperson/Vice-Chairperson/designated member of the committee.

4.9.23 The decision of the EC should be communicated to the researcher along with suggestions, if any.

4.9.24 The researcher should have an opportunity to reply/clarify to EC comments or to discuss or present her/his stand.

4.9.25 The researcher can also approach the head of the institute who serves as an appellate for EC matters.

4.9.26 The head of the institute as appellate has the power to dissolve the EC or reappoint an EC.

4.10 Review of multicentric research

Multicentre research is conducted at more than one centre by different researchers usually following a common protocol. A large number of clinical trials, clinical studies and public health research including surveys are conducted at several research centres within the country or at international sites. Multicentric research studies are carried out with the primary aim of providing a sound basis for the subsequent generalization of its results. All sites are required to obtain approval from their respective ECs, which would consider the local needs and requirements of the populations being researched and safeguard the dignity, rights, safety and well-being of the participants. There are concerns, however, related to duplication of effort in the parallel review by the involved ECs, wastage of time and also those related to communication between the committees. Therefore, in multicentric studies using a common protocol the considerations mentioned in sections 4.10.1 and 4.10.2 may be made.

4.10.1 Separate review by ECs of all participating site

- The ECs/Secretariats of all participating sites should establish communication with one another.

- If any EC does not grant approval for a study at a site the reasons must be shared with other ECs and deliberated upon.
- The EC can suggest site-specific protocols and informed consent modifications as per local needs.
- Separate review may be requested for studies with a higher degree of risk, clinical trials or intervention studies where conduct may vary depending on the site or any other reason which requires closer review and attention.

4.10.2 Common review for all participating sites in multicentric research

- In order to save time, prevent duplication of effort and streamline the review process, the ECs can decide to have one designated main EC, the decisions of which may be acceptable to other ECs. This is especially important for research involving low or minimal risk, survey or multicentric studies using anonymized samples or data or those that are public health research studies determined to have low or minimal risk.
- The meeting of the designated main EC can be attended by nominated members of ECs of the participating centres to discuss their concerns, if any, about ethics or human rights and to seek solutions and communicate the decision of the main EC to their respective ECs.
- This EC should be located in India and registered with the relevant authority (if applicable).
- Meetings should be organized at the initial and, if required, intermediary stages of the study to ensure uniform procedures at all centres.
- The site ECs, however, retain their rights to review any additional site specific requirements, ensure need-based protection of participants or make changes in the informed consent document (ICD), translations and monitoring research as per local requirements.
- The protocol may be modified to suit local requirements and should be followed after it is duly approved by the EC of the host institutes/decision of main EC is accepted.
- Adherence to protocols, including measures to terminate the participation of the erring local centres, if required should be monitored.
- The common review is applicable only for ECs in India. In case of international collaboration for research and approval by a foreign institution, etc., the local

participating sites would be required to obtain local ethical approval. See section 3.8.3 for further details.

- Sponsor/funding agencies should be informed about any site-specific changes being made, and the modified version should only be used by the concerned site.
- Plans for manuscript publication and a common final report with contributors from the participating sites should be decided upon before initiation of the study.
- Site-specific data may be published only after the appropriate authorities accept the combined report and appropriate permissions are obtained.

4.11 Continuing review

4.11.1 Ongoing research should be reviewed at regular intervals, at least once a year, (or more often, if deemed necessary depending on the level of risk) or as may be specified in the SOP of the EC and at the time of according approval, and as indicated in the communication letter.

4.11.2 The EC should continually evaluate progress of ongoing proposals, review SAE reports from all sites along with protocol deviations/violations and non-compliance, any new information pertaining to the research and assess final reports of all research activities.

4.11.3 Clinical trials under the purview of a licensing authority must comply with all regulations applicable to SAEs. The EC should also ensure compliance by the researcher. For academic and other trials, an institutional policy should be established.

4.11.4 The EC should examine the measures taken for medical management of SAEs. Participants should not have to bear costs for the management of study-related injury whether they are in the intervention arm or the control arm.

4.11.5 Compensation must be given for research-related injuries if applicable, as determined by the EC and as per regulatory requirement (if applicable).

4.11.6 For protocol deviations/violations the EC should examine the corrective actions. If the violations are serious the EC may halt the study. The EC may report to the institutional head/government authorities where there is continuing non-compliance to ethical standards.

4.11.7 Reports of monitoring done by the sponsor and DSMB reports may also be sought.

4.12 Site monitoring

4.12.1 It is recommended that ECs should follow mechanisms described in a SOP to monitor the approved study site until completion of the research to check for compliance or improve the function.

4.12.2 Monitoring can be routine or "for cause" and must be decided at a full committee meeting. For research that involves higher risk or vulnerable participants or if there is any other reason for concern, the EC at the time of initial review or continuing review can suggest that routine monitoring may be conducted at more frequent intervals. Some causes for monitoring are given in Box 4.6.

Box 4.6 Examples of "for cause" monitoring

The following situations may justify "for cause" monitoring:

- high number of protocol violations/ deviations;
- large number of proposals carried out at the study site or by the same researcher;
- large number of SAE reports;
- high recruitment rate;
- complaints received from participants;
- any adverse media report;
- adverse information received from any other source;
- non-compliance with EC directions;
- misconduct by the researcher; and
- any other cause as decided by the EC.

4.13 Record keeping and archiving

4.13.1 All documentation and communication of an EC should be dated, filed and preserved according to written procedures.

4.13.2 Confidentiality should be maintained during access and retrieval procedures by designated persons.

4.13.3 All active and inactive (closed) files should be appropriately labelled and archived separately in designated areas.

4.13.4 Records can be maintained in hard copies as well as soft copies.

4.13.5 All records must be archived for a period of at least 3 years after the completion/ termination of the study.

4.13.6 Documents related to regulatory clinical trials must be archived for 5 years after the completion/termination of the study or as per regulations.

4.13.7 Records may be archived for a longer period, if required by the sponsors/regulatory bodies.

4.13.8 EC should describe archival and retrieval mechanisms in SOPs.

4.13.9 EC records should be accessible for inspection by authorized representatives of regulatory agencies.

4.13.10 ECs may adopt methods for electronic storage of records wherever feasible. Table 4.4 gives examples of records that can be maintained.

Table 4.4 Documents to be maintained by EC for record

Type of document	Document specifics
Administrative documents	• Constitution and composition of the EC • Appointment letters • Signed and dated copies of the most recent curriculum vitae of all EC members • Signed confidentiality agreements • COI declarations of members • Training records of EC members • Financial records of EC • Registration/accreditation documents, as required • A copy of national and international guidelines and applicable regulations • Regulatory notifications • Meeting-related documents • Agenda and minutes • All communications received or made by the EC • SOPs
Proposal-related documents	• One hard copy and a soft copy of the initial research proposal and all related documents • Decision letters • Any amendments submitted for review and approval • Regulatory approvals • SAE, AE reports • Protocol deviations/violations • Progress reports, continuing review activities, site monitoring reports • All correspondence between the EC and researchers • Record of notification issued for premature termination of a study with a summary of the reasons • Final report of the study • Publications, if any

4.14 Administration and management

4.14.1 Every institution should have an office for the EC.

4.14.2 The institution should provide space, infrastructure and staff to the EC for maintaining

a full-time secretariat, safe archival of records and conduct of meeting.

4.14.3 Every institution should allocate reasonable funds for smooth functioning of the EC.

4.14.4 A reasonable fee for review may also be charged by the EC to cover the expenses related to optimal functioning in accordance to Institutional policies.

4.15 Registration and accreditation of ECs

4.15.1 ECs must ensure that processes are in place to safeguard the quality of ethical review as well as compliance with national/international and applicable regulations.

4.15.2 ECs should register with the relevant authority as per the regulatory requirements.

4.15.3 Efforts should be made to seek recognition/certification/accreditation from recognized national/international bodies such as Strategic Initiative for Developing Capacity in Ethical Review (SIDCER), Association for the Accreditation of Human Research Protection Programmes (AAHRPP), CDSCO and Quality Council of India through National Accreditation Board for Hospitals and Healthcare Providers (NABH) or any other. Such certification/accreditation should be kept updated on a continuing basis.

4.15.4 Certification/accreditation are voluntary exercises and help in quality assurance and quality improvement to ensure that ECs follow best practices in protecting the dignity, rights, safety, and well-being of their participants.