INSTITUTIONAL ETHICS COMMITTEE

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Policies and Guidelines

BODOLAND UNIVERSITY

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INSTITUTIONAL ETHICS COMMITTEE: BODOLAND UNIVERSITY
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[As per the National Ethical Guidelines for Biomedical and Health Research involving Human Participants: Indian Council of Medical Research, 2017]

INTRODUCTION

Institutional Ethics Committee (IEC), Bodoland University serves as an independent representative and competent body to review, evaluate and decide on the scientific and ethical merits of research proposals. The primary purpose of this committee is to protect the rights, safety and well being of human subjects who participate in a research project. The Ethics Committee is entrusted with the review of the proposed research protocols prior to initiation of the projects and also have a continuing responsibility of regular monitoring of the approved programs till the same are completed. Such an ongoing review is in accordance with the Declaration of Helsinki and all the international guidelines for biomedical research.

1. GENERAL PRINCIPLES

Research on human participants aiming at developing generalizable knowledge that improves health, increases understanding of disease and is ethically justified by its social value. Therefore, **protection of participants should be built into the design of the study**. 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.

1.1.1 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.

2. GENERAL ETHICAL ISSUES

The researcher and his team are responsible for protecting the dignity, rights, safety and well-being of the participants enrolled in the study. They should have the appropriate qualifications and competence in research methodology and should be aware of and comply with the scientific, medical, ethical, legal and social requirements of the research proposal. The IEC-BU is responsible for ensuring that the research is conducted in accordance with the aforementioned principles.

2.1 Benefit-risk assessment

Benefits to the individual, community or society refer to any sort of favourable outcome of the research, whether direct or indirect. The social and scientific value of research should justify the risk, which is the probability of causing discomfort or harm anticipated as physical, psychological, social, economic or legal.

2.2 Informed consent process

Informed consent protects the individual's autonomy to freely choose whether or not to participate in the research. The process involves three components – providing relevant information to potential

participants, ensuring the information is comprehended by them and assuring voluntariness of participation. Informed consent should explain medical terminology in simple terms and be in a language that the participant understands.

2.3 Privacy and confidentiality

Privacy is the right of an individual to control or influence the information that can be collected and stored and by whom and to whom that information may be disclosed or shared. Confidentiality is the obligation of the researcher/research team/organization to the participant to safeguard the entrusted information. It includes the obligation to protect information from unauthorized access, use, disclosure, modification, loss or theft.

2.4 Distributive justice

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 to solely benefit others who are better-off than themselves. Research should not lead to social, racial or ethnic inequalities.

2.5 Payment for participation

Participants may be reimbursed for expenses incurred relating to their participation in research, such as travel related expenses. Participants may also be paid for inconvenience incurred, time spent and other incidental expenses in either cash or kind or both as deemed necessary (for example, loss of wages and food supplies).

2.6 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, participant's dependents are entitled to financial compensation. The research proposal should have an in-built provision for mitigating research related harm.

2.7 Ancillary care

Participants may be offered free medical care for non-research-related conditions or incidental findings if these occur during the course of participation in the research, provided such compensation does not amount to undue inducement as determined by the IEC.

2.8 Conflict of interest

Conflict of interest (COI) is a set of conditions where professional judgement concerning a primary interest such as participants welfare or the validity of research tends to be unduly influenced by a secondary interest, financial or non-financial (personal, academic or political). COI can be at the level of researchers, EC members, institutions or sponsors. If COI is inherent in the research, it is important to declare this at the outset and establish appropriate mechanisms to manage it.

2.9 Selection of vulnerable and special groups as research participants

Vulnerable groups and individuals may have an increased likelihood of incurring additional harm as they may be relatively (or absolutely) incapable of protecting their own interests. Characteristics that make individuals vulnerable are legal status – children; clinical conditions – cognitive impairment, unconsciousness; or situational conditions –including but not limited to being economically or socially disadvantaged, (for example, certain ethnic or religious groups, individuals/communities which have hierarchical relationships, institutionalized persons, humanitarian emergencies, language barriers and cultural differences).

2.10 Community engagement

The community should be meaningfully engaged before, during and after the research to mitigate culturally sensitive issues and ensure greater responsiveness to their health needs and requirements.

2.11 Post research access and benefit sharing

The benefits accruing from research should be made accessible to individuals, communities and populations whenever relevant. Sometimes more than the benefit to the individual participant, the community may be given benefit in an indirect way by improving their living conditions, establishing counselling centres, clinics or schools, and providing education on good health practices.

3. RESPONSIBLE CONDUCT OF RESEARCH (RCR)

All members of a research team are expected to maintain high standards and to uphold the fundamental values of research. The responsible conduct of research (RCR) involves the following major components: values; policies; planning and conducting research; reviewing and reporting research; and responsible authorship and publication.

Unethical behaviour in scientific research can destroy the public's trust in science and have a negative impact on the research team. Without trust between scientists and the public, or within research teams, meaningful research is compromised. Researchers should be aware that the resources of biomedical research are precious and to be used judiciously. Where ever possible they should also seek opportunities to plan translation of research findings into public health outcomes.

There should be mechanisms for monitoring research including data capture, management , conflicts of interest, reporting of scientific misconduct, and appropriate initial and continuing training of researchers and EC members.

Ownership issues and responsibilities need to be carefully worked out well before data are collected and researchers should ensure clarity about data ownership, publication rights and obligations following data collection. MoUs vetted by the institution and/or IEC-BU should be in place.

For biological samples, donors (participants) maintain the ownership of the sample. She/he could withdraw both the biological material and the related data unless the latter is required for outcome measurement and is so mentioned in the initial informed consent document. BU shall be the custodians of the data/ samples.

Researchers are increasingly collaborating with colleagues who have the expertise and/or for resources needed to carry out particular research. This could be inter-departmental/ inter-institutional or international and also multicentre involving public and/or private research centres and agencies. The main ethical issues surrounding collaborations pertain to sharing techniques, ownership of materials and data, IPRs, joint publications, managing research findings, managing COI and commercializing research outcomes. Researchers should familiarize themselves with all aspects including local, national and international requirements for research collaboration including

necessary approvals, memorandums of understanding (MoUs) and material transfer agreements (MTA) and EC approval of collaborating institutes.

If there is exchange of biological material involved between collaborating sites, the IEC may require appropriate MoU to safeguard the interests of participants and ensure compliance while addressing issues related to confidentiality, sharing of data, joint publications, benefit sharing, etc.

The review, conduct and monitoring of collaborative research should be overseen and stakeholders must be aware of the requirements of various regulatory and funding agencies. The IEC should review the protocols in the local social and cultural context and ensure respect for sensitivities and values of participants and communities at collaborative sites. A mechanism for communication between the IECs of different participating centres should be established. In case of any conflict, the decision of the IEC-BU based on relevant facts/guidelines/law of the land shall prevail. The IEC should examine whether the researcher has the required expertise and training in the area of collaboration. The IEC-BU should protect the interests and rights of the collaborating researcher(s) and ensure that they are not treated as mere collectors of samples or data. Participating researchers from collaborating sites should be adequately represented when designing the research proposal. BU should provide opportunities for collaboration to build capacity and engage in research which is mutually beneficial.

International collaboration

On one hand collaboration in medical research could be seen as a humane interest in the health of civil society, on the other hand it could create the impression of exploitation by one country experimenting on the population of another poorer one. Due to different levels of development in terms of infrastructure, expertise, social and cultural perceptions, laws relating to IPR, ethical review procedures, etc., an ethical framework based on equality and equity is required to guide such collaborations.

The same is applicable to research undertaken with assistance and/or collaboration from international organizations (public or private). The collaboration may involve either implementation of multiple components of the research or even a single component like laboratory testing. To undertake a collaborative research, the ethical guidelines and relevant regulatory requirements from

different relevant Ministries/ Departments like DHR, DBT, DST, DAE etc. should be followed and understood before the sponsor agency/country initiates collaboration.

4. BASIC RESPONSIBILITIES

The basic responsibility of the Institutional Ethics Committee (IEC) is to ensure a competent review of all ethical aspects of the project proposals received by it in an objective manner. IECs should provide advice to the researchers on all aspects of the welfare and safety of the research participants after ensuring the scientific soundness of the proposed research. The scientific evaluation should ensure technical appropriateness of the proposed study.

The IEC may review proposals submitted by undergraduate / post-graduate students/ Ph. D. scholars/ Post Doctoral fellows/ Faculties.

The responsibilities of an IEC can be defined as follows:-

• To protect the dignity, rights and well being of the potential research participants.

• To ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customs.

• To assist in the development and the education of a research community responsive to local health care requirements.

The guidelines mentioned here will cover areas like social and behavioural sciences research for health and responsible conduct of research, public health research, research required during humanitarian emergencies and disasters, along with a few other areas like process of informed consent, research on biological materials, biobanking, Stem Cell Research etc.

COMPOSITION, AFFILIATIONS, QUALIFICATIONS, MEMBER SPECIFIC ROLES AND RESPONSIBILITIES OF THE IEC (As per ICMR Guidelines):

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 • Should be able to devote adequate time to this activity which should be protected by the institution	• 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. • 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 -	• Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process,

	• 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	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
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.
7	**Lay person(s)** Non-affiliated Qualifications - • Literate person from the public or community • Has not pursued a medical	• 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.

	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	• Assess on societal aspects if any.

N.B.: Please Refer Office order no-07 and Memo No. BU/ Estt/ IEC-AEC/03/2022/44 of Dated 12/01/2022

<u>Quorum requirements for EC meetings</u>:

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. (*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.*)

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.

Terms of reference for EC members

- The head of the institution should appoint all IEC members, including the Chairperson.
- The appointment letter issued to all members should specify the Terms Of References (TOR). 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

- Generally, the term of IEC membership may be 3 years. The duration could be extended as specified in the SOPs. A defined percentage of IEC members could be changed on a regular basis.
- IEC members may be given a reasonable honorarium for attendance at the meeting.

Additionally the IEC shall look into the following points:

The IEC 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.

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

As far as possible a separate scientific committee should review proposal before it is referred to IEC in certain issues like Stem Cell Research or research related to Radioisotopes. EC can raise scientific queries besides ethical ones as both good science and ethics are important to ensure quality of research and participant protection.

5. HOW TO APPLY FOR ETHICAL APPROVAL

Researchers should submit research proposals as soft or hard copies to the Secretariat/ Member Secretary for review in the prescribed format and with required documents as follows:

Details of documents to be submitted for IEC 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 Conflict of Interest, if any

12. Good Clinical Practice training certificate (preferably within 5 years) of investigators (clinical trials)

13. Any other research ethics/other training evidence, if applicable as per IEC 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 Health Ministry Screening Committee-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)

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. Full Research Protocol

Details of documents to be included in the protocol

The protocol should including the following:

1. The cover 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.

6. TYPES OF REVIEW

A. 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 programs by Govt. agencies such as program evaluation where the sole purpose of the exercise is refinement and improvement of the program or monitoring (where there are no individual identifiers).

B. 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.

• For multicentre research where a designated main IEC among the participating sites has reviewed and approved the study, a local IEC may conduct only an expedited review for site specific requirements in addition to the full committee common review.

• Research during emergencies and disasters.

C. 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;

• Studies involving deception of participants;

• 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.

7. ETHICAL ISSUES RELATED TO REVIEWING A PROTOCOL

A. 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 IECs must ensure that the planned research has social value.

B. 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.

Although IECs 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 IEC 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.

C. 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 IEC should review plans for risk management, including withdrawal criteria with rescue medication or procedures.

The IEC 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).

D. 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.

E. 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.

• 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.

F. Protection of research participants' privacy and confidentiality:

• IECs 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.

G. Community considerations:

• The IEC 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.

H. 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.

I. Disclosure or declaration of potential Conflict of interest:

• The IEC should review any declaration of COI by a researcher and suggest ways to manage these.

• The IEC should manage COI within the IEC and members with COI should leave the room at the time of decision making in a particular study.

J. 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.

K. 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;

• Contents of the patient/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 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.

8. TYPES OF DECISIONS BY IEC

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.

9. DOCUMENTS TO BE MAINTAINED BY EC FOR RECORD

A. Administrative documents:

• Constitution, Policy and Composition of the IEC
• 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 IEC
- SOPs

B. **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
- Serious Adverse Events, Adverse Events reports
- Protocol deviations/violations
- Progress reports, continuing review activities, site monitoring reports
- All correspondence between the IEC and researchers
- Record of notification issued for premature termination of a study witha summary of the reasons
- Final report of the study
- Publications, if any

10. REGISTRATION AND ACCREDITATION OF IEC

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

IEC should register with the relevant authority as per the regulatory requirements.

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 Programs (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.

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[DECLARATION: This document is prepared by following the National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2017 prepared by ICMR Bioethics Unit, INDIA. Further, for any dispute it is suggested to follow the above document for clarification and other relevant documents published by Ministries of Govt. of India, WHO, UNICEF etc.]