Standard Operating Procedures (SOP)

Tezpur University Ethics Committee (TUEC)

तेजपुर विश्वविद्यालय / TEZPUR UNIVERSITY

(केंद्रीय विश्वविद्यालय /A Central University)

तेजपुर-784028:: असम/ TEZPUR-784028 :: ASSAM

STANDARD OPERATING PROCEDURES (SOP)

TEZPUR UNIVERSITY ETHICS COMMITTEE (TUEC)

Prepared by:

1. **Dr. Nayanmoni Gogoi, Member TUEC,** Assistant Professor, Department of Environmental Science, Tezpur University
2. **Debajit Kumar Sarmah, Member TUEC,** Assistant Professor, Department of Law, Tezpur University
3. **Dr. Rupak Mukhopadhyay, Member Secretary TUEC** Associate Professor, Department of Molecular Biology and Biotechnology, Tezpur University

SOP Drafting Committee:

1. **Prof. Robin Doley, Member TUEC,** Professor, Department of Molecular Biology and Biotechnology, Tezpur University
2. **Dr. Rupak Mukhopadhyay, Member Secretary TUEC** Associate Professor, Department of Molecular Biology and Biotechnology, Tezpur University
3. **Dr. Nayanmoni Gogoi, Member TUEC,** Assistant Professor, Department of Environmental Science, Tezpur University
4. **Debajit Kumar Sarmah, Member TUEC,** Assistant Professor, Department of Law, Tezpur University
5. **Angel Habamon Syiem,** Assistant Professor, Department of Law, Tezpur University

Reviewed and approved by:

1. **Dr. Kangkan Pathak, Chairperson TUEC,** Professor and Head, Department of Psychiatry, Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur
2. **Prof. Dhanapati Deka**, Dean, Research and Development, Tezpur University
3. **Dr. Ashish Bhattcharjee**, Associate Professor, Department of Biotechnology, NIT-Durgapur

***

Table of Contents (TOC)

Constitution of the TUEC

TU/TUEC/SOP/I

---

1. Constitution of the TUEC

The TUEC is constituted by the Dean, Research and Development, Tezpur University, and it is comprised of members from multidisciplinary and multisectoral backgrounds. As per ICMR guidelines, there is adequate representation of age and gender, and preferably 50% of the members are non-affiliated/from outside Tezpur University. The number of members in TUEC should be between 7 (seven) and 15 (fifteen). The TUEC should keep a balance between medical and non-medical members as well as technical and non-technical members, depending upon the needs of the institution.

As per ICMR guidelines, the TUEC can have as its members, individuals from other institutions or communities with adequate representation of age and gender to safeguard the interests and welfare of all sections of the community/society. If required, subject experts will be invited to offer their views, for instance, a pediatrician for pediatric conditions, a cardiologist for cardiac disorders etc. Similarly, based on the requirement of research area, for example HIV, genetic disorders etc. the TUEC may include a member from specific patient groups in the Committee.

1.1. Composition, affiliations, qualifications, member specific roles and responsibilities of the TUEC

The details of the members constituting the TUEC, their affiliations, qualifications, roles, and responsibilities as per ICMR guidelines are comprehensively discussed below:

1.1.1. Chairperson (non-affiliated)

Qualification

- A well-respected person from any background with prior experience of having served/ serving in an ethical committee (EC)

Definition, description, roles, and responsibilities

- 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 Conflict of interest (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.

1.1.2. Member Secretary (affiliated)

Qualification

- 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

Definition, description, roles, and responsibilities

- 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

1.1.3. Basic Medical Scientist(s) (affiliated/non-affiliated)

Qualification

- 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

Definition, description, roles, and responsibilities

- 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

1.1.4. Clinician(s) (affiliated/non-affiliated)

Qualification

- Should be individual/s with recognized medical qualification, expertise, and training

Definition, description, roles, and responsibilities

- 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

1.1.5. Legal expert/s (affiliated/non-affiliated)

Qualification

- Should have a basic degree in Law from a recognized university, with experience
- Desirable: Training in medical law

Definition, description, roles, and responsibilities

- 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

1.1.6. Social scientist/ philosopher/ethicist/theologian (affiliated/non-affiliated)

Qualification

- Should be an individual with social/ behavioral 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

Definition, description, roles, and responsibilities

- 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

1.1.7. Lay person(s) (non-affiliated)

Qualification

- 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

Definition, description, roles, and responsibilities

- 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

Adapted from:

Kalita, K., N., Pathak, K. (2020) Standard Operating Procedures (SOPs), Institutional Ethics Committee, Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

Mathur, R., Thakur, K., Rathna, M., D., Pardhi, A. (2020) National Guidelines for Ethics Committees reviewing Biomedical and Health Research During Covid-19 Pandemic, ICMR - National Centre for Disease Informatics & Research, Bengaluru for Director General, Indian Council of Medical Research, New Delhi

***

Terms of Reference (TOR) for TUEC

TU/TUEC/SOP/II

---

2. Terms of Reference (TOR) for TUEC

The head of the institution will appoint all TUEC members, including the Chairperson. The appointment letter issued to all members will specify the TORs. The letter issued by the head of the institution will include, at the minimum, the following (as per ICMR guidelines):

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

Generally, the term of TUEC membership will be 2–3 years. The duration could be extended as specified in the SOPs. A defined percentage of TUEC members will be changed on a regular basis. The members may be given a reasonable honorarium for attendance at the meeting.

It would be preferable to appoint persons trained in bioethics or persons conversant with ethical guidelines and laws of the country. Members of the TUEC should not have any known record of misconduct. Substitute member may be nominated if meetings have been continuously missed (three consecutive meetings) by a member due to illness or other unforeseen circumstances.

A copy of the SOP will be made available to each member, and they should be trained on the SOP. The SOP will be available in the secretariat of the TUEC and University website.

The TUEC refers to ICMR guidelines in preparing the SOPs for all biomedical and health research. However, the TUEC may register with the other regulatory authorities as and when required.

Adapted from:

Kalita, K., N., Pathak, K. (2020) Standard Operating Procedures (SOPs), Institutional Ethics Committee, Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

Mathur, R., Thakur, K., Rathna, M., D., Pardhi, A. (2020) National Guidelines for Ethics Committees reviewing Biomedical and Health Research During Covid-19 Pandemic, ICMR - National Centre for Disease Informatics & Research, Bengaluru for Director General, Indian Council of Medical Research, New Delhi

***

Quorum Requirement for TUEC Meetings

TU/TUEC/SOP/III

---

3. Quorum Requirement for Meetings

A TUEC 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. The committee 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 terms of references (TORs) as regular members and can attend meetings in the absence of regular members.

- A minimum of 50%+1 members must be present in the meeting room
- The quorum should include both medical, non-medical or technical or/and non-technical members*
- Minimum one non-affiliated member should be part of the quorum
- Preferably the lay person should be part of the quorum
- The quorum for reviewing regulatory clinical trials should be in accordance with current CDSCO requirements
- 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.*

Adapted from:

Kalita, K., N., Pathak, K. (2020) Standard Operating Procedures (SOPs), Institutional Ethics Committee, Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

Mathur, R., Thakur, K., Rathna, M., D., Pardhi, A. (2020) National Guidelines for Ethics Committees reviewing Biomedical and Health Research During Covid-19 Pandemic, ICMR - National Centre for Disease Informatics & Research, Bengaluru for Director General, Indian Council of Medical Research, New Delhi

***

Recruiting Vulnerable Populations for Research

TU/TUEC/SOP/IV

---

4. Recruiting Vulnerable Populations for Research

4.1. Responsibility:

4.1.1. Researcher/investigator:

Recognize the vulnerability of the participant and ensure additional safeguards are in place for their protection, Justify inclusion/exclusion of vulnerable populations in the study, COI issues must be addressed, Have well defined procedures (SOPs) to ensure a balanced benefit-risk ratio, ensure that prospective participants are competent to give informed consent, take consent of the appropriate guardian/caregiver/LAR when a prospective participant lacks the capacity to consent, respect dissent from the participant, seek permission of the appropriate authorities where relevant, such as for institutionalized individuals, tribal communities, etc., Research should be conducted within the purview of existing relevant guidelines/regulations.

4.1.2. TUEC Members:

During review, determine whether the prospective participants for a particular research are vulnerable, examine whether inclusion/exclusion of the vulnerable population is justified, ensure that COI do not increase harm or lessen benefits to the participants, carefully determine the benefits and risks to the participants and advise risk minimization strategies wherever possible, suggest additional safeguards, such as more frequent review and monitoring, including site visits, it is desirable to have empowered representatives from the specific populations during deliberations, TUECs have special responsibilities when research is conducted on participants who are suffering from mental illness and/or cognitive impairment. They should exercise caution and require researchers to justify cases for exceptions to the usual requirements of participation or essentiality of departure from the guidelines governing research which should be kept minimum and clearly stated in protocol and in the Informed Consent Document (ICD). Chairperson, TUEC should give specific suggestions to researcher and to the sponsors. Secretariat shall do the documentation. TUEC may in its initial discussion seek clarification from the investigator specific issues as per feedback from the reviewers. It may suggest modification in the protocol.

4.1.3. Sponsor/Institute:

The sponsor, whether a government, an institution, or a pharmaceutical company, should justify the inclusion of vulnerable groups in the protocol and make provisions for protecting their safety, the sponsor must enable monitoring and ensure that procedures are in place for quality assurance (QA) and quality control (QC), the sponsor should ensure protection of the participants and research team if the research is on sensitive topics.

4.2. Detailed Description:

The following is a list which is not exclusive of vulnerable groups for bringing transparency on the issue:

- economically and socially disadvantaged (unemployed individuals, orphans, abandoned)
- individuals, persons below the poverty line, ethnic minorities, sexual minorities – lesbian/ gay/bisexual and transgender (LGBT) unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate which may lead them to give consent
- children (up to 18 years)
- women in special situations (pregnant or lactating women, or those who have poor decision-making powers/poor access)
- tribals and marginalized communities
- refugees, migrants, homeless, persons or populations in conflict zones, riot areas or disaster situations
- afflicted with mental illness and cognitively impaired individuals, differently abled
- terminally ill or are in search of new interventions having exhausted all therapies
- suffering from stigmatizing or rare diseases; or
- have diminished autonomy due to dependency or being under a hierarchical system (students, employees, subordinates, defence services personnel, healthcare workers, institutionalized individuals, under trials and prisoners etc.).

4.3. Specific issues of some vulnerable groups:

4.3.1. Women in special situations:

Women have equal rights to participate in research and should not be deprived arbitrarily of the opportunity to benefit from research. Informed consent process for some women can be challenging because of cultural reasons. Hence, the women may consider consulting their husbands or family members, if necessary. Although autonomy of the woman is important, the researcher must follow the requirements of local cultural practices so as not to disturb the harmony in the household/family/community. Participation in any intervention has specific issues of pregnancy, contraceptives, and benefits of some trial or diagnostic tests. When specific issues of high sensitivities like domestic violence, dowry, sexual offences, genetic disorders etc. are planned for research then strict confidentiality and privacy need to be maintained. There may be need for additional counseling center and help for law enforcement agencies as additional safety measure for the participants.

4.3.2. Individuals with mental illness/cognitive impairment:

According to the Mental Healthcare Act (MHCA), 2017, "mental illness" means a substantial disorder of thinking, mood, perception, orientation or memory that grossly impairs judgment, behavior, capacity to recognize reality or ability to meet the ordinary demands of life, mental conditions associated with the abuse of alcohol and drugs, but does not include mental retardation which is a condition of arrested or incomplete development of the mind of a person, specially characterized by sub normality of intelligence. Presence of a mental disorder is not synonymous with incapacity of understanding or inability to provide informed consent. Section 99 of MHCA needs to be strictly adhered to in this regard. No study will be considered in prohibited treatment as described in the MHCA 2017. Rights with Persons with Disability Act 2016 deals a section of persons with disability due to mental illness and other conditions of arrested development including intellectual disability, autism, cerebral palsy etc. and the relevant provisions need to be strictly adhered to. Conscious mental activities such as thinking, understanding, learning, and remembering are defined as cognition. Those in whom these activities are not fully functional are regarded as cognitively impaired. Such individuals or groups include people who are without full intellectual potential (intellectually disabled, previously called mentally retarded), unconscious, suffering from neuropsychological disorders such as dementia or delirium, and those who cannot

fully comprehend or participate in the informed consent process, either temporarily or permanently. Other sources or reasons for cognitive impairment affecting the ability to give informed consent include, but are not limited to, being too young (children do not yet develop the necessary cognitive abilities to give informed consent); being in extreme pain; being under the influence of medication, illicit drugs, or alcohol; mental retardation; and traumatic brain injury (Annexure-IVA/TUEC/SOP).

Some of the conditions may have risk of harming self and others and following considerations may need to be addressed:

- During the informed consent process, prospective participants must be informed about how the researcher will address a participant's suicidal ideation or other risks of harm to themselves or others
- It should be disclosed to the participant that her/his confidentiality may be breached for reporting to family members, police, or other authorities or they may have to be admitted in the hospital upon expression of such thoughts of harm to self or others
- While some interventions, like hospitalization and treatment for suicidality/ homicidal ideas, may be primarily for the participants' own benefit, they themselves may not perceive these as such and may want to refuse to participate if any such intervention is required
- Interventions should be of short duration, as least restrictive as possible and invoked only, when necessary, in accordance with relevant laws
- Some research designs may reduce or violate human participant protections/rights or specific requirements of informed consent by resorting to deception to achieve the objectives of the research for public good.

4.3.3. Individuals with diminished autonomy due to dependence or being in a hierarchical system:

While reviewing protocols that include students, employees, subordinates, defense services personnel, healthcare workers, institutionalized individuals, under trials, prisoners, and others the TUEC, must ensure the following:

- Enrolling participants as described above is specifically pertinent to the research questions and is not merely a matter of convenience
- Individuals in a hierarchical position may not be able to disagree to participate for fear of authority and therefore extra efforts are required to respect their autonomy
- It is possible for the participant to deny consent and/or later withdraw from the study without any negative repercussions on her/his care
- Mechanisms to avoid coercion due to being part of an institution or hierarchy should be described in the protocol. Specific issues of Informed Consent need to be properly addressed and researcher will be needed to respond appropriately (Annexure-IVB/TUEC/SOP).

4.3.4. Children:

Children are individuals who have not attained the legal age of consent (up to 18 years). At younger ages, children are considered vulnerable because their autonomy is compromised as they do not have the cognitive ability to fully understand the minute details of the study and make decisions. At older ages, although they may attain the cognitive ability to understand the research, they still lack legal capacity to consent. Therefore, the decision regarding participation and withdrawal of a child in research must be taken by the parents/ (Legally acceptable/authorized Representative (LAR) in the best interests of their child/ward. Guideline available in ICMR "National Ethical Guidelines for Bio-Medical Research involving Children, 2017" need to be strictly adhered to. Children can be included in research if the situation, condition, disorder or disease fulfils one of the following conditions:

- It is exclusively seen in childhood
- Both adults as well as children are involved, but the issues involved are likely to be significantly different in both these populations
- Both adults as well as children are involved in a similar manner and are of similar nature in terms of morbidity, severity and/or mortality, wherever relevant, and studies in adults have demonstrated the required degree of safety and efficacy
- Test interventions are likely to be at least as advantageous to the individual child participant as any available alternative intervention

- Risk of test interventions that is not intended to benefit the individual child participant is low as compared to the importance of the knowledge expected to be gained (minor increase over minimal risk)
- Research is generally permitted in children if safety has been established in the adult population or if the information likely to be generated cannot be obtained by other mean
- The physiology of children is different from that of adults, and the pharmacokinetics of many drugs is age-dependent based on the maturation of the drug metabolism pathways. For example, children metabolize many drugs much more rapidly as compared to adults, hence the dose of the drug per kg of body weight that needs to be given, is much higher in children as compared to adults.
- The absorption of drugs also varies with age; pharmacokinetics and toxicity profile vary with growth and maturation from infancy to adulthood
- The adverse effects of many drugs may also be different in children as compared to adults. For instance, tetracyclines cause teeth discoloration in young children, aspirin use is associated with Reye's syndrome in children
- Age-appropriate delivery vehicles and formulations (e.g., syrups) are needed for accurate, safe, and palatable administration of medicines to infants and children
- The pathophysiology of many disorders is dependent on a child's growth, development, and adaptive plasticity. Examples include adaptive changes in the motor system following a perinatal stroke
- The TUEC will do the benefit–risk assessment to determine whether there is a need to put into place additional safeguards/protections for the conduct of research in children. For example, research should be conducted in child-friendly settings, in the presence of parent(s) and where child participants can obtain adequate medical and psychological support (Annexure-IVC/TUEC/SOP)
- The TUEC will take into consideration the circumstances of the children to be enrolled in the study including their age, health status, and other factors and potential benefits to other children with the same disease or condition, or to the society.

Consent of the parent/LAR is required when research involves children. Special issues in relation to consent in this regard are:

- The TUEC will determine if consent of one or both parents would be required before a child could be enrolled. This may be on recommendation of reviewer
- Generally, consent from one parent/LAR may be considered sufficient for research involving no more than minimal risk and/or that offers direct benefit to the child. Consent from both parents may have to be obtained when the research involves more than minimal risk and/or offers no benefit to the child
- Only one parent's consent is acceptable if the other parent is deceased, unknown, incompetent, not reasonably available, or when only one parent has legal responsibility for the care and custody of the child, irrespective of the risk involved
- Whenever relevant, the protocol should include a parent/LAR information sheet that contains information about specific aspects relevant to the child such as effects on growth and development, psychological well-being, and school attendance, in addition to all components described in the participant information sheet
- When the research involves sensitive issues related to neglect and abuse of a child, the TUEC may waive the requirement of obtaining parental/LAR consent and prescribe an appropriate mechanism to safeguard the interests of the child
- Cognitively impaired children or children with developmental disorders form one of the most vulnerable populations. In fact, their parents are also vulnerable and there is a high likelihood of therapeutic misconception. The potential benefits and risks must be carefully explained to parents to make them understand the proposed research
- Research involving institutionalized children would require assent of the child, consent of parents/LAR, permission of the relevant institutional authorities (for example, for research in a school setting: the child, parents, teacher, principal, or management may be involved).

Assent:

In addition to consent from parents/LARs, verbal/oral or written assent, as approved by the TUEC, should be obtained from children of 7–18 years of age. As children grow, their mental faculties

develop, and they can understand and respond. Respecting the child's reaction, the child is had a party to the consent process by the researcher, who explains the proposed research in a very simple manner, in a language that ensures that the child understands the request to participate in the research. A child's agreement to participate in research is called assent. If the child objects, this wish must be respected. At the same time, mere failure to object should not be construed as assent. However, if the test intervention is likely to be lifesaving and is available only if the child participates in the study, the dissent by the child may be disregarded provided parental consent and prior approval from the TUEC is obtained. Content of the assent form must be in accordance with the developmental level and maturity of the children to be enrolled and explained while considering the differences in individual understanding. The language of the assent form must be consistent with the cognitive, social, and emotional status of the child. It must be simple and appropriate to the age of the child. Sample of assent need to be specific and should contain information paragraph wise about the necessity; procedure; discomfort, if any; information about help on need; right to refuse to enroll for study.

Waiver of Assent:

All the conditions that are applicable to waiver of informed consent in adults also apply for waiver of assent in children. If the available intervention is anticipated to benefit the child but would be available only if the child participates in the study, waiver of assent could be allowed. However, this situation should be accepted only in exceptional cases where all forms of assent/consent have failed. In such cases, approval of the TUEC should be obtained.

Some issues to be considered while attaining assent are detailed below:

- There is no need to document assent for children below 7 years of age
- For children between 7 and 12 years, verbal/oral assent must be obtained in the presence of the parents/LAR and should be recorded
- For children between 12 and 18 years, written assent must be obtained. This assent for also must be signed by the parents/LAR
- Adolescents may have the capacity to give consent like adults. However, as they have not attained the legal age to provide consent, it is termed as assent and the consent of the parents/LAR should be obtained. If the latter will affect the validity of the study, waiver of

consent from the relevant adult should be taken and recorded with the approval of the TUEC, for example, in behavioral studies of intravenous (IV) drug users where parental consent may not be possible.

4.3.5. Sexual minorities and sex workers:

There are unique challenges associated with research on sexual minorities and sex workers such as privacy, confidentiality, possibility of stigma, discrimination and exploitation resulting in increased vulnerability. Protection of their dignity and provision of quality healthcare under these circumstances should be well addressed in the research proposal, preferably in consultation with the community before the proposal is finalized. It is advisable to have a representative of the sexual minority group/ lesbian/ gay/bisexual and transgender (LGBT) community as a special invitee/member to participate in the meeting of the TUEC if there is a research proposal involving these participants. The TUEC may suggest setting up of a community advisory board to act as an interface between the researcher(s) and the community. Among the LGBT community there are inhibitions between the different groups, so details of the research should be explained to each group separately. Peer educators or champions among the LGBT community could be educated and sensitized first. They would in turn explain the details to the potential participants from the community who would then understand them better.

4.3.6. Tribal population:

Research on tribal populations should be conducted only if it is of a specific therapeutic, diagnostic, and preventive nature with appropriate benefits to the tribal population. Due approval from competent administrative authorities, like the tribal welfare commissioner or district collector, should be taken before entering tribal areas. Whenever possible, it is desirable to seek help of government functionaries/local bodies or registered NGOs who work closely with the tribal groups and have their confidence. Where a panchayat system does not exist, the tribal leader, other culturally appropriate authority, or the person socially acceptable to the community may serve as the gatekeeper from whom permission to enter and interact should be sought. Informed consent should be taken in consultation with community elders and persons who know the local language/dialect of the tribal population and in the presence of appropriate witnesses. Even with permission of the gatekeeper, consent from the individual participant must be sought. Additional precautions should be taken to avoid inclusion of children, pregnant women and elderly people

belonging to particularly vulnerable tribal groups. Benefit sharing with the tribal group should be ensured for any research done using tribal knowledge that may have potential for commercialization (Annexure-IVD/TUEC/SOP).

4.3.7. Other vulnerable groups:

Other vulnerable groups include the economically and socially disadvantaged, homeless, refugees, migrants, persons or populations in conflict zones, riot areas or disaster situations. Additional precautions should be taken to avoid exploitation/retaliation/ reward/credits and other inducements when such individuals are to be recruited as research participants. Autonomy of such individuals is already compromised, and researchers must justify their inclusion. TUEC members will satisfy them with the justification provided to include these participants and record the same in the proceedings of the TUEC meeting. Additional safety measures will be strictly followed by the TUEC. The informed consent process should be well documented. There should not be any undue coercion or incentive for participation. A person's refusal to participate should be respected and there should be no penalization. The TUEC will carefully determine the benefits and risks of the study and examine risk minimization strategies.

4.4. Review Process

The investigator working in the vulnerable groups listed above shall adhere to all the applicable laws and regulations of Appropriate Government. The investigators clearly state the need for such research along with anticipated issues of conflict, if any and the measures to mitigate such happenings. The TUEC will review proposal and submitted documents and may seek suggestions from reviewer/experts both internal and external. Any clarification sought by TUEC need to be clarified by the investigator.

Adapted from:

Kalita, K., N., Pathak, K. (2020) Standard Operating Procedures (SOPs), Institutional Ethics Committee, Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

Mathur, R., Thakur, K., Rathna, M., D., Pardhi, A. (2020) National Guidelines for Ethics Committees reviewing Biomedical and Health Research During Covid-19 Pandemic, ICMR - National Centre for Disease Informatics & Research, Bengaluru for Director General, Indian Council of Medical Research, New Delhi

***

Annexure-IVA/TUEC/SOP

Annexure-IVB/TUEC/SOP

Annexure-IVC/TUEC/SOP

Annexure-IVD/TUEC/SOP

Annexure-IVA/TUEC/SOP

Research Involving Cognitively Impaired & Mentally Ill Adult

Investigator: **TUEC:**

Study Title:

The purpose of this checklist is to provide support for TUEC members or the Designated Reviewer when reviewing research involving adults as mentioned above.

For review, this checklist is to be completed by the Designated Reviewer to document determinations required by the regulations and protocol specific findings justifying those determinations.

1. Research Involving Cognitively Impaired /mentally ill Adults in which there is Anticipated Direct Benefit to the subject (All items must be "Yes")		
□ Yes	□ No	One of the following is true (Check the box that is true) The risk to the participants is presented by an intervention or procedure that holds out prospect of direct benefit for the individual subject More than minimal risk to participants is presented by monitoring procedure that is likely to contribute to the participants well-being
□ Yes	□ No	The risk is justified by the anticipated benefit to the participants
□ Yes	□ No	The relation of anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches
□ Yes	□ No	The proposed plan for the assessment of the capacity to consent is adequate
□ Yes	□ No	Assent is required of: (One of the following must be "Yes") One of the following is true (Check box that is true) All Participants All Participants capable of being consulted None of the participants
□ Yes	□ No	The consent document includes a signature line for a legally authorized representative

2. Research Involving Cognitively Impaired/mentally ill Adults in which there is No Anticipated Direct Benefit to the subject (All items must be "Yes")		
□ Yes	□ No	The proposed plan for the assessment of the capacity to consent is adequate
□ Yes	□ No	The objectives of the trial cannot be met by means of study of participants who can give consent personally
□ Yes	□ No	The foreseeable risks to the participants are low
□ Yes	□ No	The negative impact on the subject's well-being is minimized and low
□ Yes	□ No	The trial is not prohibited by law
□ Yes	□ No	Participants have a disease or condition for which the procedures in the research are intended
□ Yes	□ No	Participants will be particularly closely monitored
□ Yes	□ No	Participants will be withdrawn if they appear to be unduly distressed
□ Yes	□ No	The proposed plan for the assessment of the capacity to consent is adequate
□ Yes	□ No	Assent is required of (One of the following must be "Yes") One of the following is true (Check box that is true) All Participants All Participants capable of being consulted None of the participants
□ Yes	□ No	The consent document includes a signature line for a legally authorized representative/Nominated Representative

Comments:

Name & Sign of Reviewer: **Date:**

Annexure-IVB/TUEC/SOP

Research Involving Students, Employees or Residents/Dependents

Investigator: **TUEC:**

Study Title:

Participants who are students, employees or residents require special considerations.

The proposed plan for the assessment of the capacity to consent is adequate	□ Yes	□ No
Have the participants been assured that their status (education, employment, and/or promotion) will not be affected by any decision to participate or not?	□ Yes	□ No
Have the risks to participants been minimized?	□ Yes	□ No
Have participants been assured that participation is voluntary (no signs of coercion)?	□ Yes	□ No
Have participants been assured that confidentiality will be protected or maintained?	□ Yes	□ No

Comments:

Name & Sign of Reviewer: **Date:**

Annexure-IVC/TUEC/SOP

Requirements for Research Involving Children

Investigator: **TUEC:**

Study Title:

RISK DETERMINATION	BENEFIT ASSESSMENT	TUEC ACTION
□ Minimal risk	With direct benefit □ Without direct benefit □	Approved □ Not Approved □
	Only potential to child	Approved □ Not Approved □
	No direct benefit to individual but offer general knowledge about the child's condition or disorder and may benefit to the society or future generations are likely to benefit	Approved □ case by case (with special safeguards Not Approved □
□ Less than minimal risk	With direct benefit □ Without direct benefit □	Approved □ Not Approved □
	Only potential to child	Approved □ Not Approved □
	No direct benefit to individual but offer general knowledge about the child's condition or disorder and may benefit to the society or future generations are likely to benefit	Approved □ case by case (with special safeguards Not Approved □
□ Minor increase over minimal risk or Low risk	With direct benefit □ Without direct benefit □	Approved □ Not Approved □
	Only potential to child	Approved □ Not Approved □

	No direct benefit to individual but offer general knowledge about the child's condition or disorder and may benefit to the society or future generations are likely to benefit	Approved □ case by case (with special safeguards Not Approved □
□ More than minimal risk or High risk	With direct benefit □ Without direct benefit □	Approved □ Not Approved □
	Only potential to child	Approved □ Not Approved □
	No direct benefit to individual but offer general knowledge about the child's condition or disorder and may benefit to the society or future generations are likely to benefit	Approved □ case by case (with special safeguards Not Approved □

i) **Minimal risk –** Probability of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in routine daily life activities of an average healthy individual or general population or during the performance of routine tests where occurrence of serious harm or an adverse event (AE) is unlikely

ii) Risk may not be more than a minor increase over minimal risk, consent of both parents required under normal circumstances

iii) Approval to proceed with this category of research must be made by the TUEC with input from selected experts

	Yes	No	NA
Does the research pose greater than minimal risk to children?	□	□	□
If yes: Are convincing scientific and ethical justification given?	□	□	□
If yes: Are adequate safeguard in place to minimize these risks?	□	□	□
Does the study involve normal volunteers?	□	□	□
If yes: Is the inclusion of normal volunteers justified?	□	□	□
Have appropriate studies been conducted on animals and adults justified?	□	□	□
If No: Is the lack of appropriate studies conducted on animals and adults justified?	□	□	□
Will older children be enrolled before younger ones?	□	□	□

Is permission of both parents necessary?	□	□	□
If Yes-please justify	□	□	□
Will efforts be made to ensure that parents'	□	□	□
Permission to involve their children in research studies is free from coercion, exploitation, and/or unrealistic promises?	□	□	□
Are provisions made to obtain the assent of children over 7 and, where appropriate, honoring their dissent?	□	□	□
Are provisions made to protect participants' privacy and the confidentially of information regarding procedures?	□	□	□
Are there special problems that call for the presence of a monitor or TUEC member during consent procedures?	□	□	□
Are special needs of adolescents such as counseling and confidentiality accounted for in the research design?	□	□	□
Are there any special problems such as confidentiality and reporting that might arise in sensitive research about child abuse or sexual practices of teenagers?	□	□	□
Does the research involve implications for other family member? (for example, genetic risk, HIV infection, Hepatitis C)	□	□	□
If Yes: Are adequate mechanisms in place to deal with other members of the family?	□	□	□
Should parents be required to be present during the conduct of the research? (Are proposed participants very young? Are the procedures involved painful? Must subject need to stay overnight in the hospital when they otherwise would not have to?)	□	□	□

Comments:

Name & Sign of Reviewer: **Date:**

Annexure-IVD/TUEC/SOP

Requirement for Research Involving Pregnant or nursing women, Foetuses & nursing infant

Investigator: **TUEC:**

Study Title:

RISK DETERMINATION	BENEFIT ASSESSMENT	TUEC ACTION
□ Minimal	With or without direct benefit	Approvable
□ Less than minimal risk	With or without direct benefit	Approvable
□ Minor increase over minimal risk or Low risk	With or without direct benefit	Approvable
□ More than minimal risk or High risk	Potential benefit	Approvable
□ More than minimal risk or High risk	No direct benefit to individual but offer general knowledge about the child's condition or disorder and may benefit to the society or future generations are likely to benefit	Approvable on case to case basis with special safeguards

	Yes	No	NA
Where scientifically appropriate, has preclinical studies including studies on pregnant animals, and clinical studies including studies on non-pregnant women been conducted and data made available for assessing potential risks to pregnant or nursing women, nursing infant and fetuses	□	□	□
The risk to the fetus or nursing infant is not greater than minimal, or any risk to the fetus which is greater than minimal is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus or nursing infant	□	□	□
Any risk, is the least possible, for achieving the objectives of the research	□	□	□

The women's consent or the consent of her legally authorized representative is obtained in accordance with the informed consent provisions, unless altered or waived in accord with SOPs	□	□	□

	Yes	**No**	**NA**
The women or her legally authorized representatives, as appropriate, is fully informed regarding the reasonably foreseeable impact of the research on the fetus or resultant child	□	□	□
If the research involves minors who are pregnant, assent and permission will be obtained in accordance with the Schedule Y and ICMR guidelines	□	□	□
No inducements, monetary or otherwise, will be offered to terminate a pregnancy	□	□	□
Individuals engaged in the research will have no part in any decisions as to the timing, method or procedures used to terminate a pregnancy; and	□	□	□
Individuals engaged in the research will have no part in determining the viability of a fetus	□	□	□
Does this research promise therapeutic or preventive benefits (e.g., Example of such trials are, to test the efficacy and safety of a drug for reducing perinatal transmission of HIV infection from mother to child, trials for detecting foetal abnormalities and for conditions associated with or aggravated by pregnancy)	□	□	□
Does the study involve discontinuation of nursing for the sake of participation in research	□	□	□
Is the cessation of breast-feeding to the nursing child justified?	□	□	□
Is breast feeding harmful to the infant?	□	□	□
Does the research have provisions for compensation in terms of supplying supplementary food such as milk formula?	□	□	□
Can this research be conducted in women who are not pregnant or nursing	□	□	□
Does this research protect or advance the health of pregnant or nursing women or foetuses or nursing infants	□	□	□

Is this research related to termination of pregnancy and is as per the Medical Termination of Pregnancy Act, GOI, 1971	☐	☐	☐
Does this research violate any provisions of the Medical Termination of Pregnancy Act, GOI, 1971	☐	☐	☐

	Yes	**No**	**NA**
Is this research related to pre-natal diagnostic techniques in pregnant Women	☐	☐	☐
Is this research limited to detect the foetal abnormalities or genetic disorders as per the Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, GOI, 1994 and not for sex determination of the foetus	☐	☐	☐
Does this research violate any provisions of the Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, GOI, 1994	☐	☐	☐

Comments:

Name & Sign of Reviewer: **Date:**

Confidentiality Agreements

TU/TUEC/SOP/V

5. Confidentiality Agreements

It refers to the secrecy or non-disclosure agreements designed to protect trade secrets, information, and expertise from being misused by those who have learned about them. Privacy and confidentiality of research participants should be considered while selecting sites for data collection, choosing sensitive research areas, specific contexts, and settings. In some circumstances participants become more vulnerable in research because of heightened psychological, social, physical, or legal risks. Breach of confidentiality in these types of research may cause serious harm to vulnerable participants. It is important to protect study participants from potential future risks and harm by establishing culturally sensitive and context specific safeguards. TUEC will ensure that certain measures are taken to protect privacy and confidentiality of individuals as stated by ICMR guidelines (Annexure-V/TUEC/SOP).

Researchers must safeguard the confidentiality of personally identifiable records, the collected data at demographic sites must be stored in an encrypted format with primary identifiers accessible only to restricted designated individuals who are bound by a confidentiality agreement. For an instance, to confirm if the researcher has taken adequate measures for data security, confidentiality of information, disclosure permissions, and stated appropriate use of the accessed data; maintaining the privacy and confidentiality of the respondent's identity, researchers have an obligation to report the extent or the patterns of behavior, such as suicidal tendency or infanticide, to the concerned authorities; sharing raw data including audio-visual material should protect confidentiality of the individual and research setting by sufficiently processing data to mask identifiers before sharing; maintain confidentiality and safeguard the information for basic research; during storage of biospecimens and data with personal identifiers; during genetic diagnosis/testing and screening; confirm privacy of donors related to biological materials and/or data; confirm physical safety and security of the involved devices and computer servers etc.

Adapted from:

Kalita, K., N., Pathak, K. (2020) Standard Operating Procedures (SOPs), Institutional Ethics Committee, Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

Mathur, R., Thakur, K., Rathna, M., D., Pardhi, A. (2020) National Guidelines for Ethics Committees reviewing Biomedical and Health Research During Covid-19 Pandemic, ICMR - National Centre for Disease Informatics & Research, Bengaluru for Director General, Indian Council of Medical Research, New Delhi

***

Annexure-V/TUEC/SOP

Agreement on Confidentiality and Conflict of Interest

In the course of my activities as a member of the TUEC, Tezpur University I may be provided with confidential information and documentation (which we will refer to as the "Confidential Information"). I agree to take reasonable measures to protect the Confidential Information; subject to applicable legislation, including the access to it, as per the right to Information Act, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the TUEC's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information (including any minutes or notes I have made as part of my Committee duties) to the Chairperson upon termination of my functions as a Committee member.

Undersigned Signature: **Date:**

Whenever I have a conflict of interest, I shall immediately inform the committee not to count me toward a quorum for consensus or voting.

I, Dr./ Mr /Ms._____ have read and I accept the aforementioned terms and conditions as explained in this Agreement.

Undersigned Signature: **Date:**

Training Personnel and TUEC members

TU/TUEC/SOP/VI

---

6. Training Personnel and TUEC members

TUEC members should be encouraged to keep abreast of all national and international developments in ethics through orientation courses on related topics by its own members or regular training organized by constituted body(ies), so that they become aware of their role and responsibilities. Any change in the regulatory requirements should be brought to their attention and they should be aware of local, social, and cultural norms, as this is the most important social control mechanism. Therefore, every TUEC member must be either trained in human research protection and/or Good Clinical Practice (GCP) at the time of induction into the TUEC or must undergo training and submit training certificates within 6 months of appointment; or must be willing to undergo training or update their skills/knowledge during their tenure as a TUEC member. TUEC members should undergo initial and continuing training in human research protection, applicable TUEC SOPs, and related regulatory requirements. All training programs should be documented.

Adapted from:

Kalita, K., N., Pathak, K. (2020) Standard Operating Procedures (SOPs), Institutional Ethics Committee, Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

Mathur, R., Thakur, K., Rathna, M., D., Pardhi, A. (2020) National Guidelines for Ethics Committees reviewing Biomedical and Health Research During Covid-19 Pandemic, ICMR - National Centre for Disease Informatics & Research, Bengaluru for Director General, Indian Council of Medical Research, New Delhi

***

Conflict of Interest (COI)

TU/TUEC/SOP/VII

7. Conflict of Interest (COI) and Agreements

COI refers to a set of conditions whereby professional judgement concerning a primary interest, such as participant's welfare or the validity of research either is or perceived to be unduly influenced by a secondary interest. The secondary interest may be financial or non-financial, personal, academic, or political. This is not inherently wrong, but COI can influence the choice of research questions and methods, recruitment and retention of participants, interpretation and publication of data and the ethical review of research. It is, therefore, necessary to develop and implement policies and procedures to identify, mitigate and manage such COI which can be at the level of researcher, ethics committee or at the level of institution. Every TUEC member must sign a confidentiality and conflict of interest agreement/s. Research institutions, researchers and research ECs must follow the steps in Identifying, mitigating, and managing COI as given below:

The broad responsibilities of those involved in research, with respect to COI, are given below:

7.1. Research institutions must:

- develop policies and SOPs to address COI issues that are dynamic, transparent, and actively communicated
- implement policies and procedures to address COI and conflicts of commitment, and educate their staff about such policies
- monitor the research or check research results for accuracy and objectivity and
- not interfere in the functioning and decision making of the TUEC

7.2. Researchers must:

- ensure that documents submitted to the TUEC include disclosure of COI (financial or nonfinancial) that may affect their research
- guard against conflicts of commitment that may arise from situations that place competing demands on researchers' time and loyalties; and

- prevent intellectual and personal conflicts by ensuring they do not serve as reviewers for grants and publications submitted by close colleagues, relatives and/or students

7.3. TUEC must:

- evaluate each study considering any disclosed COI and ensure appropriate action is taken to mitigate this and
- require their members to disclose their own COI and take appropriate measures to recuse themselves from reviewing or decision making on protocols related to their COI; and

make appropriate suggestions for management if COI is detected at the institutional or researchers' level.

Adapted from:

Kalita, K., N., Pathak, K. (2020) Standard Operating Procedures (SOPs), Institutional Ethics Committee, Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

Mathur, R., Thakur, K., Rathna, M., D., Pardhi, A. (2020) National Guidelines for Ethics Committees reviewing Biomedical and Health Research During Covid-19 Pandemic, ICMR - National Centre for Disease Informatics & Research, Bengaluru for Director General, Indian Council of Medical Research, New Delhi

***

Review of New Proposals/Protocols

TU/TUEC/SOP/VIII

8. Review of New Research Proposals/Protocols

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 predefined study assessment form and for factors as described below (Table 8):

Table 8. Ethical issues related to reviewing a research proposal/protocol (Mathur 2017)

Type	Description
i) 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 ethical committees (ECs) must ensure that the planned research has social value
ii) 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 • 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 • 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

iii) 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 • 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)
iv) 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
v) 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

vi)	**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
vii)	**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
viii)	**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
ix)	**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
x)	**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
xi)	**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 legally acceptable/authorized representative (LARs)

8.1. Exemption from Ethics Review of Research Protocols

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 behavior 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)

8.2. Expedited Review of Research Protocols

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 SAE s/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

8.3. Full committee review of Research Protocols

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 8 for further details)
- 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 research for deciding whether 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

Adapted from:

Mathur, R. (2017) National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, Indian Council of Medical Research, pp. 38-39, ISBN: 978-81-910091-94

Mathur, R., Thakur, K., Rathna, M., D., Pardhi, A. (2020) National Guidelines for Ethics Committees reviewing Biomedical and Health Research During Covid-19 Pandemic, ICMR - National Centre for Disease Informatics & Research, Bengaluru for Director General, Indian Council of Medical Research, New Delhi

Kalita, K., N., Pathak, K. (2020) Standard Operating Procedures (SOPs), Institutional Ethics Committee, Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

***

Annexure-VIIITUEC/SOP [Initial Review; Expedited Review (Annexure 1); Exemption from Review (Annexure 2)]

Logo of the Institute

Application Form for Initial Review

.....

(Name of the Institution) **EC Ref. No.** *(For office use):*

General Instructions : a) Tick one or more options as applicable. Mark NA if not applicable
b) Attach additional sheets if required

SECTION A - BASIC INFORMATION

1. ADMINISTRATIVE DETAILS

(a) Name of Organization: .....

(b) Name of Ethics Committee: .....

(c) Name of Principal Investigator: .....

(d) Department/Division: ..... (e) Date of submission: dd mm yy

(f) Type of review requested[1] :

Exemption from review ☐ Expedited review ☐ Full committee review ☐

(g) Title of the study: .....

.....

.....

Acronym/ Short title, (If any): .....

(h) Protocol number (If any): ..... Version number: .....

(i) Details of Investigators:

Name	Designation and Qualification	Department and Institution	Address for communication[2]
Principal Investigator/Guide			
Co-investigator/student/fellow			

(j) Number of studies where applicant is a:

i) Principal Investigator at time of submission ii) Co-Investigator at time of submission:

....

(k) Duration of the study: .....

[1] *Refer to National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017 on Page 36 Table 4.2. for types of review*
[2] *Include telephone/mobile, fax numbers and email id*

2. FUNDING DETAILS AND BUDGET

(a) Total estimated budget for site: .....

At site..... In India..... Globally .....

(b) Self-funding ☐ Institutional funding ☐ Funding agency *(Specify)* ☐

.....

SECTION B - RESEARCH RELATED INFORMATION

3. OVERVIEW OF RESEARCH

(a) Lay summary[3] (within 300 words): .....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

(b) Type of study:

Basic Sciences	☐	Clinical	☐	Cross Sectional	☐
Retrospective	☐	Epidemiological/ Public Health	☐	Case Control	☐
Prospective	☐			Cohort	☐
Qualitative	☐	Socio-behavioural	☐	Systematic Review	☐
Quantitative	☐	Biological samples/ Data	☐		
Mixed Method	☐	Any others *(Specify)*	☐		

.....

4. METHODOLOGY

(a) Sample size/ number of participants *(as applicable)*

At site..... In India..... Globally .....

Control group..... Study group .....

Justification for the sample size chosen (100 words); In case of qualitative study, mention the criteria used for saturation .....

.....

.....

.....

.....

.....

[3] *Summarize in the simplest possible way such that a person with no prior knowledge of the subject can easily understand it.*

(b) Is there an external laboratory/outsourcing involved for investigations?[4] Yes ☐ No ☐ NA ☐

(c) How was the scientific quality of the study assessed?

Independent external review ☐ Review by sponsor/Funder ☐ Review within PI's institution ☐

Review within multi-centre research group ☐ No review ☐

Date of review: dd mm yy

Comments of scientific committee, if any (100 words)

.....

.....

.....

.....

SECTION C: PARTICIPANT RELATED INFORMATION

5. RECRUITMENT AND RESEARCH PARTICIPANTS

(a) Type of participants in the study:

Healthy volunteers ☐ Patients ☐ Vulnerable persons/ Special groups ☐

Others ☐ *(Specify)* .....

Who will do the recruitment? .....

Participant recruitment methods used:

Posters/ leaflets/Letters ☐ TV/Radio ads/ Social media/ Institution website ☐ Patients / Family/ Friends visiting hospitals ☐ Telephone ☐

Others ☐ *(Specify)* .....

(b) i. Will there be vulnerable persons / special groups involved ? Yes ☐ No ☐ NA ☐

ii. If yes, type of vulnerable persons / special groups

Children under 18 yrs	☐	Pregnant or lactating women	☐
Differently abled (Mental/Physical)	☐	Employees/Students/Nurses/Staff	☐
Elderly	☐	Institutionalized	☐
Economically and socially disadvantaged	☐	Refugees/Migrants/Homeless	☐
Terminally ill (stigmatized or rare diseases)	☐		
Any other *(Specify)*:	☐	.....	

iii. Provide justification for inclusion/exclusion .....

.....

.....

iv. Are there any additional safeguards to protect research participants?.....

.....

.....

[4] *If participant samples are sent outside for investigations, provide details of the same and attach relevant documentation such as an MTA / MoU*

(c) Is there any reimbursement to the participants? Yes ☐ No ☐

If yes, Monetary ☐ Non-monetary ☐ *Provide details*

.....

.....

(d) Are there any incentives to the participants? Yes ☐ No ☐

If yes, Monetary ☐ Non-monetary ☐ *Provide details*

.....

.....

(e) Are there any participant recruitment fees/ incentives for the study provided to the PI / Institution?

If yes, Monetary ☐ Non-monetary ☐ *Provide details* Yes ☐ No ☐

.....

.....

6. BENEFITS AND RISKS

(a) i. Are there any anticipated physical/social/psychological discomforts/ risk to participants? Yes ☐ No ☐

If yes, categorize the level of risk[5] :

Less than Minimal risk ☐ Minimal risk ☐

Minor increase over minimal risk or low risk ☐ More than minimal risk or high risk ☐

ii. Describe the risk management strategy: .....

.....

.....

(b) What are the potential benefits from the study?	Yes	No	If yes,	Direct	Indirect
For the participant	☐	☐		☐	☐
For the society/community	☐	☐		☐	☐
For improvement in science	☐	☐		☐	☐

Please describe how the benefits justify the risks .....

.....

.....

.....

(c) Are adverse events expected in the study[6] ? Yes ☐ No ☐ NA ☐

Are reporting procedures and management strategies described in the study? Yes ☐ No ☐

If Yes, Specify .....

.....

.....

7. INFORMED CONSENT

(a) Are you seeking waiver of consent? If yes, please specify reasons and skip to item no. 8 Yes ☐ No ☐

.....

.....

[5]For categories of risk refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 6 Table 2.1

[6]The term adverse events in this regard encompass both serious and non-serious adverse events.

(b) Version number and date of Participant Information Sheet (PIS):.....

Version number and date of Informed Consent Form (ICF):.....

(c) Type of consent planned for :

Signed consent ☐ Verbal/Oral consent ☐ Witnessed consent ☐ Audio-Video (AV) consent ☐

Consent from LAR ☐ (If so, specify from whom) ..... For children<7 yrs parental/LAR consent ☐ Verbal assent from minor (7-12 yrs) along with parental consent ☐ Written assent from minor (13-18 yrs) along with parental consent ☐

Other ☐ *(specify)* .....

(d) Who will obtain the informed consent?

PI/Co-I ☐ Nurse/Counselor ☐ Research Staff ☐ Other ☐ *(Specify)* .....

Any tools to be used .....

(e) Participant Information Sheet (PIS) and Informed Consent Form (ICF)

English ☐ Local language ☐ Other ☐ *(Specify)*.....

List the languages in which translations were done .....

If translation has not been done, please justify .....

.....

(f) Provide details of consent requirements for previously stored samples if used in the study[7]

.....

.....

(g) Elements contained in the Participant Information Sheet(PIS) and Informed Consent Form (ICF)

Simple language	☐	Data/ Sample sharing	☐	Compensation for study related injury	☐
Risks and discomforts	☐	Need to recontact	☐	Statement that consent is voluntary	☐
Alternatives to participation	☐	Confidentiality	☐	Commercialization/ Benefit sharing	☐
Right to withdraw	☐	Storage of samples	☐	Statement that study involves research	☐
Benefits	☐	Return of research results	☐	Use of photographs/ Identifying data	☐
Purpose and procedure	☐	Payment for participation	☐	Contact information of PI and Member Secretary of EC	☐
Others(Specify)	☐				

.....

8. PAYMENT/COMPENSATION

(a) Who will bear the costs related to participation and procedures[8] ?

PI ☐ Institution ☐ Sponsor ☐ Other agencies ☐ *(specify)*

.....

(b) Is there a provision for free treatment of research related injuries? Yes ☐ No ☐ N/A ☐

If yes, then who will provide the treatment? .....

(c) Is there a provision for compensation of research related SAE? If yes, specify. Yes ☐ No ☐ N/A ☐

Sponsor ☐ Institutional/Corpus fund ☐ Project grant ☐ Insurance ☐

(d) Is there any provision for medical treatment or management till the relatedness is determined for injury to the participants during the study period? If yes, specify. Yes ☐ No ☐ N/A ☐

.....

(e) Is there a provision for ancillary care for unrelated illness during the study period? If yes, please specify.

Yes ☐ No ☐ N/A ☐

[7]Information on re-consent requirements can be found at National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017, Page 54 in Section 5.8.

[8]Enclose undertaking from PI confirming the same

9. STORAGE AND CONFIDENTIALITY

(a) Identifying Information: Study Involves samples/data. *If Yes, specify* Yes ☐ No ☐ NA ☐

Anonymous/Unidentified ☐ Anonymized: Reversibly coded ☐ Irreversibly coded ☐ Identifiable ☐

If identifiers must be retained, what additional precautions will be taken to ensure that access is limited /data is safeguarded? (e.g. data stored in a cabinet, password protected computer etc.) .....

.....

.....

.....

.....

(b) Who will be maintaining the data pertaining to the study? .....

(c) Where will the data be analyzed[9] and by whom? .....

(d) For how long will the data be stored? .....

(e) Do you propose to use stored samples/data in future studies? Yes ☐ No ☐ Maybe ☐

If yes, explain how you might use stored material/data in the future?.....

.....

.....

.....

SECTION D: OTHER ISSUES

10. PUBLICATION, BENEFIT SHARING AND IPR ISSUES

(a) Will the results of the study be reported and disseminated? If yes, specify. Yes ☐ No ☐ NA ☐

.....

.....

(b) Will you inform participants about the results of the study? Yes ☐ No ☐ NA ☐

(c) Are there any arrangements for continued provision of the intervention for participants, if effective, once the study has finished? If yes describe in brief (Max 50 words) Yes ☐ No ☐ NA ☐

.....

.....

(d) Is there any plan for post research benefit sharing with participants? If yes, *specify* Yes ☐ No ☐ NA ☐

.....

.....

(e) Is there any commercial value or a plan to patent/IPR issues? If yes, please provide details Yes ☐ No ☐ NA ☐

.....

(f) Do you have any additional information to add in support of the application, which is not included elsewhere in the form? If yes, provide details. Yes ☐ No ☐

.....

.....

.....

.....

[9] *For example, a data entry room, a protected computer etc.*

SECTION E: DECLARATION AND CHECKLIST[10]

11. DECLARATION (Please tick as applicable)	
☐	I/We certify that the information provided in this application is complete and correct.
☐	I/We confirm that all investigators have approved the submitted version of proposal/related documents.
☐	I/We confirm that this study will be conducted in accordance with the latest ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants and other applicable regulations and guidelines including responsible.
☐	I/We confirm that this study will be conducted in accordance with the Drugs and Cosmetics Act 1940 and its Rules 1945 as amended from time to time, GCP guidelines and other applicable regulations and guidelines.
☐	I/We will comply with all policies and guidelines of the institute and affiliated/collaborating institutions where this study will be conducted.
☐	I/We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the EC approved protocol.
☐	I/We declare that the expenditure in case of injury related to the study will be taken care of.
☐	If applicable, I/We confirm that an undertaking of what will be done with the leftover samples is provided, if applicable.
☐	I/We confirm that we shall submit any protocol amendments, adverse events report, significant deviations from protocols, progress reports (if required) and a final report and also participate in any audit of the study if needed.
☐	I/We confirm that we will maintain accurate and complete records of all aspects of the study.
☐	I/We will protect the privacy of participants and assure safety and confidentiality of study data and biological samples.
☐	I/We hereby declare that I/any of the investigators, researchers and/or close relative(s), have no conflict of interest (Financial/Non-Financial) with the sponsor(s) and outcome of study.
☐	I/We have the following conflict of interest (PI/Co-PI): 1. …… …… 2. …… ……
☐	I/We declare/confirm that all necessary government approvals will be obtained as per requirements wherever applicable.

Name of PI……

Signature of PI…… dd mm yy

Name of Co-PI……

Signature of Co-PI…… dd mm yy

Name of Guide……

Signature of Guide…… dd mm yy

[10]*These formats are adaptable and can be modified by the Ethics Committee members depending on their needs and requirements*

Acknowledgement for Receipt of Application (Copy to be provided to PI)

12. CHECKLIST

S. No	Items	Yes	No	NA	Enclosure No	EC Remarks (If applicable)
ADMINISTRATIVE REQUIREMENTS						
1	Cover letter	☐	☐	☐		
2	Brief CV of all Investigators	☐	☐	☐		
3	Good Clinical Practice (GCP) training of investigators in last 3 years	☐	☐	☐		
4	Approval of scientific committee	☐	☐	☐		
5	EC clearance of other centers*	☐	☐	☐		
6	Agreement between collaborating partners*	☐	☐	☐		
7	MTA between collaborating partners*	☐	☐	☐		
8	Insurance policy/certificate	☐	☐	☐		
9	Evidence of external laboratory credentials in case of an externally outsourced laboratory study QA/QC certification	☐	☐	☐		
10	Copy of contract or agreement signed with the sponsor or donor agency	☐	☐	☐		
11	Provide all significant previous decisions (e.g. those leading to a negative decision or modified protocol) by other ECs/Regulatory authorities for proposed study (whether in same location or elsewhere) and modification(s) to protocol	☐	☐	☐		
PROPOSAL RELATED						
12	Copy of the detailed protocol[11]	☐	☐	☐		
13	Investigators Brochure (If applicable for drug/biologicals/device trials)	☐	☐	☐		
14	Participant Information Sheet (PIS) and Participant Informed Consent Form (ICF)(English and translated)	☐	☐	☐		
15	Assent form for minors (12-18 years) (English and Translated)	☐	☐	☐		
16	Proforma/Questionnaire / Case Report Forms (CRF)/ Interview guides/ Guides for Focused Group Discussions (FGDs) (English and translated)	☐	☐	☐		
17	Advertisement/material to recruit participants (fliers, posters etc)	☐	☐	☐		

PERMISSION FROM GOVERNING AUTHORITIES

	Other permissions	Required	Not required	Received	Applied dd/ mm/yy	EC Remarks
18	CTRI	☐	☐	☐		
19	DCGI	☐	☐	☐		
20	HMSC	☐	☐	☐		
21	NAC-SCRT	☐	☐	☐		
22	ICSCR	☐	☐	☐		
23	RCGM	☐	☐	☐		
24	GEAC	☐	☐	☐		
25	BARC	☐	☐	☐		
26	Tribal Board	☐	☐	☐		
27	Others (Specify)	☐	☐	☐		

ANY OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY

	Item	YES	NO	NA	Enclosure no.	EC remarks
28		☐	☐	☐		
29		☐	☐	☐		

**For multicentre research.*

MTA-Material transfer agreement; CTRI-Clinical Trial Registry-India; DCGI-Drug Controller General of India; HMSC- Health Ministry's Screening Committee; NAC-SCRT- National Apex Committee for Stem Cell Research and Therapy; IC-SCR-Institutional committee for Stem Cell Research; RCGM- Review Committee on Genetic Manipulation; GEAC- Genetic Engineering Approval Committee; BARC- Bhabha Atomic Research Centre

[11]Refer to National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017, section 4 Page no. 35 Box 4.4(b)

(Annexure 2)

Logo of the Institute

Application Form for Exemption from Review

.....

(Name of the Institution) **EC Ref. No.** *(For office use):*

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Choose reasons why exemption from ethics review is requested[14]?
   - i. Research on data in the public domain/ systematic reviews or meta-analyses ☐
   - ii. Observation of public behavior/ information recorded without linked identifiers and disclosure would not harm the interests of the observed person ☐
   - iii. Quality control and quality assurance audits in the institution ☐
   - iv. Comparison among instructional techniques, curricula, or classroom management methods ☐
   - v. Consumer acceptance studies related to taste and food quality ☐
   - vi. Public health programmes by government agencies[15] ☐
   - vii. Any other (please specify in 100 words): .....

.....

.....

.....

.....

Signature of PI: ..... dd mm yy

Comments of EC Secretariat: .....

Signature of Member Secretary: ..... dd mm yy

[14]Select the category that applies best to your study and justify why you feel it should be exempted from review. For a detailed understanding of the type of studies that are exempt from review, refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 51 Table 4.2.

[15]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)

Review of Progress of Continuing Proposals/Protocols (Annual Report)

TU/TUEC/SOP/IX

9. Review of Progress of Continuing Proposals/Protocols or Annual Report

This SOP monitor the progress of the study, which was previously approved; not only for the changes but to ensure continued protection of the rights and welfare of research participants and appropriate data management. This should be read together with SOP. This SOP applies to continuing research protocols at intervals appropriate to the degree of risk but not less than once a year. Depending upon the degree of risk to the participants, the nature of the study, the vulnerability of the study participants and duration of the study, TUEC may choose to review the study more frequently. It is the responsibility of the TUEC Secretariat to send reminders to PIs regarding the submission of Continuing Review Application/Annual Status Report. All the approved studies must at least be reviewed annually. The TUEC Secretariat is responsible for determining the date of continuing review if the project will be reviewed more frequently in the year. This decision is taken during the TUEC meeting wherein the project is finally approved. TUEC is responsible for reviewing the study progress, the occurrence of unexpected events or problems, and the rate of accrual of participants. The protocol, informed consent documents and assent documents are examined to ensure that the information remains accurate and data security is taken care of. The Principal Investigator (PI) should ensure that during this period there is no sharing of any kind of information regarding its findings in form of communication to any authority/platform including media and social/professional unless taken permission from the TUEC. However, views and comment from experts in the field may be collected for generation of background information and help otherwise. But there should not be any ethical conflict. The TUEC has the same options for decision making on a continuing review application as for an initial review application. The decision is made as, approval to continue the study, revision, or disapproval.

The activities and responsibilities of the TUEC are described in the table below (Table 9):

Table 9. Activities and responsibilities of the TUEC in reviewing of progress of continuing proposals/protocols or annual report

Activities	Responsibilities
Fixing date for annual/continuing review	TUEC Secretariat
Notify investigators	do
Manage continue review of package	do
Verify contents of package	do
Agenda preparation	do
Review process	TUEC Members
Communicate TUEC decision to PI	TUEC Secretariat
Store original documents	do

Detailed Instructions:

Determination of the date of continuing review(s):

- The secretariat will look through the master file of projects approved by the TUEC for the due date of continuing reviews
- Continuing review of the study should not be conducted through an expedited review

Notification to the Investigators:

- Reminders in email are sent from TUEC secretariat to the Investigators for submission of an annual status of reports/Continuing review applications for studies that were approved by TUEC 2 months before expiry of the final TUEC approval
- The timeline for submission of the relevant documents will be 2 weeks from the date of email communication

Management of continuing review application upon receipt:

- The Secretariat will receive the Continuing Review Application submitted by the Investigators for each approved study

- Upon receipt of the Continuing Review Application, the Secretariat of the TUEC will perform the following: a) verifying the contents of the package; b) continuing review applications will be checked by the TUEC Secretariat for completeness before submission to TUEC

Review of Continuing Review Application:

- The Member Secretary will review the Continuing review Application and will record his/her comments on the application and the same will be forwarded to the TUEC
- In case of previously approved and not initiated studies for reasons like fund crisis, other resources like reagent crisis or any other valid reasons, the concerned investigator should submit the progress report [Annexure-IX/TUEC/SOP – Continuing Review/Annual report format (Annexure 3)] along with other necessary documents as mentioned in the SOP, however the same will be communicated by the Member-Secretary in the TUEC meeting and the decision of the Committee will be communicated to the investigator
- The annual review for not-initiated studies may be permitted up to a period of three years from the initial approval. If the investigator prefers to obtain the approval from the TUEC for continuation the study after three years, he/she should present the study with recent literature review and provide justification for continuation
- In case any clarifications or queries are raised by the Member Secretary the same will be intimated to PI and reply will be obtained

Preparation of Agenda of Meeting:

- The Secretariat will follow procedures on the preparation of meeting agenda and place the forwarded Annual Progress Report/Continuing Review Application on the agenda for the full board review meeting of the TUEC

Review Process:

- The TUEC members will use the Continuing Review/Annual Report Application Form (to guide the review and deliberation process. The TUEC members could arrive at any one of the following decisions at the TUEC meeting: a. project can be continued without any modifications/revisions recommended - studies for which modifications have been suggested by the TUEC might not proceed until the conditions set by the TUEC have been met; b. studies

should be amended and submitted to TUEC for amendment as per format/as per suggestion/disapproved

- These decision of TUEC will be accorded and kept in record by Member Secretary in minutes.

Storage of original documents:

- The TUEC secretariat will file the documents pertaining to continuing review in master file of the concerned research study

Communicate the TUEC decision to the PI(s):

- The Secretariat will notify the Principal Investigator (PI) of the decision. If TUEC has recommended modifications, the decision will be communicated to the PI, and he/she will be requested to resubmit the relevant documents within 1 month for the approval till then the project is suspended
- PI will be communicated about the decision within 2 working days after the minutes are finalized.

Adapted from:

Kalita, K., N., Pathak, K. (2020) Standard Operating Procedures (SOPs), Institutional Ethics Committee, Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

Mathur, R., Thakur, K., Rathna, M., D., Pardhi, A. (2020) National Guidelines for Ethics Committees reviewing Biomedical and Health Research During Covid-19 Pandemic, ICMR - National Centre for Disease Informatics & Research, Bengaluru for Director General, Indian Council of Medical Research, New Delhi

***

Annexure-IX/TUEC/SOP – Continuing Review/Annual report format (Annexure 3)

(Annexure 3)

Logo of the Institute

Continuing Review / Annual report format

.....

(Name of the Institution) **EC Ref. No.** *(For office use):*

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Date of EC Approval: dd mm yy Validity of approval: dd mm yy
2. Date of Start of study: dd mm yy Proposed date of Completion: dd mm yy

   Period of Continuing Report: dd mm yy ---- to ------ dd mm yy
3. Does the study involve recruitment of participants? Yes ☐ No ☐

   (a) If yes, Total number expected..... Number Screened: ..... Number Enrolled: .....

   Number Completed:..... Number on followup:.....

   (b) Enrolment status – ongoing / completed/ stopped

   (c) Report of DSMB[16] Yes ☐ No ☐ NA☐

   (d) Any other remark.....

   .....

   (e) Have any participants withdrawn from this study since the last approval? Yes ☐ No ☐ NA☐

   If yes, total number withdrawn and reasons: .....

   .....

   .....
4. Is the study likely to extend beyond the stated period ?[17] Yes ☐ No ☐

   If yes, please provide reasons for the extension. .....

   .....

   .....
5. Have there been any amendments in the research protocol/Informed Consent Document (ICD) during the past approval period?

   If No, skip to item no. 6 Yes ☐ No ☐

   (a) If yes, date of approval for protocol and ICD : dd mm yy

   (b) In case of amendments in the research protocol/ICD, was re-consent sought from participants? Yes ☐ No☐

   If yes, when / how: .....

   .....

   .....

[16] *In case there is a Data Safety Monitoring Board (DSMB) for the study provide a copy of the report from the DSMB. If not write NA.*

[17] *Problems encountered since the last continuing review application with respect to implementation of the protocol as cleared by the EC*

6. Is any new information available that changes the benefit - risk analysis of human participants involved in this study? Yes ☐ No ☐

If yes, discuss in detail: .....

.....

.....

7. Have any ethical concerns occurred during this period? Yes ☐ No ☐

If yes, give details:.....

.....

8. (a) Have any adverse events been noted since the last review? Yes ☐ No ☐

Describe in brief: .....

.....

.....

(b) Have any SAE's occurred since last review? Yes ☐ No ☐

If yes, number of SAE's :..... Type of SAE's: .....

.....

.....

(c) Is the SAE related to the study? Yes ☐ No ☐

Have you reported the SAE to EC? If no, state reasons Yes ☐ No ☐

.....

.....

9. Has there been any protocol deviations/violations that occurred during this period?

If yes, number of deviations .....

Have you reported the deviations to EC? If no, state reasons Yes ☐ No ☐

.....

.....

10. In case of multicenteric trials, have reports of off-site SAEs been submitted to the EC ? Yes ☐ No ☐ NA ☐

11. Are there any publications or presentations during this period? If yes give details Yes ☐ No ☐

.....

.....

Any other comments:.....

.....

Signature of PI: ..... dd mm yy

Review of Amendments of Research Proposals/Protocols

TU/TUEC/SOP/X

---

10. Review of Amendments of Research Proposals/Protocols

This SOP explains how protocol amendments, or any other amendments are reviewed by the TUEC. It applies to amended study protocols/ documents, tools and letters that are submitted for TUEC approval. Amendments made to protocols, or any other amendments related to the study may not be implemented until reviewed and approved by the TUEC. The TUEC secretariat to manage protocol amendments/documents and letters.

Receipt of the Amendment Files:

a. The amendment/documents forwarded by Investigator are received by the secretariat. The amendment /documents along with the covering letter should be accompanied by Amendment Reporting document
b. The secretariat will confirm that the: changes or modifications in the amended version are marked along with detailed summary of changes
c. The Secretariat will check for completeness of documents and informs Investigators if any document(s) is/are missing or incomplete and request to resubmit the same
d. The TUEC Secretariat follows the same procedure of circulation of the received documents to the TUEC Members as in the initial review and includes the proposal for discussion in the upcoming scheduled meeting (Expedited or Full board) depending upon the nature of amendment i.e., minor, or major and nature of risk to the participants [Annexure-IX/TUEC/SOP – Application/Notification form for Amendments (Annexure 4)]
e. The procedures of board meetings and the decision of the TUEC is communicated to the investigators in writing. The decision can be approved/recommendation or suggestion for modification/ not approved. If the decision is ‘not approved’ then the reason is communicated to the researcher in writing
f. Modification suggested is also communicated in writing specifically. TUEC Secretariat does this in a week time. If modification is suggested, then the investigator is asked to resubmit

within 2 weeks of TUEC secretariat communication and the matter may be placed in full board or expedited meeting as appropriate by the Member Secretary

g. Storage of documents include amendments, research proposals as per the SOP for documentation and archival

h. Minor amendments and notifications: Minor amendments (those that do not increase the risk or decrease the potential benefit to subjects) may be approved by expedited review subcommittee. Member Secretary decides about the nature of amendment to be major or minor considering standard guidelines

i. The sub-committee may even take opinion of members in telecommunication modes for saving resources and for time constraints.

Adapted from:

Kalita, K., N., Pathak, K. (2020) Standard Operating Procedures (SOPs), Institutional Ethics Committee, Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

Mathur, R., Thakur, K., Rathna, M., D., Pardhi, A. (2020) National Guidelines for Ethics Committees reviewing Biomedical and Health Research During Covid-19 Pandemic, ICMR - National Centre for Disease Informatics & Research, Bengaluru for Director General, Indian Council of Medical Research, New Delhi

***

Annexure-IX/TUEC/SOP – Application/Notification form for Amendments (Annexure 4)

(Annexure 4)

Logo of the Institute

Application/Notification form for Amendments

.....

(Name of the Institution) **EC Ref. No.** *(For office use):*

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Date of EC approval: dd mm yy Date of start of study dd mm yy

2. Details of amendment(s)

S.No	Existing Provision	Proposed Amendment	Reason	Location in the protocol/ICD [18]

3. Impact on benefit-risk analysis Yes ☐ No ☐

If yes, describe in brief: .....

.....

4. Is any reconsent necessary? Yes ☐ No ☐

If yes, have necessary changes been made in the informed consent? Yes ☐ No ☐

5. Type of review requested for amendment:

Expedited review (No alteration in risk to participants) ☐

Full review by EC (There is an increased alteration in the risk to participants) ☐

6. Version number of amended Protocol/Investigator's brochure/ICD: .....

Signature of PI: ..... dd mm yy

[18] *Location implies page number in the ICD/protocol where the amendment is proposed.*

Reporting of Research Proposals/Protocols with Deviation or Violation

TU/TUEC/SOP/XI

11. Reporting of Research Proposals/Protocols with Deviation or Violation

This SOP provide instructions for action taking and maintaining records that identify investigators/institutes who do not follow the procedures mentioned in the approved protocol or do not comply with national / international guidelines for the conduct of human research, including those who fail to respond to the TUEC's requests. This SOP applies to all TUEC approved research protocols involving human subjects. The designated member of the Secretariat is responsible for collecting and recording the non-compliance list from the study team, sponsor/monitors or TUEC.

The activities and responsibilities of the TUEC are described below (Table 11):

Table 11. Activities and responsibilities of the TUEC in reporting deviation/violation of research protocols

Activities	Responsibilities
Information about Protocol deviation/violation	Members/sponsor/monitor/study team
Calling for discussion either subcommittee/full board	Member Secretary
Notification to investigator(s)	TUEC Secretariat
Keeping record & follow up	do

Detailed Instructions:

Whenever protocol deviation/non-compliance/violation has been observed:

a. Ensure that the issues as well as the details of non-compliance involving research investigators are included in the agenda of the TUEC meeting
b. Maintain a file that identifies investigators who are found to be non-compliant with national/international regulations or who fail to follow protocol approval stipulations or fail to respond to the TUEC request for information/action

c. Especially, TUEC may elect to suspend or terminate approval of current studies or refuse subsequent applications from the investigators cited. Such decisions are recorded in the minutes [Annexure-XI/TUEC/SOP – Protocol Violation/Deviation Reporting Form (Reporting by case) (Annexure 5)]

The TUEC's decision:

The chairperson notifies the investigator of the TUEC's action in writing, when the TUEC

a. Suspends or
b. Terminates approval of a current study or
c. Refuses subsequent applications from an investigator cited for non-compliance

Notification to the investigator(s):

a. The TUEC Secretariat members record the TUEC's decision
b. Draft a notification letter
b. Get the Chairperson and Member-Secretary to sign and date the letter
c. Make four copies of the notification letter
d. Send the original copy of the notification letter to the investigator
e. Send a copy of the notification letter to the relevant national authorities and institutes
f. Send the third copy to the sponsor or the sponsor's representative of the study, if any

Keeping records and following up:

a. Keep the last copy of the notification letter in the "non-compliance" file
b. Store the file in the shelf with an appropriate label
c. Follow up the action after a reasonable time.

Adapted from:

Kalita, K., N., Pathak, K. (2020) Standard Operating Procedures (SOPs), Institutional Ethics Committee, Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

Mathur, R., Thakur, K., Rathna, M., D., Pardhi, A. (2020) National Guidelines for Ethics Committees reviewing Biomedical and Health Research During Covid-19 Pandemic, ICMR - National Centre for Disease Informatics & Research, Bengaluru for Director General, Indian Council of Medical Research, New Delhi

***

Annexure-XI/TUEC/SOP – Protocol Violation/Deviation Reporting Form (Reporting by case) (Annexure 5)

Logo of the Institute

(Annexure 5)

Protocol Violation/Deviation Reporting Form (Reporting by case)

.....

(Name of the Institution) **EC Ref. No.** *(For office use):*

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Date of EC approval dd mm yy Date of start of study dd mm yy
2. Participant ID: ..... Date of occurrence dd mm yy
3. Total number of deviations /violations reported till date in the study: .....
4. Deviation/Violation identified by: Principal Investigator/study team ☐ Sponsor/Monitor ☐
   SAE Sub Committee/EC ☐
5. Is the deviation related to (Tick the appropriate box) :

Consenting	☐	Source documentation	☐
Enrollment	☐	Staff	☐
Laboratory assessment	☐	Participant non-compliance	☐
Investigational Product	☐	Others *(specify)*	☐
Safety Reporting	☐		

6. Provide details of Deviation/Violation: .....

.....

.....

.....

7. Corrective action taken by PI/Co-I: .....

.....

.....

.....

8. Impact on (if any): Study participant ☐ Quality of data ☐
9. Are any changes to the study/protocol required? Yes ☐ No ☐

   If yes, give details.....

.....

Signature of PI: ..... dd mm yy

Managing Premature Termination/Suspension/Discontinuation of Research Proposals/Protocols

TU/TUEC/SOP/XII

---

12. Management of Premature Termination/Suspension/Discontinuation of Research Proposals/Protocols

This SOP explains the procedure for management of premature or termination or suspension or discontinuation of a research study by the TUEC. Research studies will be terminated as per the recommendation of the TUEC, PI, sponsor or other authorized bodies wherein subject enrollment and subject follow-up are discontinued before the scheduled completion of the study. This SOP applies to any study approved by TUEC that is being recommended for termination/suspension/discontinuation before its scheduled completion. The TUEC may terminate a previously approved study when the safety or benefit of the study participants is doubtful or at risk. TUEC will review the termination suggested by Principal Investigator (PI), sponsor, or other authorized bodies. The secretariat is responsible for management of the premature termination/ suspension/discontinuation process.

The activities and responsibilities of the TUEC are detailed below (Table 12):

Table 12. Activities and responsibilities of the TUEC in evaluation of premature termination/suspension/discontinuation of research proposals/protocols

Activities	Responsibilities
Receive study discontinuation/termination/suspension report	TUEC Secretariat
Review/discuss the report at TUEC	TUEC Members
Notification to investigator(s)	TUEC Secretariat
Storage of document(s)	do

Detailed Instructions:

Receiving recommendation for study termination / suspension /discontinuation:

a. The secretariat will receive recommendation and comments from PI, sponsor, or other authorized bodies for premature termination of study in appropriate format and document it appropriately

b. The TUEC members/Chairperson can prematurely terminate the study if protocol noncompliance/violation is detected and TUEC decision is to terminate the study due to any reason. e.g., Frequency of SAEs occurring at study site may require the study to be prematurely terminated for the safety of the patients

c. The secretariat will inform the PI to prepare and submit a protocol termination package along with Premature Termination Report (available at TUEC office and shared at time of submission of initial review application) [Annexure-XII/TUEC/SOP – Premature Termination/Suspension/ Discontinuation Report Format (Annexure 7)]

d. The secretariat will receive the study protocol termination prepared and submitted by the PI and verify the contents of the report for inclusion of: Premature Termination Report/suspension/discontinuation signed and dated by the PI and/or other material (letter from Principal Investigator/sponsor etc.)

e. The Secretariat will check the completeness of the information

f. The Secretariat will receive and acknowledge the reports

Review and discuss the termination/suspension/discontinuation report:

- TUEC will review the termination report suspension/discontinuation at regular full board meeting or expedited review meeting
- The Secretary in the meeting will inform of the premature termination suspension/discontinuation of the project and the TUEC members will review the Premature Termination Report along with relevant SAE reports, if any If the Premature Termination Report suspension/discontinuation is unclear/more information is required from the PI, the Secretariat is instructed to send a query to the PI
- The Committee mentioned that if the concerned investigators do not submit necessary documents for review even after three reminders (in monthly intervals) from the Secretariat, the TUEC approvals for such studies would be terminated. The same will be ratified during the next full board meeting

Notification to the PIs:

- The Secretariat will prepare a notification letter acknowledging the acceptance of termination/suspension/discontinuation or query letter to request information regarding the premature termination /suspension/discontinuation
- The Secretariat will send the notification letter to the PI for their records within 14 days after the meeting
- If a query is sent to PI, on receipt of the reply letter, it is reviewed in the forthcoming full board meeting /expedited review meeting and steps as in above will be performed by the secretariat

Storage of the report(s):

- The secretariat will keep the original version of the premature termination suspension/discontinuation report in the study file and send the file to archive
- The study documents will be stored for a period of 5 years or more from the date of project termination.

Adapted from:

Kalita, K., N., Pathak, K. (2020) Standard Operating Procedures (SOPs), Institutional Ethics Committee, Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

Mathur, R., Thakur, K., Rathna, M., D., Pardhi, A. (2020) National Guidelines for Ethics Committees reviewing Biomedical and Health Research During Covid-19 Pandemic, ICMR - National Centre for Disease Informatics & Research, Bengaluru for Director General, Indian Council of Medical Research, New Delhi

***

Annexure-XII/TUEC/SOP – Premature Termination/Suspension/ Discontinuation Report Format (Annexure 7)

(Annexure 7)

Logo of the Institute

Premature Termination/Suspension/ Discontinuation Report Format

.....

(Name of the Institution) **EC Ref. No.** *(For office use):*

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Date of EC approval: dd mm yy Date of start of study: dd mm yy
2. Date of last progress report submitted to EC: dd mm yy
3. Date of termination/suspension/discontinuation: dd mm yy
4. Tick the appropriate

   Premature Termination ☐ Suspension ☐ Discontinuation ☐

   Reason for Termination/Suspension/Discontinuation: .....

   .....

   .....

   .....

   Action taken post Termination/ Suspension/Discontinuation (if any): .....

   .....

   .....

   .....

5. Plans for post study follow up/withdrawal[21] (if any): .....

   .....

   .....

6. Details of study participants:

   Total participants to be recruited: ..... Screened: ..... Screen failures:.....

   Enrolled:..... Consent Withdrawn:..... Reason (Give details): .....

   .....

   .....

   Withdrawn by PI:..... Reason(Give details): .....

   .....

[21] *Describe post-termination/suspension/ discontinuation follow up plans if any. Also describe any withdrawal plans for the study.*

Active on treatment: ..... Completed treatment : ..... Participants on follow-up: .....

Participants lost to follow up: ..... Any other: ..... Number of drop outs:.....

Reasons for each drop-out: .....

.....

.....

.....

7. Total number of SAEs reported till date in the study: .....

   Have any unexpected adverse events or outcomes observed in the study been reported to the EC? Yes ☐ No☐

8. Have there been participant complaints or feedback about the study? Yes ☐ No☐

   If yes, provide details:.....

   .....

9. Have there been any suggestions from the SAE Sub Committee? Yes ☐ No☐

   If yes, have you implemented that suggestion? Yes ☐ No☐

10. Do the procedures for withdrawal of enrolled participants take into account their rights and welfare? Yes ☐ No☐

    (e.g., making arrangements for medical care of research participants): If Yes, provide details

    .....

    .....

    Summary of results (if any): .....

    .....

    .....

    .....

    .....

    .....

Signature of PI: ..... dd mm yy

Site Monitoring

TU/TUEC/SOP/XIII

---

13. Site Monitoring

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

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 TUEC at the time of initial review or continuing review can suggest that routine monitoring may be conducted at more frequent intervals.

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 Serious Adverse Events (SAE) reports
- high recruitment rate
- complaints received from participants
- any adverse media report
- adverse information received from any other source
- non-compliance with TUEC directions
- misconduct by the researcher; and
- any other cause as decided by the TUEC.

Adapted from:

Kalita, K., N., Pathak, K. (2020) Standard Operating Procedures (SOPs), Institutional Ethics Committee, Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

Mathur, R., Thakur, K., Rathna, M., D., Pardhi, A. (2020) National Guidelines for Ethics Committees reviewing Biomedical and Health Research During Covid-19 Pandemic, ICMR - National Centre for Disease Informatics & Research, Bengaluru for Director General, Indian Council of Medical Research, New Delhi

***

Review of Study Completion of Research Proposals/Protocols (Final Report)

TU/TUEC/SOP/XIV

14. Review of Study Completion of Research Proposals/Protocols (Final Report)

This SOP provides instructions on the review of Study Completion/Final Report for every study previously approved by the TUEC. This SOP applies to the review of the Study Completion Report which is a mandatory review of each investigator's activities presented to the TUEC as a written report of study completed. Although TUEC provides a Study Completion/Final Report Form [Annexure-XIV/TUEC/SOP – Study completion/Final report format (Annexure 12)] to the investigator, additional information (letter format, form provided by the Sponsor, etc.) may be submitted to provide adequate and sufficient information. The study completion report should be submitted by the study PI in the prescribed formats. It is the responsibility of the TUEC members to review the study completion report and notify it or request for further information, if necessary.

The activities of the review process and the responsibilities undertaken are given below (Table 14):

Table 14. Activities and responsibilities of the TUEC in evaluation of research completion report

Activities	Responsibilities
Submission of Study Completion Report	Principal Investigator
Checking submitted documents for completion	TUEC Secretariat
Circulation among TUEC Members	do
Including in next meeting agenda	do
Presenting report in next TUEC meeting	Principal Investigator (PI)
Review process	TUEC members
Communication with investigator	TUEC Secretariat
Storage of original documents & closing of study file	do

The evaluation procedures are detailed below:

Before each TUEC meeting

a. The TUEC Secretariat will receive 14 hard copies Study Completion Reports from the PI along with email submission with attached documents
b. The Secretariat will follow the guidelines given in the Management of Research study Submission for receiving and checking the report documents
c. The TUEC Secretariat will review the report for completeness before submission to the TUEC Members
d. The Member Secretary should keep the study completion reports on the agenda for TUEC meeting

Before and during the TUEC meeting

a. TUEC member(s) will review a copy of the completion report
b. The PI will present the report to the Committee
c. The members will discuss the report in the TUEC meeting
d. If appropriate to the discussions, the chairperson may call for consensus to accept it or request
b. further information or take any other action

After the TUEC meeting

a. The secretariat will note the decision in the meeting minutes and the study will be considered as closed if the document is accepted
b. The TUEC decision is communicated to the investigator. In case, further information /action is requested; the same should be followed by the PI and communicated to the TUEC secretariat within 30 days. This update will be tabled in the full board meeting of TUEC
c. Once the report is accepted by TUEC, the Secretariat will file the report in the study master file
d. The TUEC secretariat will archive the entire study and the report for a period of 5 years or more (as mentioned in the protocol) from the date of completion of the project, if the report is accepted

In some sponsored study the final report may need to be accepted by relevant agencies and the study will be considered closed only after acceptance by the funding agency. The issues of copyright of data etc. in such studies need to be ascertained before closure of the study. The Investigator will need to give necessary undertaking in this regard.

Adapted from:

Kalita, K., N., Pathak, K. (2020) Standard Operating Procedures (SOPs), Institutional Ethics Committee, Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

Mathur, R., Thakur, K., Rathna, M., D., Pardhi, A. (2020) National Guidelines for Ethics Committees reviewing Biomedical and Health Research During Covid-19 Pandemic, ICMR - National Centre for Disease Informatics & Research, Bengaluru for Director General, Indian Council of Medical Research, New Delhi

***

Annexure-XIV/TUEC/SOP – Study completion/Final report format (Annexure 12)

(Annexure 12)

Logo of the Institute

Study completion/Final report format

.....

(Name of the Institution) **EC Ref. No.** *(For office use):*

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Date of EC approval: dd mm yy
2. Date of start of study: dd mm yy Date of study completion: dd mm yy
3. Provide details of:

   a) Total number of study participants approved by the EC for recruitment: .....

   b) Total number of study participants recruited: .....

   c) Total number of participants withdrawn from the study (if any): .....

   Provide the reasons for withdrawal of participants[23] : .....

   .....

   .....

4. Describe in brief the publication/ presentation/dissemination plans of the study findings. (Also, mention if both positive and negative results will be shared) .....

   .....

   .....

5. Describe the main ethical issues encountered in the study (if any) .....

   .....

   .....

   .....

   .....

6. State the number (if any) of Deviations/Violations/ Amendments made to the study protocol during the study period

   Deviations: ..... Violation: ..... Amendments: .....

7. Describe in brief plans for archival of records / record retention:.....

   .....

   .....

   .....

   .....

[23] *Explanation for the withdrawal of participants whether by self or by the PI*

8. Is there a plan for post study follow-up? Yes ☐ No☐

If yes, describe in brief: .....

.....

.....

.....

.....

9. Do you have plans for ensuring that the data from the study can be shared/ accessed easily? Yes ☐ No☐

If yes, describe in brief: .....

.....

.....

.....

.....

10. Is there a plan for post study benefit sharing with the study participants? Yes ☐ No☐

If yes, describe in brief: .....

.....

.....

.....

.....

11. Describe results (summary) with Conclusion [24] : .....

.....

.....

.....

.....

12. Number of SAEs that occurred in the study: .....

13. Have all SAEs been intimated to the EC ? Yes ☐ No☐

14. Is medical management or compensation for SAE provided to the participants? Yes ☐ No☐

If yes, provide details.....

.....

.....

.....

.....

Signature of PI: ..... dd mm yy

[24] *For sponsored studies, if the final report is not available from sponsor, it may be submitted later to the EC once it is ready.*

Inspection, Assessment and Audit of TUEC

TU/TUEC/SOP/XV

---

15. Inspection, Assessment, and Audit of TUEC

This SOP outlines the procedure for self-assessment of the TUEC members/staff and internal audit of the TUEC to maintain high standards of research. This SOP is applicable to the TUEC members and staffs. The Chairpersons, Member Secretaries and TUEC staff will be responsible for the assessment and audit of TUEC.

The TUEC will perform inspection, assessment, and audit following the instructions given detailed below:

- The Chairperson will perform assessment of the TUEC members annually. This assessment will cover regularity in attendance to TUEC meetings, quality of review, time taken to review documents, completion of study assessment forms, etc.
- The Chairperson will also perform self-assessment annually
- The Member Secretary will perform assessment of the Administrative Staff of the TUEC annually
- Evaluation forms will be circulated to individual members and the respective TUEC staff via email and a copy of the same will be maintained in the TUEC records

15.1. Internal Audit

- On receipt of written/ mailed communication regarding audit, the TUEC Staff will prepare and make necessary arrangements
- The information and files requested by the auditors should be made available by the Secretariat
- Auditor will be appointed by Director for internal audit

15.2. Audit Procedure

- The audit involves review of TUEC records, minutes, membership files, protocols, TUEC correspondence etc.

- The internal audit report will be prepared by the auditors
- A signed copy of the report will be forwarded to the TUEC Member Secretary

15.3. Correction Procedure(s)

- The audit report will be discussed in the TUEC meeting. Based on the TUEC recommendations corrective/preventive action plan will be implemented within 2 months of receipt of the TUEC recommendations

  Action plan will be communicated by the Member Secretary to the Auditor.

Adapted from:

Kalita, K., N., Pathak, K. (2020) Standard Operating Procedures (SOPs), Institutional Ethics Committee, Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

Mathur, R., Thakur, K., Rathna, M., D., Pardhi, A. (2020) National Guidelines for Ethics Committees reviewing Biomedical and Health Research During Covid-19 Pandemic, ICMR - National Centre for Disease Informatics & Research, Bengaluru for Director General, Indian Council of Medical Research, New Delhi

***