LGB Regional Institute of Mental Health

Standard Operating Procedures

Institutional Ethics Committee

SOP No	List of Standard Operating Procedures
001	Writing, Reviewing, Distributing & Amending SOPs for the Institutional Ethics Committee (IEC)
002	Constitution of Institutional Ethics Committee (IEC)
003	Management of protocol submissions
004	Board meeting Procedures
005	Recruiting Vulnerable Populations for Research
006	Continued Education & Training on Ethical Issues
007	Conflict of Interest on Ethical Issues in Bio Medical Research
008	Review of Protocols
009	Review of Study Progress Reports (Continuing Review/Annual Report)
010	Review of amendments of protocols and related documents
011	Review of Serious Adverse Event Reporting
012	Review of Record Keeping & Archiving
013	Management of Premature Termination/Suspension/Discontinuation of Research Proposal
014	Management of Site Monitoring
015	Reporting of Protocol deviation/violation
016	Dealing with Participants' Requests/Complaints
017	Review of Study Completion/Final Reports
018	Constitution of Data Safety Monitoring Board(DSMB)
019	Inspection, Assessments and Audit of IEC

Institutional Ethics Committee

Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

Preparing Standard Operating Procedures (SOPs): Writing, Reviewing, Distributing & Amending SOPs for the Institutional Ethics Committee (IEC)

LGB/IEC/SOP/ 001/01

Effective from 01/03/2020

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1. Purpose

This SOP defines the process for writing, reviewing, distributing, and amending SOPs within the LGBRIMH, Tezpur. The SOPs will provide clear, unambiguous instructions to conduct activities of the IEC in accordance with the ICMR guidelines 2017, Schedule 'Y" (Drugs and Cosmetic Act 1940: Amendment 20th Jan 2005 Amendment 2017), WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011, and International Conference on Harmonization, Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance April 1996, Code Federal Regulations Title 21

2. Scope

The scope of this SOP will apply to the procedures of writing, reviewing, distributing, and amending SOPs within the IEC, Secretariat and related investigators.

3. Responsibilities

It is the responsibility of the Director, LGBRIMH to appoint the SOP Team on recommendation of Chairman, IEC to formulate the SOPs by following the same procedures, format, and coding system when drafting or editing any SOP of the IEC. The SOP team will prepare the draft SOPs. The draft SOPs will be reviewed and approved by the IEC members. SOP team will be responsible to amend the SOPs as and when required. It is the responsibility of the IEC Member Secretary and staff for maintaining control on all the SOPs. The SOP will bear the effective date and validity. The IEC Secretariat will notify all concerned user via email of document updates (recent version). SOPs will be reviewed by the members of IECs. The Chairpersons of IECs will approve the SOPs. The SOPs will then be signed by the Director, LGBRIMH for further use.

SOP team will consist of Member Secretaries of IEC, administrative staff and one or two other IEC members. The team will-

Assess the request(s) for SOP revision in consultation with the Secretariat and Chairperson

- ✓ Propose a new, or modification in existing SOPs as needed
- ✓ Select the format and coding system for the SOPs
- ✓ Draft the SOP
- ✓ Review the draft SOP
- ✓ Submit the draft for approval to the Chairperson

3.1 Secretariat of IEC:

a. Co-ordinates activities of writing, reviewing, distributing and amending SOPs
b. Maintains on file all current SOPs and the list of SOPs
c. Maintains an up-to-date distribution list for each SOP distributed
d. Distributes the SOPs with a receipt to all users
e. Ensures all ethics committee members and investigators have access to the SOPs
f. Ensures the IEC members and investigators are working according to current version of SOPs

3.2 SOP team:

a. Proposes required SOPs
b. Selects the format and coding system
c. Drafts the SOP in consultation with ethics committee members and others involved
d. Assesses the request(s) for SOP revision in consultation with the secretariat and Director

3.3 <u>Chairperson of the IEC</u>:

a. Reviews and approves the SOPs

b. Signs and dates when receives the approved SOPs

3.4 Ethics Committee Members:

a. Review the draft SOPs when received from the SOP team and provide suggestions/comments on the same

b. Sign and date when they receive the approved SOPs

c. Maintain a file of all SOPs received

d. Return all out-of-date SOPs to the Secretariat upon receipt of the new/revised SOPs

4 Flow Chart

Activity	**Responsibility**
Appoint SOP teams	Director on suggestion of Chairman, IEC
List all relevant SOP	SOP team
Design /format layout of SOP	SOP team
Draft new/revise SOP	SOP team
Review new/revised SOP	SOP team
Approval for implementation	Chairman & Director
Implement, disseminate and archive SOP	IEC member/Secretariat/Investigators
Review and request for revision for existing SOP	IEC member/Secretariat/Investigators
Manage and archive all SOP	Secretariat

Procedure

Request for new/review of SOP in prescribed format by IEC member, Investigator of LGBRIMH, Secretariat
SOP team formed if the IEC approves the request. If not approved then Chairman, IEC communicates to the person requesting new/review of SOP through the Secretariat
SOP prepared/revised by the team within 3 months & put for discussion in Research Forum
SOP prepared/revised put in IEC in full forum and approval taken from Chairman, IEC
Final approval from Director, LGBRIMH for implementation by Member Secretary
Record/archive/distribution by Secretariat

5 Detailed instructions

5.1 Identify the need for new or amendment to the SOP

Any member of the IEC, secretariat or investigators of LGBRIMH, can make a request for designing an entirely new SOP, can put forth his / her request by using the Request Form for Formulation of new SOP/ Revision of an SOP Form (AF 05-001/1.0) to suggest improvement/discrepancy of SOP. This Formulation of new SOP/ Revision of an SOP Form (AF 05-001/1.0) are submitted to the Secretariat. The Secretariat will forward the request to the Chairperson, IEC and Director, LGBRIMH. The Chairperson will inform all IEC members about this request in a regular full board meeting. If IEC members agree to the request, the information will be discussed with the Director and he/she will appoint an appropriate SOP team.

5.2 Appoint the SOP Team

The Director appoints the appropriate individuals who have a thorough understanding of ethical review process to form the SOP writing team led by Member Secretary. This designated team will proceed with the task of formulation / revision process of the SOP. If IEC members do not agree to the request, no further action will be taken. The Chairperson will inform the person/ IEC member who made the request for formulation of new SOP/modification of the existing SOP in writing about the decision through the Secretariat.

5.3 List all relevant SOPs

The SOP team will

a. Write down step by step all IEC procedures.

b. Organize, divide and name each process.

c. Make a list of SOPs with coding reference (Annex 1: AF 01-001/01.0)

5.4 Design a Format and layout

Each SOP should be given a number and a title that is self-explanatory and is easily understood. A unique code number with the format SOP/XXX/YY.W will be assigned to each SOP item by theSecretariat.*XXX* is a three-digit number assigned specifically to the SOP. *YY* is a two-digit number identifying the version of the SOP, and *W* is a one-digit number identifying the version of SOP with minor changes in the SOP. The number of version should be started from 01 and the W should be started with 0, for example, SOP001/01.1 is the SOP number 001 version 01 with one minor revision i.e. 01.1. Each annex will be given unique code number with the format *AF/BB-XXX/YY.W*. AF is the abbreviation for Annex Form. BB is a two-digit number identifying the number of the annex, for example AF/01-001/01.0 means Annex Form number one of the *SOP/001/01.0* Each SOP will be prepared according to the template for standard operating procedures (Annex 2 –AF 02-001/01.0*)*.

5.5 <u>Write, Review and Approve new SOP</u> With reference to section 5.3 and 5.4 the SOP team will prepare the draft SOP. If an SOP supersedes a previous version, indicate the previous SOP version and the main changes in SOP/001/01.0 **SOP/001/01.0** in the Document History form (Annex 3 – AF 03-001/01.0).

5.6 <u>Reviews by Consultation</u>

The draft SOP should be discussed and consulted with LGBRIMH investigators before discussion with IEC members. The draft SOP will be discussed with members of IEC during the full board meeting. Members can put forth their suggestions / comments on the draft / revised SOP. The suggestions agreed upon unanimously by all IEC members will be incorporated and the final

draft SOP will be formulated. The final version will be reviewed and approved by the Chairperson, IEC. The Chairpersons will sign and date the SOP on the first page of the SOP document. This approved document will then be submitted to the Director, LGBRIMH for acceptance for implementation in the Institute. This date of approval is declared as the effective date for implementing the SOP. The specific SOP team would stand automatically dissolved once the Chairperson IEC takes the final decision regarding the SOP.

5.7 Implement, distribute and file all SOPs

The approved SOPs will be implemented from the effective date and will be distributed to the IEC members, and the investigators by the Secretariat according to the distribution list (Annex 4 – AF 04-001/01.0). For public access, two printed and signed copies will be displayed in the library, Secretariat, LGBRIMH and its website. When revised version is distributed, the old version will be retrieved from all persons and destroyed. The old version will be no longer effective. One complete original set of current SOPs will be filed centrally in the SOP Master file, by the Secretariat and keep the file in the Secretariat. Photocopies made from the paper versions of the SOP will be considered official only if stamped and signed by the Member Secretary. A distribution log should be maintained (AF 04-001/01.0)

5.8 Review and request for a revision of an existing SOP

Any member of the IEC, Secretariat or investigators of LGBRIMH who notices an inconsistency between two SOPs or has any suggestions on how to improve a procedure should use the form in (Annex 5 – AF 05-001/01.0) to make a request. If the IEC agrees with the request, an appropriate team will be designated by the Director to proceed with the revision process. If the committee does not agree, the Secretariat will inform the person who made the request of the decision. Revision of the SOPs will be reviewed and approved in the same manner as new SOPs. The Secretariat will regularly prepare the amendment or addendum (if any) to the existing SOP according to the approved discussion points in the IEC meetings. The Secretariat will review the SOPs at least every 2years and incorporate the addendum and record the dates of review on the SOP Master file even if no change is made.

5.9 Manage and archive superseded SOPs

Superseded SOPs should be retained and clearly marked “superseded” and archived in the archival file by the Secretariat**.** The process of evolution of previous SOPs of the IEC will be documented in a defined format (AF 03-001/01.0).

6 References

1. WHO Operational Guidelines for Ethical Review Committee that Review Biomedical Research (Geneva 2000) WHO Operational Guidelines for Ethical Review Committee that Review Biomedical Research (Geneva 2000
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) (1996) International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) (1996)
3. ICMR Ethical Guidelines for Biomedical research on Human Participants, ICMR (2017)
4. Schedule Y (Drugs and Cosmetic Act 1940; with amendments)
5. SOP. IHEC. ICMR. NIE 2017 (v02.1)
6. IEC.SOP.v5. Tata Memorial Centre. 2018.

7.Annexure

ANNEX 1	AF 01-001/01.0	List of IEC SOPs
ANNEX 2	AF 02-001/01.0	Template for Standard Operating Procedures
ANNEX 3	AF 03-001/01.0	Document History
ANNEX 4	AF 04-001/01.0	Log of SOP Recipients
ANNEX 5	AF 05-001/01.0	Request for Revision of an SOP

Annexure: AF 01-001/01.0

List of SOPs

Topic No.	**Topics/ Standard Operating Procedures (SOPs)**	**SOP Code(LGB/IEC/ SOP/xxx/yy/w)**
1	Preparing Standard Operating Procedures (SOPs): Writing, Reviewing, Distributing & Amending SOPs for the Institutional Ethics Committee (IEC)	SOP/001/01.0
2	Constitution of Institutional Ethics Committee (IEC)	SOP/002/01.0
3	Management of protocol submissions	SOP/003/01.0
4	Board Meetings/committee in general	SOP/004/01.0
5	Recruiting vulnerable population	SOP/005/01.0
6	Continued Education & Training on Ethical Issues	SOP/006/01.0
7	Conflict of Interest	SOP/007/02.1
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Annexure: AF 02/ 001/02.1

Template for Standard Operating Procedures

Name of Institution : LGB Regional Institute of Mental health, Tezpur	
Title: *Title which is self-explanatory and is easily understood*	
SOP No: LGB/IEC/*SOP/xxx/yy.w*	Page: ? of ?

TITLE
Title which is self-explanatory and is easily understood

Effective Date:
Supersedes:
Author: Date:…….
(Name).
Approved by: Date:…….
(Name)

Main Text:

1 **Purpose** -summarizes and explains the objectives of the procedure.

2 **Scope** – states the range of activities that the SOP applies to.

3 **Responsibility** – *refers to person(s) assigned to perform the activities involved in the SOP*

4 **Flow chart** – *simplifies the procedures in step by step sequence and states clearly the responsible person(s) or position for each activity*

5 **Detailed instructions** – *describe procedures step by step in short and clear phrases or sentences. Split a long sentence into shorter ones.*

6 **Glossary** – clarifies uncommon or ambiguous words or phases by explanation.

7 **Reference** – lists sources of the information given in the SOP.

8 **ANNEX** -*documents that explain further or clarify complex descriptions. "Description-by-example" is always recommended to avoid difficult texts which may be hard to understand.*

Annexure: AF 03/001/01.0 Document History of particular SOP

SOP Code: SOP/xxx/yy/

Author	Checked by	Version	Date
AAA	BBB	w	DDMMYYYY

Annexure: AF 04/001/02.1

Table 1: Log of SOP Recipients in IEC

No.	Name of Recipients	SOP#	#of Copies	Signature	Date
1	*Chairperson*	*SOP/001/01.0* *SOP/002/01.0* *SOP/003/01.0*			DDMMYYYY
2	*Dr. XXXX*	*SOP/001/01.0* *SOP/002/01.0* *SOP/003/01.0*			
3					
4					
5					
6					

Annexure: AF 05/001/01.0

Request for formulation of new/Revision of an SOP

This form is to be completed by any member whenever a necessity arises to formulate a new SOP or problem or a deficiency in an SOP is identified and maintained with the SOP until an authorized replacement is in place

SOP CodeNo:	
Title:	
Details of problems or deficiency in the SOP:	Need to formulate an entirely new SOP (i.e. SOP not existing previously)
Identified by: (name of the person, designation)	Date (DD/MM/YYYY):
The sections given below are to be filled by the Secretariat	
Discussed in IHEC meeting held on:	
Formulation of new SOP / revision required: □ Yes □ No	
If yes, to be carried out by whom?	
If no, why not? Whether the decision communicated to the requester? □ Yes □ No Date of communication	
Date SOP finalized:	
Date SOP approved:	
Date SOP becomes effective:	

Institutional Ethics Committee

Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

Constitution of Institutional Ethics Committee (IEC)
SOP/002/01.0

Author: Dr. K N Kalita

Checked by: Dr. K Pathak

LGB Regional Institute of Mental Health, Tezpur

Constitution of Institutional Ethics Committee (IEC)
SOP/002/01.0

1.Purpose

The IEC is established to formalize and specify Institution's commitment to the promotion of high scientific and ethical standards in research conducted at LGBRIMH by valuing community interests. The purpose of the IEC is to cultivate a pluralistic and democratic exchange of scientific and ethical values and concerns, and to critically analyze them while looking for opportunities to enhance the scientific and ethical integrity of Institution. One of the main purpose of IEC is dissemination of ethical information and making the environment research friendly for the students, faculties and researchers along with making all aware of responsible code of conduct of research..

2. Scope

This SOP applies to the constitution of the IEC. The IEC-LGBRIMH will review all research projects undertaken in and by persons associated with LGBRIMH whomsoever may be and any external agencies/individuals for compliance with Ethical guidelines provided by ICMR – 2006, 2017 and MoHFW (Department of Health Research) Notification 20th January 2005 (Requirements and guidelines for permission to import and / or manufacture of new drugs for sale or to undertake clinical trials), 30th January 2013 (Compensation in case of injury or death due to clinical trial), 1st February 2013 (Permission to conduct clinical trials), 8th February 2013 (Registration of Ethics Committee), ICH guidelines and CDSCO GCP Guidelines. The IEC of LGBRIMH was constituted initially in 2007 to meet the academic needs of the students enrolled in various courses of LGBRIMH. Registration of ethics committees is initiated on 12 December 2019 as per related provisions. The projects will also be reviewed with reference to the guidelines/regulations of the country of origin of the sponsor for international studies along with concurrence with relevant financial and intellectual property related issues. And the ICMR guideline for multicentre studies will be appropriated. In due course of time appropriate steps will be taken for quality assurance in research through accredition.

3. Responsibility

The IEC has the responsibility, within the Institution, for the following objectives:

a. Ensuring the competent review and evaluation of all scientific and ethical aspects of research projects received compliance with the appropriate laws, and welfare of participants.

b. Creation, development, revision and implementation of SOPs /guidelines for the IEC

c. Continuing education and training programs to ensure that IEC members are qualified to perform their specific duties.

d. Training other research individuals in ethical conduct of research.

3.1 **Mandate of IEC** The IEC through its Members independently functions for maintaining a consistent scientific and ethical framework for research, integrating ethical values into practice, policy relationships, and organizational activities.

3.2. Terms of Reference of IEC

a. Ensure the highest ethical and scientific standards of research at LGBRIMH and members will be conversant with different guidelines, legal issues and will follow the relevant SOPs

b. Review and approve, proposals for clinical, basic, translational and public health research projects (Intra and Extra mural) for scientific and ethical content

c. Improve ethical standards and issue guidelines on ethical dilemmas related to human participants' in research projects

d. Function as a forum to advise the investigators in case of any ethical issues that may arise from human research participants, families or public

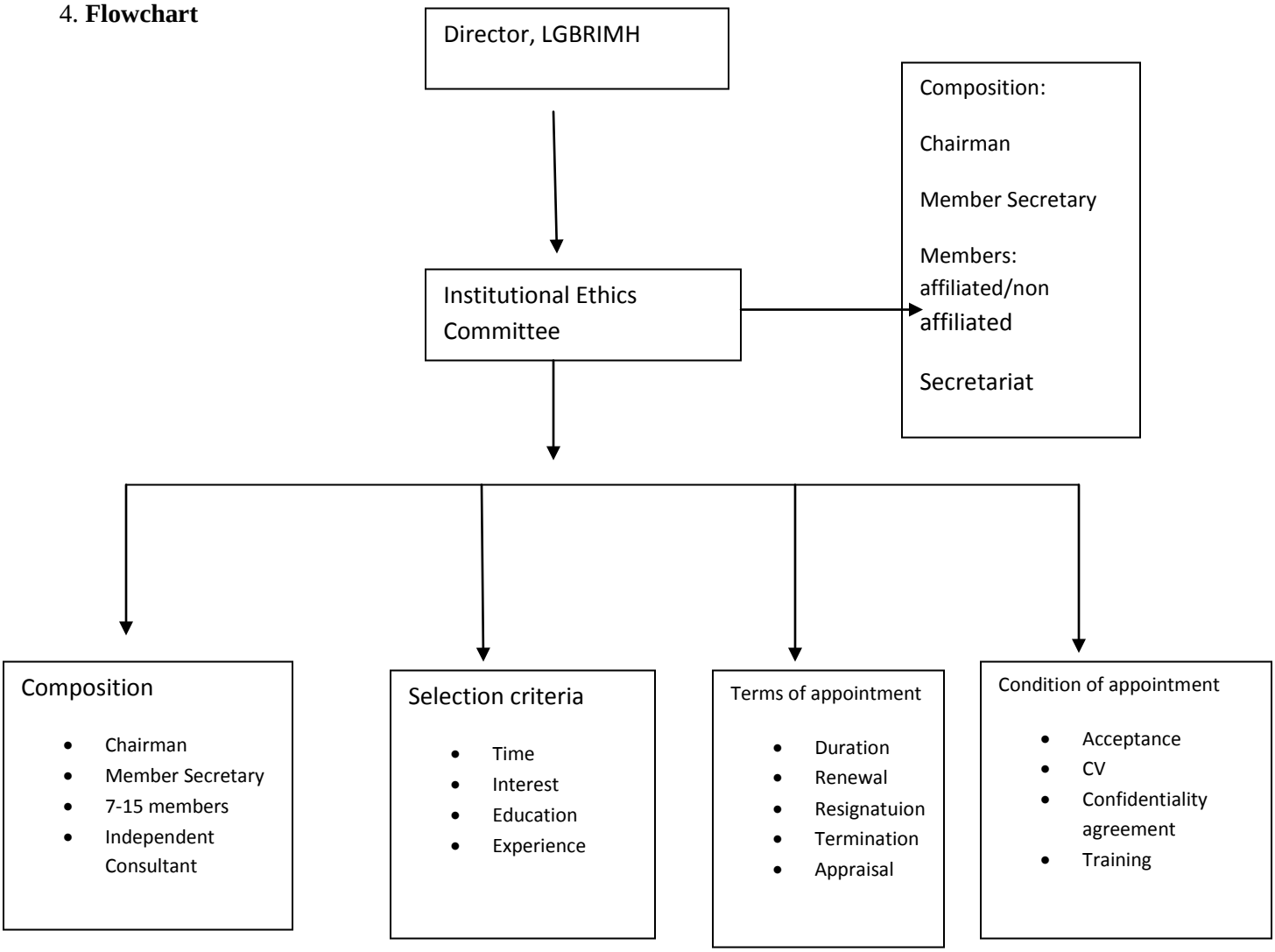
e. Maintain leadership as an accepted standard of reference in the fields of public health research for the region through appropriate registration and accredition.

f. Update and revise SOPs and guidelines periodically, for effective functioning of IEC

g. Conduct continuing education in public health research bioethics, workshops and interactive discussions for all categories of in investigators and prevent misconduct in areas of research

h. Function not to address or interfere in matters of administration or as a grievance cell for staff members

4. **Flowchart**



5. 1 **Ethical basis**

a. The committee consists of members who collectively have the qualifications and experience to review and evaluate the scientific, medical and ethical aspects of a proposed research project.

b.The IEC recognizes that national and/ or local ethics committees and concerned regulatory bodies may also review the approved protocols(and vice versa) prior to their implementation in study settings as specified in the protocol

c. In evaluating protocols and ethical issues, the IEC is aware of the diversity of laws, cultures and practices governing research and medical practices in various regions

d. The IEC also seeks to be informed, as appropriate, by national / other local ethics committees and researchers of the impact of the research it has approved.

e. The IEC is guided in its reflection, advice and decision by the ethical principles expressed in the Declaration of Helsinki and its amendments by World Medical Association.

f. It makes further reference to various national and International Ethical Guidelines for e.g Policy statement on ethical considerations involved in research on human subjects, ICMR 1980,Ethical guidelines for biomedical research on human subjects. New Delhi: ICMR2000,2006,20017, Good clinical practice. Central Drugs Standard Control Organization; 2004, Schedule Y of the Drugs and Cosmetics Act, 1940, as amended , The Nuremberg Code, 1947, Declaration of Helsinki: ethical principles for medical research involving human Subjects, The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont report1979,Federal Policy for the Protection of Human Subjects 2001,2017. Good clinical practice guidelines E6 (R1), Integrated Addendum to ICH E6(R1), Report and Recommendations of the National Bioethics Advisory Commission. Bethesda, International ethical guidelines for biomedical research involving human subjects. Geneva: Council for International Organizations of Medical Sciences; 2002,2016, Nuffield Council on Bioethics; 2007, Universal Declaration on Bioethics and Human Rights. Paris2005,Guidelines for international collaboration/research projects in health research,ICMR, Environmental Protection Act and rules, 1986, The Biological Diversity Act, 2002, Foreign Contribution (Regulation) Act, 2010, Defining the role of authors and contributors ICMJE, National ethical guidelines for bio-medical research involving children, 2017, rules for vulnerable tribal groups, The Mental Healthcare Act and rules, 2017, G.S.R. 313(E) 2016, Clinical Trials Registry, Guidelines for Good Clinical Laboratory Practices (GCLP).ICMR,Good Manufacturing Practices. CDSCO, Good Clinical Practice Guidelines for clinical trials of ASU Medicine, Atomic Energy Regulatory , Biomedical Waste Management Rules , The Pre-Conception and Pre-Natal Diagnostic Techniques, Import/export policy for human biological samples etc as updated.

g. The IEC establishes its own Standard Operating Procedures based on the ICMR guidelines (2006, 2017), Schedule Y (Drugs and Cosmetics Act 1940, amendment 20th Jan 2005, 30th January 2013 - Compensation in case of injury or death due to clinical trial, 1st February 2013 -Permission to conduct clinical trials, 8th February 2013 Registration of Ethics Committee), Operational Guidelines for Ethics Committees that Review Biomedical Research (WHO 2000), and ICH-GCP, 1996. IEC will also refer and make the members conversant with list of documents mentioned in the references of ICMR guideline 2017. IEC seeks to fulfill the requirements for international assurances and is established and functions in accordance with the national law and regulations

5.2. Composition and Constitution of I EC

IEC will be multi-disciplinary and multi-sectoral in composition. It is composed of a minimum of 7 and

maximum of 15 members. 50% of the members will be non affiliated or from outside LGBRIMH. They will collectively posses the qualifications and experience to review and evaluate the scientific, medical and ethical aspects of the proposed research

The committee should have adequate representation of age, gender etc. to safeguard the interests and welfare of all sections of the society. Members are expected to be aware of local, social and cultural norms, as this is the most important social regulated mechanism.

5.2.1Composition shall be as follows:

a. Chairperson (non affiliated)

b. One -two persons from basic medical science (affiliated/non affiliated)

c. One -two clinicians from various Institutes (affiliated/non affiliated)

d. One legal expert or retired judge (affiliated/non affiliated)

e. One social scientist/ representative of non-governmental voluntary agency (affiliated/non affiliated)

f. One philosopher/ ethicist/ theologian (affiliated/non affiliated)

g. One lay person from the community (Non affiliated)

h. Member Secretary (affiliated)

5.2.2. Membership

The Director,LGBRIMH, will appoint all members including the Chairperson and the Member Secretary. The IEC Member-Secretary will coordinate between IEC, Investigators and the Director and relevant agencies. The member secretary will be the nodal and coordinating person for the IEC.

5.2.3Criteria for selection of members:

a. Members are selected on their personal capacities but not for any position held, based on their interest, ethical and/or scientific knowledge and expertise, experience in the domain field and profile

b. Conflict of interest will be avoided while making appointments, but where unavoidable, there will be transparency with regard to such interests

c. New members will be identified according to the requirement i.e. as per the composition specified in this SOP and provided the potential member fulfills the conditions of appointment as defined in this SOP.

5.2.4The following credentials/qualities is sought in IEC members:

a. Experience and education

b. Interest and motivation

c. Commitment and availability

d. Respect for divergent opinions

e. Integrity and diplomacy

5.3 Terms of Appointment

a. Duration

The members of the IEC will be appointed for duration of3 years. The appointment procedure for membership will be followed so that it allows for continuity, development and maintenance of expertise within the IEC, and the regular input of fresh ideas and approaches. The members may be reappointed for three more years. 50% of Members will retire in rotation to keep the IEC function active all round the time. Selection of Member Secretary and other members should be done at least 3 months in advance respectively. Member Secretary designate should be inducted into the IEC as an observer before s/he takes on the mantle in the new IEC.

If a regular member resigns, or ceases to be a member due to disqualification, or death, a new member will be appointed for the remaining term as per the Conditions of appointment.

b. Resignation / Replacement procedure

The members who have resigned may be replaced at the discretion of the Director. IEC members who decide to resign must provide the written notification of their proposed resignation date at least 30 calendar days prior to the next scheduled meeting to the Director through the Secretariat. In case of resignation, Director would appoint a new member keeping the composition of IEC appropriate.

c. Termination / Disqualification/Removal procedure

A member shall be relieved or terminated of his/her membership in case of

- Conduct unbecoming for a member of the IEC
- Inability to participate in the meetings on any grounds

- Failure to attend more than 3 consecutive meetings of the IEC and subsequent to review of the membership by the IEC

- Relocation to another city or any such matter

In all such situations/circumstances, Director will serve a letter of termination to the member on recommendation of Secretariat. Documentation of the termination will be recorded in the minutes of the next duly constituted IEC meeting and the IEC membership roster and circulars will be revised.

5.4. Conditions of appointment of a Member of IEC

a. Name, age, gender, profession, and affiliation of IEC members will be publicized both in online and offline way. Members must accept the appointment in writing. Members must submit a one page CV and appropriate training certificates/ undertaking to undergo such training

b. Conflict of interest, if any, must be disclosed. Members must apprise themselves of the relevant documents, codes, ICH GCP guidelines and the ICMR ethical guidelines, concerned national regulations and IEC-LGBRIMH SOPs.

c. Members are required to sign the confidentiality agreement at the start of their term. The confidentiality agreement protects the privacy and confidentiality of all parties whose information may be disclosed to the IEC in the course of its work. These documents may be shared with relevant agencies as per relevant guideline and rules/regulations

5.5 . Independent consultants/ Experts

The IEC may call upon, or establish a standing list of, independent consultants who may provide special expertise to the IEC on proposed research protocols, when the Chairperson / Member secretary or the IEC members determine that a study will involve procedures or information that is not within the area of expertise of the IEC members. These consultants may be specialists in ethical or legal aspects, specific diseases or methodologies or they may be representatives of communities, patients, or special interest groups. These consultants must sign the confidentiality agreement regarding meeting, deliberations, and related matters. These consultants or subject experts and cannot vote for a decision.

5.6. Office bearers

The IEC will have the following office bearers who have the expertise and professional qualifications to review the proposals submitted.

5.6.1Chairperson

The IEC Chairperson should be a highly respected individual necessarily from outside LGBRIMH, fully capable of managing the IEC and the matters brought before it, with fairness and impartiality. The task of making the IEC a respected part of the institutional community will fall primarily on the shoulders of Chairperson. The IEC must be perceived to be fair and impartial, immune from pressure either by institute's administration, the investigators whose protocols are brought before it, or other professional and nonprofessional sources. The IEC Chairperson will respect the diverse backgrounds, perspectives, and sources of expertise of all IEC members, especially the contributions of the non-scientists, and must have the ability to foster such respect among the IEC members.

5.6.2 Member Secretary

The Member Secretary will be a faculty member from LGBRIMH, nominated by the Director, LGBRIMH who will be committed to the task of coordinating and managing the activities of the committee. S/he will be responsible for scheduling the meetings, describing the agenda and ensuring that the function of the committee is conducted as per the norms and policies described in the SOPs. In addition to this, the Member-Secretary will supervise secretariat at regular intervals not less than once in a week.

The Member Secretary is responsible for conducting regular training to IEC members and the staff of the secretariat in the SOPs for IEC functioning.

In case of non-availability of the IEC Member-Secretary, the Director will nominate an appropriate substitute for the temporary period till the regular IEC Member-Secretary resumes his/ her duties.

5.6.3The Affiliated Members

The Affiliated Members of the IEC will be nominated by the Director, LGBRIMH for supporting the Members and Member-Secretary in the IEC activities at recommendation of the research forum of LGBRIMH. The conditions of appointment, terms of reference, terms of appointment and other relevant conditions lay down for the Members of the IEC are applicable to the affiliated Members too.

5.6.4The Secretariat The Secretariat is composed of the Member Secretary, IEC, and the supporting staff. The supporting staff consists of staff members of LGBRIMH appointed by the Director, LGBRIMH.

5.6.5 The secretariat shall have the following functions

a. Organization of an effective and efficient tracking procedure for each proposal received
b. Preparation, maintenance and distribution of study files to the IEC Members
c. Organization of regular IEC meetings
d. Preparation of the agenda and the minutes of the meetings
e. Maintenance of the IEC records and archives
f. Communication with IEC members and Investigators
g. Arrangement of training for investigators and IEC members
h. Provision of the necessary administrative support for IEC related activities to the Member Secretary, IEC
g. preparation of annual reports
h. Follow up any procedural and legal issues that may arise

5.6.6 The IEC Supportive Staff: Working Rules

a. There will be a designated permanent staff member, who will look after the day to activities of the IEC Secretariat
b. The designated person will also obtain support from one more staff member who will be nominated by the Director, LGBRIMH. The term for this staff member will be as decided by Director, LGBRIMH but it should not be too short as these issues are to be handled by properly trained persons. In case of any shifting of responsibility of support staff appropriate replacement of manpower will be ensured by Director, LGBRIMH.
c. The supportive staff will report to the Member Secretary, IEC.
d. Secretariat should support the Member Secretary in all their functions and should be trained in documentation and filing procedures under confidentiality agreement.

5.7. Roles and Responsibilities of the IEC

a. The Committee's primary responsibility will be determining the scientific and ethical validity of the research and the protection of the safety, rights, dignity, wellbeing and confidentiality of the research participants.
b. Participate in the IEC meetings and ensure ethical conduct of research with confidentiality agreement
c. Review and discuss research proposals assigned for evaluation through competent initial and continuing review of all scientific, ethical, medical and social aspects of research proposals received by it in an objective, timely and independent manner by attending meetings,

participation in discussion and deliberations.
d. Ensure that universal ethical values and international scientific standards are followed in terms of local community values and customs
e. Assist in the development and education of the research community in the institute (including researchers, clinicians, students and others), responsive to local healthcare requirements.
f. Responsibilities of members should be affirmed appropriately as mentioned in the SOPs
given at the time of their appointment.
g. Ensure that privacy of the individual and confidentiality of data including the documents of EC meetings is protected.
h. Reviews progress reports, final reports and AE/SAE and gives needful suggestions regarding care of the participants and risk minimization procedures, if applicable.
i Recommend appropriate compensation for research related injury, wherever required.
j. Declare conflict of interest, if any to Chairperson.
k. Carry out work delegated by the Chairperson.
l. Participate in continuing education activities in biomedical ethics and biomedical research.
m. Provide information and documents related to training obtained in biomedical ethics and biomedical research to the IEC secretariat.

5.8. Quorum Requirements All research projects for approval by the full board of the IEC shall be reviewed at convened meetings at which a majority of the members of the IEC are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting. Quorum requirement for any IEC meeting is 50% of total members +1 of the membership or minimum five members whichever is higher.

The members representing medical scientists and clinicians should have post-graduate qualification and adequate experience in their respective fields and aware of their role and responsibilities as committee members. A person may have dual responsibility based on education and experience e.g. if the Chairperson is a legal person he may add his expertise as legal expert too.

A quorum should include both medical, non medical, technical, non technical members. Preferably a lay person should be part of the quorum. Minimum of one non affiliated person should be part of trhe quorum. If for any reason the Chairperson is unable to attend any meeting, alternate Chairperson will chair that meeting. A written documentation to this effect from the Chairperson will be obtained and filed. The Members will select one person among them as an alternate Chairperson by consensus who should be non-affiliate of LGBRIMH. The minutes of such meeting and the decision letters of the study protocols and study related other documents discussed in that meeting would bear the signature of the Officiating Chairperson. The quorum for reviewing regulatory clinical trials should be in accordance with current CDSCO requirements. No decision is valid without fulfillment of quorum.

5.9. Decision making
Decisions are arrived at by consensus by the members of IEC. The members who are unable to attend the meeting could give their written comments on the protocol/s to the Chairperson and the Member Secretary prior to the proposed meeting. Their views will be taken into consideration, if they have submitted their comments in a written communication. Wherever needed, IEC may invite outside expert/s for guidance to provide opinion/suggestion, in which the IEC may decide upon. They may maintain a

panel of subject experts e.g. cardiologist, Pediatrician etc. However, this member/s will not be involved in decision-making. Any committee member with a conflicting interest in a proposal will abstain from deliberations and in the decision making process on that proposal, except to provide information as requested by the committee. Such abstentions will be recorded in the minutes.

Scientific Advisory Committee or any such body by any name should review the research proposals before it is placed for IEC clearance. IEC can raise scientific queries besides ethical ones as both good science and ethics are important to ensure quality of research and participant protection.

5.10. Education for IEC Members

IEC members have a need for initial and continued education regarding the science and ethics of biomedical research. All IEC members must be conversant with ICMR Guidelines for Research involving Human Subjects 2017, Schedule Y of Drugs and Cosmetics Act & respective ethical and GCP guidelines. They should be trained in human research and right protection, IEC functions and SoPs.
IEC members will receive introductory training material in research bioethics and functioning of IECs and will be exposed to ongoing opportunities for enhancing their capacity for ethical review. The IEC members will be encouraged to attend to national and international training programmes /conferences/seminars in the field of research ethics to help in improving the ethical conduct of research, Ethics Committee submissions and review. The IEC Secretariat will organize workshops from time to time to impart training. The training programs should be scheduled and spread over the year and it shall include local, social, cultural norms and interplay with ethical issues. All relevant updates on bio-ethics will be brought to the attention of the IEC Members/ Investigators of LGBRIMH.

5.11. Annual activity report

The Member Secretary in Consultation with the Chairperson, IEC shall prepare an annual activity report of the IEC for submission to the Director, NIE and accreditation. This shall include: quanatative evaluation of annual activites, list of proposal received and decisions related to it, status of current proposals.

5.12. Honorarium

All the non affiliated members of the IEC will be paid honorarium as per relevant rules for attending the IEC meetings and training programmes/workshops conducted.

5.13. Dissolving of the IEC

a. At any point of time, if the Institute ceases to exist, the IEC is automatically dissolved.
b. The Director, LGBRIMH following written notification to each of the members, may also dissolve the IEC at any time.

6. References

1. ICMR Ethical Guidelines for Biomedical research on Human Participants, ICMR (2017)
2. SOP. IEC. ICMR. NIE 2017 (v02.1)
3. IEC.SOP.v5. Tata Memorial Centre. 2018.

7. Annexure

ANNEX 1	AF 01-002/01.0	Template CV of members
ANNEX 2	AF 02-002/01.0	Conflict of Interest
ANNEX 3	AF 03-002/01.0	Confidentiality Certificate of all Members
ANNEX 4	AF 04-002/01.0	Confidentiality Certificate of observer attendee
ANNEX 5	AF 05-002/01.0	Confidentiality Certificate of Independent Consultant
ANNEX 6	AF 06-002/01.0	Training Certificate or Undertaking to undergo training in Ethical issues including GCP guidelines
ANNEX 7	AF 07-002/01.0	Offer/appointment letter from Director
ANNEX8	AF 08-002/01.0	Acceptance/Rejection of offer letter

ANNEX 1 (AF 01-002/01.0) **Template CV of members, IEC, LGBRIMH**

Last Name	First Name	Middle Name		
Date of Birth (dd/mm/yyyy):		Gender:		
Mailing Address (Professional and Residential with Pin Code)				
Telephone (Office):		Mobile Number:		
Telephone (Residence):		Email:		
Academic Qualifications (Most recent qualification first)				
Degree/Certificate	Year	Institution, Country		
Professional Experience (most recent position first)				
Month and Year	Title	Institution/Company, Country		
Experience to serve on Ethics Committees (if yes, else NA)				
Organization (Govt/Pvt/Independent)	Role (Member / Chairperson)	Period		
Area of expertise			Yes	No
1. Basic Medical Science				
2. Clinician				
3. Legal / Regulatory function				
4. Social Science/ Philosophy / Ethics / Theology				
5. Lay person/ Representative of NGO				
6. Others(Please Specify)				
Signature:	Date:	Place:		

ANNEX 2 (AF 02-002/01.0)

CONFLICT OF INTEREST

It has been recognized that the potential for conflict of interest will always exist but faith and confidence are vested in the IEC and its Chairperson to manage the issues of conflict so that the ultimate outcome of protection of human participants is achieved. In accordance of the policy of the IEC, LGBRIMH (IEC) he/she shall not participate in the review, comment or approval of any activity in which he/she have a conflict of interest, except to provide information as requested by the IEC. The Undersigned will immediately disclose to the Chairperson of the IEC any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the committee, and to abstain from any participation in discussions or recommendations in respect of such proposals. If an applicant submitting a protocol believes that an IEC member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol. The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the IEC member(s) in question. The IEC may elect to investigate the applicant's claim of the potential conflict. Examples of conflict of interest cases may be any of the following: A member is involved in a potentially competing research program. Access to funding or intellectual information may provide an unfair competitive advantage. A member's personal biases may interfere with his or her impartial judgment.

Agreement on Confidentiality and Conflict of Interest

In the course of my activities as a member of the IEC, LGBRIMH 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 IEC'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:

ANNEX 3 (AF 03-002/01.0)

CONFIDENTIALITY UNDERTAKING FORM FOR IEC MEMBERS, LGBRIMH

In recognition of the fact, that I, Dr/Mr/Ms. _____ herein referred to as the "Undersigned", have been appointed as a member of the IEC and would be requested to assess research studies involving human participants in order to ensure that they are conducted in a humane, scientific and ethical manner, with the highest standards of care according to the applied national, local regulations, institutional policies and guidelines, sign the following undertaking in the capacity of Member / Chairperson of IEC of LGBRIMH, Tezpur. Whereas, the appointment of the undersigned as a member of the IEC is based on individual merits and not as an advocate or representative of a home province/ territory/ community nor as the delegate of any organization or private interest; Whereas, the fundamental duty of an IEC member is to independently review research protocols involving human participants and make a determination and the best possible objective recommendations, based on the merits of the submissions under review; Whereas, the IEC must meet the highest ethical standards in order to merit the trust and confidence of the communities with respect to the protection of the rights and well being of human participants; The undersigned, as a member of the IEC is expected to meet the same high standards of ethical behavior to carry out its mandate. This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a member of the IEC. Any written information provided to the Undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly. As such, the Undersigned agrees to hold all Confidential or Proprietary trade secrets ("information") in trust or confidence and agrees that it shall be used only for contemplated purposes, shall not be used for any other purpose or disclosed to any third party. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the IEC, LGBRIMH and shall be returned to the IEC secretariat after review. The Undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the Undersigned confirms that his/her performance of this agreement is consistent with LGBRIMH's policies and any contractual obligations it may have to third parties.

Undersigned Signature date

ANNEX 4 (AF 04-002/01.0)

CONFIDENTIALITY AGREEMENT FORM FOR OBSERVER ATTENDEES

I, _____, understand that I am allowed to observe IEC, LGBRIMH activities and attend the IEC meeting/ scheduled on _____ at _____am/ pm as an Observer. I understand that the course of the observer ship / meeting of the IEC some confidential information may be disclosed or discussed. Upon signing this form, I ensure that to take reasonable measures to keep the information and discussion as confidential and ensure confidential documents will be returned to the Secretariat after completion of the review and IEC meeting.

Signature of the Observer with Date _____

Signature of Member Secretary/Chairperson of IEC, LGBRIMH……

I, _____ acknowledge that I have received a copy of this Agreement signed by Member Secretary/Chairperson, IEC, LGBRIMH and me.

Undersigned Signature Date

ANNEX 5 (AF 05-002/01.0)

CONFIDENTIALITY AGREEMENT FORM FOR INDEPENDENT CONSULTANTS

I, _____ (Name and Designation) as a non-member of IEC, LGBRIMH understand that the copy (ies) given to me by the IEC is (are) confidential. I shall use the information only for the indicated purpose as described by the IEC and shall not duplicate, give or distribute these documents to any person(s) without permission from the IEC. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as confidential.

Undersigned Signature with Date …….

Signature of Chairperson/Member Secretary of IEC with Date……..

I, _____ acknowledge that I have received a copy of this Agreement signed by Chairperson, IEC and me.

Signature of the recipient

AF 06-002/01.0 Undertaking to undergo training in Ethical issues including GCP guidelines

Undertaking by a member of the Ethics Committee (EC) when training certificate is not available at the time of submission of request for registration of EC to the Department of Health Research (DHR) through the DHR online portal (https://naitik.gov.in)

1. I, Dr./Mr./Mrs. (name), (Designation) from (Affiliation), a member of Ethics Committee (EC) for Biomedical and Health Research involving Human Participants namely, (name of Ethics Committee), in M/S (Firm/Hospital/Institute/Organization name), have been appointed to serve as (Role in EC) in the above Ethics Committee.

2. I agree to undergo an ethics training involving Human Research Protection, Ethics Committee functions and Standard Operating Procedures, National Ethical Guidelines for Biomedical and Health Research Involving Human Participants as specified by Indian Council of Medical Research, Good Clinical Practice (GCP) Guidelines (if applicable) and relevant regulations of the country and also to submit the certificate of such training to the National Ethics Committee Registry for Biomedical & Health Research (NECRBHR) in the Department of Health Research within a period of 6 months from the date of provisional registration of the Ethics Committee.

Name of designated member Signature: Date: Place:	Name of Director, LGBRIMH: Signature: Date: Place:

Institute Seal

Annexure (AF 07-002/01.0) Letter of Offer/Appointment

Memo No. dated:

From
Dr. S K Deuri
Director, LGBRIMH
Tezpur, 784001

To
……..
……..
……..

Sub: Appointment as Chairman/ Member Secretary/Member/Independent Consultant/Reviewer of Institutional Ethics Committee, LGBRIMH (IEC, LGBRIMH)

Dear Sir/Madam,

I wish this letter reaches you in good spirit and health. I am happy to acknowledge your experience and immense contribution in your selected area of work. Research always needs to be seen from multiple angles and rights of the participants always need to be protected. Again we have the responsibility of carrying forward and building new scientific evidences that will help the future generation. I believe you can contribute specially in this area and hence I would like to nominate you as Chairperson/member secretary/member/independent consultant/reviewer for the Institutional Ethics Committee (IEC, LGBRIMH). Future communication will be done form the Secretariat of IEC, LGBRIMH in this regard.

Kindly reply back to my office/ Secretariat, IEC, LGBRIMH either by post or by mail (iec.lgbrimh@yahoo.com; lgbrimh@yahoo.co.in) with the following filled up documents.

Thank you

(Dr. S K Deuri)
Director
Copy to: Any relevant authority (Administrative authority/Departmental Head/Supervising authority)

Enclosure:

1. Acceptance/ Rejection letter
2. CV in the attached format
3. Any training certificate in ethics or an undertaking as per format
4. A cancelled cheque/ Bank account No with IFSC & MICR code

Annexure 8 (AF 08-002/01.0)

Letter of Acceptance/rejection of offer (strike off whichever not applicable)

To
Dr. S K Deuri
Director, LGBRIMH
Tezpur, 784001

Sub: Appointment as Chairman/ Member Secretary/Member/Independent Consultant/Reviewer

Ref No.

Dated:

Dear Sir,

With reference to the subject cited above I am happy to be acknowledged for my area of work. I am happy to accept the offer and I am enclosing the relevant documents along with it/ I am sorry for not being able to accept the offer at present for my preoccupations but I will look forward for any such opportunity in future (strike off whichever not applicable).

Thank you

With warm regards,

…….
……..
…….
……
(Name in Full, Signature, affiliation, address)

Institutional Ethics Committee

Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

Management of protocol submissions

LGB/IEC/SOP/ 003/01

Author: Dr. K N Kalita

Checked by: Dr. K Pathak

1. Purpose:

This standard operating procedure is designed to describe how the Secretariat of the IEC, LGBRIMH manages protocol submissions to the IEC for review.

2. Scope:

Protocol submissions include:
a. Initial review
b. Expedited review
c. Exemption from review
d. Amendment to the protocol
e. Submission of Serious Adverse effects or deviance/violation
f. Continuing review of approved protocols
g. Protocol Termination
h. Study completion

3. Responsibility:

It is the responsibility of the IEC secretariat to receive record, distribute for review and get the submission packages approved by the IEC, as well as to deliver the review results to the protocol applicants.

4. **Flowchart**

Submission of protocol by applicant in prescribed format to Secretariat
Secretariat Review for completeness and categories accordingly; if needed appoints Independent Consultant, communicates with applicant and IEC members and puts for IEC meeting
Communication of IEC decision by IEC Secretariat

5. **Detailed Information**

5.1 For the initial review of study, investigators should submit all study related documents to the IEC, no fewer than fourteen (14) days before the next scheduled meeting. The PI should submit research proposal to the IEC for review and approval under any of the 5 sections mentioned below:

- Initial Review Application/exemption from review/expedited review
- Resubmission of Study with Corrections
- Protocol Amendment or any other amendments
- Annual Status Reports /Continuing Review of the study
- Study Completion / Termination
- Submission of Serious Adverse Events and Deviations/Violations
- Any other documents

The IEC secretariat will accept new submissions from Principal Investigators only after ensuring that continuing review applications/status reports of the previously approved studies have been submitted by the Principal investigator (PI) in a timely manner. The IEC shall not process a new research proposal from the PI unless the PI has submitted continuing review application/status reports for ongoing IEC approved studies. The PI will submit 8 (eight) hard copies of proposed research related documents as mentioned in the annexure along with a related mail of all documents to corporate email id of IEC, LGBRIMH (iec.lgbrimh@yahoo.com)

The documents to be submitted to IEC for review are:

i. Cover letter to the Member Secretary
ii. Type of review requested
iii. Application form for initial review
iv. The correct version of the informed consent document (ICD) in English and the local language(s). Translation and back translation certificates (if applicable)
v. Case record or report form/questionnaire
vi. Recruitment procedures: advertisement, notices (if applicable)
vii. Patient instruction card, diary, etc. (if applicable)
viii. Investigator's brochure (as applicable for drug/biologicals/device trials)
ix. Details of funding agency/sponsor and fund allocation (if applicable)
x. Brief curriculum vitae of all the study researchers
xi. A statement on Conflict of Interest, if any
xii. GCP training certificate (preferably
xiii. within 5 years) of investigators (clinical trials)
xiv. Any other research ethics/other training evidence, if applicable as per EC SOP
xv. List of ongoing research studies undertaken by the principal investigator (if applicable)
xvi. Undertaking with signatures of investigators
xvii. Regulatory permissions (as applicable)
xviii. Relevant administrative approvals (such as Health Ministry's Special Committee's approval for International trials)
xix. Institutional Committee for Stem Cell Research (IC-SCR) approval (if applicable)
xx. MoU in case of studies involving collaboration with other institutions (if applicable)
xxi. Clinical trial agreement between the sponsors, investigator and the head of the institution(s) (if applicable
xxii. Documents for clinical trial registration if applicable
xxiii. Insurance policy if applicable
xxiv. Indemnity policy if applicable
xxv. Any additional document as per situation (e.g. multicentric and international collaborative studies)
xxvi. Protocol

The details of documents to be included in the Protocol are as follows:

i. the face page carrying the title of the proposal with signatures of the investigators;
ii. brief summary/ lay summary;
iii. background with rationale of why a human study is needed to answer the research question;
iv. justification of inclusion/exclusion of vulnerable populations;
v. clear research objectives and end points (if applicable);
vi. eligibility criteria and participant recruitment procedures;
vii. detailed description of the methodology of the proposed research, including sample size (with justification),

viii. type of study design (observational, experimental, pilot, randomized, blinded, etc.), types of data collection, intended intervention, dosages of drugs, route of administration, duration of treatment and details of invasive procedures, if any;
ix. duration of the study;
x. justification for placebo, benefit–risk assessment, plans to withdraw. If standard therapies are to be withheld justification with for the same
xi. procedure for seeking and obtaining informed consent with a sample of the patient/participant information sheet and informed consent forms in English and local languages. AV recording if
xii. applicable; informed consent for stored samples;
xiii. plan for statistical analysis of the study;
xiv. plan to maintain the privacy and confidentiality of the study participants;
xv. for research involving more than minimal risk, an account of management of risk or injury;
xvi. proposed compensation, reimbursement of incidental expenses and management of research related injury/illness during and after research period;
xvii. provision of ancillary care for unrelated illness during the duration of research;
xviii. an account of storage and maintenance of all data collected during the trial; and
xix. plans for publication of results – positive or negative – while maintaining confidentiality of personal information/ identity.
xx. ethical considerations and safeguards for protection of participants

5.2 The secretariat will examine the proposal for its completeness and will communicate accordingly to the PI specifically. The secretariat will also examine the financial matters that may be related to the proposal like any processing fee by the applicant approved by the institute, any remuneration for the review by reviewer including independent one as approved by the institute rules. The secretariat will stamp and put the appropriate protocol code (IEC/ YYYY/MM/XX, Y is year, M is month, X is number of protocol) for the proposal. It will store both hard and safe copies of the same and will ensure its safety and confidentiality. All communication form secretariat will accompany the associated allotted research protocol Id of the project. IEC may adopt a system for pre meeting preview by subject experts and obtain clarification from researcher in advance to save time. IEC may adopt strategy to appoint primary and secondary reviewer and member secretary will identify such persons. Specific comments on scientific and ethical areas may be sought. Such experts may take part in IEC meetings through video conferencing too but they will not be part of decision making.

5.3 The secretariat will segregate the proposal received as for format as given in ICMR guideline 2017. They are as follows

5.3.1 Proposals exempted from review:

- Proposals with less than minimal risk where there are no linked identifiers, for example;
    - research conducted on data available in the public domain for systematic reviews or meta-analysis;
    - observation of public behaviour when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person;
    - quality control and quality assurance audits in the institution;
    - comparison of instructional techniques, curricula, or classroom management methods;
    - consumer acceptance studies related to taste and food quality; and

- public health programmes by Govt agencies such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers).

5.3.2 Proposal for Expedited Review:

Proposals that pose no more than minimal risk may undergo expedited review, for example;

• research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples;

• research involving clinical documentation materials that are non-identifiable (data, documents, records);

• modification or amendment to an approved protocol including administrative changes or correction of typographical errors and change in researcher(s);

• revised proposals previously approved through expedited review, full review or continuing review of approved proposals;

• minor deviations from originally approved research causing no risk or minimal risk;

• progress/annual reports where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee; and

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

• research during emergencies and disasters

5.3.3 Proposals for full committee review:

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

• research involving vulnerable populations, even if the risk is minimal;

• research with minor increase over minimal risk

• studies involving deception of participants

• research proposals that have received exemption from review, or have undergone expedited review/undergone subcommittee review should be ratified by the full committee, which has the right to reverse/or modify any decision taken by the subcommittee or expedited committee;

• amendments of proposals/related documents (including but not limited to informed consent documents, investigator's brochure, advertisements, recruitment methods, etc.) involving an altered risk;

• major deviations and violations in the protocol;

• any new information that emerges during the course of the research for deciding whether or not to terminate the study in view of the altered benefit–risk assessment;

• research during emergencies and disasters either through an expedited review/ scheduled or unscheduled full committee meetings. This may be decided by Member Secretary depending on the urgency and need;

• prior approval of research on predictable emergencies or disasters before the actual crisis occurs for implementation later when the actual emergency or disaster occurs.

6. References

1. ICMR Ethical Guidelines for Biomedical research on Human Participants, ICMR (2017)
2. SOP. IEC. ICMR. NIE 2017 (v02.1)
3. IEC.SOP.v5. Tata Memorial Centre. 2018.

7. Annexure 1. (AF 01.q/001/ 03.0) Common forms Package of Ethics committee as per ICMR guideline

Annexure	**Code (AF qq/xxx/yy.w)**	**description (Application for……)**
Annexure 1	AF 1.0/003/01.0	initial review
Annexure 1.1	AF1.1/003/01.0	Expedited review
Annexure 1.2	AF1.2/003/01.0	Exemption from review
Annexure 1.3	AF1.3/003/01.0	Continuing review/annual report
Annexure 1.4	AF1.4/003/01.0	Amendment
Annexure 1.5	AF1.5/003/01.0	Protocol violation/deviation report
Annexure 1.6	AF1.6/003/01.0	Serious adverse event report
Annexure 1.7	AF1.7/003/01.0	Premature termination/suspension/discontinuation
Annexure 1.8	AF1.8/003/01.0	Clinical trial
Annexure 1.9	AF1.9/003/01.0	Serious adverse event reporting(clinical trial)
Annexure 1.10	AF1.10/003/01.0	Human genetic testing
Annexure 1.11	AF1.11/003/01.0	Socio behavioral and public health research
Annexure 1.12	AF1.12/003/01.0	study completion/final report
Annexure 1.13	AF1.13/003/01.0	CV for investigators
Annexure 2	AF2/003/01.0	Guideline for application submission
Annexure 3	AF3/003/01.0	Guideline for ascertaining level of risk
Annexure4	AF4/003/01.0	Protocol Template
Annexure 5	AF05/003/01.0	Informed Consent Document template
Annexure 6	AF 06/003/01.0	Cover letter
Annexure 7	AF 07/003/01.0	Document Receipt Form

Annexure (AF 07/003/ 01.0) Document Receipt form

Protocol Number:		**Submitted date:**	
Type of Submission	□ Initial Review □ Protocol Amendments □ Expedited review □ Exemption from review	□ Continuing Review of Approved Protocols □ Protocol Termination □ Study Completion	
Protocol Title:			
Principal Investigator:			
Designation:			
Documents submitted:	□ Complete		
	Check what documents are received later on.		
Documents to be submitted later:	□ Information for subjects □ Informed consent form □ Case report forms (CRF) □ Study budget □ Investigator's brochure □ Others……		
Received by:			
Date received:			

Please bring the document for further communication

Annexure : 1.0 (AF 1.0 / 003 / 1.0)

Application Form for Initial Review

Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

IEC Ref. No. *(For office use):IEC/XXXX(year)/Type of Review/number*

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) Title of the study/Thesis/disseratation/project/article.....

(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): Nature of Proposed research: part of academic curriculum/individual research/ collaborative research (intramural:intradepartmental/interdepartmental/extramural): Name of the departments involved:.....

Name of Course: .....Year of admission.....Year of expected Completion.....

.....

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

(i) Details of Investigators:

Name	Designation and Qualification	Department and Institution	Phone, email & address for communication[2]
Principal Investigator/student/fellow			
Co-investigator/student/fellow/Guide/CoGuide			

(j) Number of Active Studies where applicant is a Principal Investigator:.....

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

(l) Does the research needs registration/permission of any agency like CTRI/DCGI/SHMRC etc: Yes/No(please Specify).....

(attach relevant document).....

[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)* ☐

(if Funding from Outside India then comment on FCRA regulations).....

SECTION B - RESEARCH RELATED INFORMATION

3. OVERVIEW OF RESEARCH (attach a copy of protocol as per format)

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

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

(b) Type of study: (tick all possible)

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 Departmental Committee/Scientific Advisory Committee, if any (100 words): (attach copy)

.....

.....

.....

.....

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): Please attach Copy

Version number and date of Informed Consent Form (ICF): Please attach Copy

(c) Type of consent planned for :

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

Consent from LAR/NR ☐ (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

(LAR/NR: legally applicable representative/nominated representative) 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 Assamese/Hindi/Bengali/Others(specify).....

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 ☐
Others(Specify) ☐		Secretary of IEC

.....

8. PAYMENT/COMPENSATION

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

PI/CoPI ☐ 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 guide- lines 2017.
☐	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 IEC approved protocol.
☐	I/We declare that the expenditure in case of injury related to the study will be taken care of.
☐	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 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 confidentiality of 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-I): 1. .... 2. ....
☐	I/We declare/confirm that all necessary government approvals will be obtained as per requirements wherev- er applicable.

Name of PI: .....

Signature: ..... dd mm yy

Name of Co-PI: .....

Signature: ..... dd mm yy

Name of Guide: .....

Signature: ..... dd mm yy

Name of HOD: .....

Signature: ..... dd mm yy

(Format adapted from ICMR[10])

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 advisory 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

Annexure : 1.1 (AF 1.1 / 003 / 1.0)

Application Form for Expedited Review

Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

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

Title of study: .....

.....

.....

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

.....

.....

1. Choose reasons why expedited review from EC is requested[12] ?
   - i. Involves non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples. ☐
   - ii. Involves clinical documentation materials that are non-identifiable (data, documents, records). ☐
   - iii. Modification or amendment to approved protocol (administrative changes/correction of typographical errors and change in researcher(s)). ☐
   - iv. Revised proposal previously approved through expedited review, full review or continuing review of approved proposal. ☐
   - v. Minor deviation from originally approved research causing no risk or minimal risk. ☐
   - vi. Progress/annual report where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee. ☐
   - vii. For multicentre research where a designated EC has approved the proposal, a participating EC may review participating centre specific information and modifications in the study proposal through full committee meeting/expedited review depending on the importance of local consent related issues involved specific to the centre. ☐
   - viii. Research during emergencies and disasters (See Section 12 of ICMR Ethical Guidelines, 2017). ☐
   - ix. Any other (please specify) .....

     .....

2. Is waiver of consent being requested? Yes ☐ No ☐
3. Does the research involve vulnerable persons[13] ? Yes ☐ No ☐

   If Yes give details: .....

   .....

   .....

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

Comments of EC Secretariat: .....

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

[12] *Refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 51 Table 4.2*

[13] *For details, refer to application for initial review, Section-C, 5(b)*

* *In case this is first submission, leave it blank*

(Annexure 1.2 (AF 1.2/003/01.0)

Application Form for Exemption from Review

Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

(Name of the Institution) **IEC 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)*

(Annexure 1.3 (AF/1.3/003/01.0)

Continuing Review / Annual report format

Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

(Name of the Institution) **IEC 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

(Annexure 1.4 (AF/1.4/003/01.0)

Application/Notification form for Amendments

Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

(Name of the Institution) **IEC 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.*

(Annexure 1.5 9AF1.5/003/01.0)

Protocol Violation/Deviation Reporting Form (Reporting by case)

Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

(Name of the Institution) **IEC 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

Version 2.0

(Annexure 1.6 (AF 1.6/003/01.0)

Serious Adverse Event Reporting Format (Biomedical Health Research)

Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

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

Title of study: .....

.....

.....

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

.....

.....

1. Participant details :

Initials and ID	Age at the time of event	Gender	Weight:..... (Kgs)
.....	.....	Male ☐ Female ☐	Height: ..... (cms)
.....	.....		

2. Suspected SAE diagnosis:.....

3. Date of onset of SAE: dd mm yy

Date of reporting SAE: dd mm yy

Describe the event [19]:

.....

.....

.....

.....

.....

.....

.....

4. Details of suspected intervention causing SAE [20]

.....

.....

.....

.....

.....

.....

5. Report type: Initial ☐ Follow-up ☐ Final ☐

If Follow-up report, state date of Initial report dd mm yy

6. Have any similar SAE occurred previously in this study? If yes, please provide details. Yes ☐ No ☐

.....

.....

.....

.....

[19] *Duration, setting, site, signs, symptoms, severity, criteria for regarding the event serious*

[20] *Refers to research intervention including basic, applied and operational research or clinical research, except for investigational new drugs. If it is an academic clinical trial, mention name, indications, dosage, form and strength of the drug(s)*

7. In case of a multi-centric study, have any of the other study sites reported similar SAEs ? (Please list number of cases with details if available)

.....

.....

8. Tick whichever is applicable for the SAE: (Kindly note that this refers to the Intervention being evaluated and NOT disease process)

A. Expected event ☐ Unexpected event ☐

B.

Hospitalization	☐	Increased Hospital Stay	☐	Death	☐	Congenital anomaly/birth defect	☐
Persistent or significant disability/incapacity	☐	Event requiring intervention (surgical or medical) to prevent SAE	☐	Event which poses threat to life	☐	Others	☐

.....

In case of death, state probable cause of death.....

C. No permanent/significant functional/cosmetic impairment ☐

Permanent/significant functional/cosmetic impairment ☐

Not Applicable ☐

9. Describe the medical management provided for adverse reaction (if any) to the research participant. (Include information on who paid, how much was paid and to whom).

.....

.....

10. Provide details of compensation provided / to be provided to participants (Include information on who pays, how much, and to whom).....

.....

11. Outcome of SAE

Fatal ☐ Recovered ☐

Continuing ☐ Unknown ☐

Recovering ☐ Other *(specify)* ☐

.....

12. Provide any other relevant information that can facilitate assessment of the case such as medical history

.....

.....

.....

13. Provide details about PI's final assessment of SAE relatedness to research.

.....

.....

.....

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

(Annexure 1.7 (AF 1.7/003/01.0)

Premature Termination/Suspension/ Discontinuation Report Format

Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

(Name of the Institution) **IEC 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

(Annexure 1.8 (AF 1.8/003/01.0)

Application Form for Clinical Trials

Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

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

Title of study: .....

.....

.....

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

.....

.....

1. Type of clinical trial Regulatory trial ☐ Academic trial ☐

CTRI registration number: ..... NABH accreditation number:..... EC registration number:.....

2. If regulatory trial, provide status of CDSCO permission letter

Approved and letter attached ☐ Applied, under process ☐

Not applied (State reason) ☐.....

3. Tick all categories that apply to your trial

Phase - I	☐	Phase II	☐
Phase III	☐	Phase IV or Post Marketing Surveillance	☐
Investigational medicinal products	☐	Investigational New drug	☐
Medical devices	☐	New innovative procedure	☐
Drug/device combination	☐	Bioavailability/Bioequivalence studies	☐
Non-drug intervention	☐	Repurposing an existing intervention	☐
Indian system of medicine (AYUSH)	☐	Stem cells	☐
Phytopharmaceutical drug	☐	Approved drug for any new indication	
Others (specify)	☐	or new route of administration	☐

.....

4. Trial design of the study

I. Randomized	☐	Factorial	☐
Non randomized	☐	Stratified	☐
Parallel	☐	Adaptive	☐
Cross-over	☐	Comparison trial	☐
Cluster	☐	Superiority trial	☐
Matched-pair	☐	Non-inferiority trial	☐
Others *(specify)*	☐	Equivalence trial	☐

.....

II. If there is randomization, how will the participants be allocated to the control and study group(s)?

.....

.....

III. Describe the method of allocation concealment (blinding / masking), if applicable.

.....

.....

5. List the primary / secondary outcomes of the trial.

.....

.....

6. Is there a Contract Research Organization (CRO) /Site Management Organisation (SMO) / Any other agency such as public relation/human resource? Yes ☐ No ☐

If yes, Name and Contact details: .....

.....

.....

State how the CRO/SMO/agency will be involved in the conduct of the trial (tick all that apply)

Project management	☐	Clinical and medical monitoring	☐
Regulatory affairs	☐	Data management	☐
Statistical support	☐	Medical writing	☐
Site management	☐	Audits, quality control, quality assurance	☐
Finance management	☐	Recruitment and training	☐
Administrative support	☐	Others *(specify)*	☐

.....

7. Please provide the following details about the intervention being used in the protocol

I. Drug/s, device/s and/or biologics; if yes, provide regulatory approval details. Yes ☐ No ☐ NA ☐

.....

.....

II. Already approved drugs or a combination of two or more drugs with new indications / change in dosage form / route of administration. If yes, provide details. Yes ☐ No ☐ NA ☐

.....

.....

III. Provide contact details of who prepared and /or is manufacturing the drug/s, device/s and biologics.

.....

.....

IV. Provide details of patent of the drug/s, device/s and biologics.

.....

.....

8. Describe in brief any preparatory work or site preparedness for the protocol? Yes ☐ No ☐ NA ☐

If yes, provide details (100words).....

.....

.....

.....

.....

9. Is there an initial screening/ use of existing database for participant selection? Yes ☐ No ☐ NA ☐

If Yes, provide details[22].....

.....

.....

.....

10. Is there any anticipated incidence, frequency and duration of adverse events related to the intervention?

If yes, provide details of arrangements made to address them. Yes ☐ No ☐ NA ☐

.....

.....

.....

11. Does the study use a placebo?

If yes, justify the use of the placebo and risks entailed to participants. Yes ☐ No ☐ NA ☐

.....

.....

.....

12. Will current standard of care be provided to the control arm in the study? Yes ☐ No ☐ NA ☐

If no, please justify.

.....

.....

.....

13. Are there any plans to withdraw standard therapy during the study? If yes, please justify. Yes ☐ No ☐ NA ☐

.....

.....

.....

14. Are there any rules to stop the protocol in case of any adverse events? If yes, please specify. Yes ☐ No ☐ NA ☐

.....

.....

.....

.....

15. Does the study have a Data and Safety Monitoring Plan? If no, please justify. Yes ☐ No ☐

.....

.....

.....

[22] In order to select participants for your protcol does the protocol require you to screen an initial population or refer to an existing database before shortlisting participants. If yes, provide details on the same

16. Participant Information Sheet(PIS) and Informed Consent Form (ICF)

English ☐ Local language ☐
(certified that local version (s) is/are a true translation of the English version and can be easily understood by the participants)

Other *(Specify)* ☐

.....

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

Justify if translation not done.....

.....

17. Involvement/consultation of statistician in the study design Yes ☐ No ☐ NA ☐

18. Is there any insurance coverage of the trial? If yes, provide details. Yes ☐ No ☐

.....

.....

.....

I. Is the PI registered with Medical Council of India (MCI) or the State Medical Council registration?

Please provide details. Yes ☐ No ☐

.....

.....

II. Is the PI trained in GCP in last 3 years? If yes, Pleaseenclose certificate Yes ☐ No ☐

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

(Annexure 1.9 (AF 1.9/003/01.0)

Serious Adverse Event Reporting Format (Clinical trials)

Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

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

Title of study: .....

.....

.....

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

.....

.....

1. Participant details :

Initials and Case No./ Subject ID	Age at the time of event	Gender	Weight: ..... (Kgs)
.....	.....	Male ☐	Height: ..... (cms)
.....		Female ☐	

2. Report type: Initial ☐ Follow-up ☐ Final ☐

If Follow-up report, state date of Initial report dd mm yy

What was the assessment of relatedness to the trial in the initial report?

By PI – Related ☐ Unrelated ☐ By Sponsor – Related ☐ Unrelated ☐ By EC – Related ☐ Unrelated ☐

3. Describe the event and specify suspected SAE diagnosis:.....

.....

.....

4. Date of onset of SAE: dd mm yy Date of reporting: dd mm yy

5. Onset lag time after administration of intervention: Location of SAE (Clinic/Ward/Home/Other)

....

6. Details of suspected study drug/device/investigational procedure causing SAE:

I. Suspect study drug (include generic name) device/intervention: .....

.....

II. Indication(s) for which suspect study drug was prescribed or tested: .....

.....

III. Route(s) of administration, daily dose and regimen, dosage form and strength : .....

.....

IV. Therapy start date: dd mm yy Stop date: dd mm yy

7. Was study intervention discontinued due to event? Yes ☐ No ☐

8. Did the reaction decline after stopping or reducing the dosage of the study drug / procedure? Yes ☐ No ☐

If yes, provide details about the reduced dose.....

9. Did the reaction reappear after reintroducing the study drug / procedure? Yes ☐ No ☐ NA ☐

If yes, provide details about the dose.....

10. Concomitant drugs history and lab investigations:

I. Concomitant drug (s) and date of administration: dd mm yy

.....

.....

II. Relevant test/laboratory data with dates: dd mm yy

.....

.....

III. Patient relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc).....

.....

.....

11. Have any similar SAE occurred previously in this study? If yes, please provide details. Yes ☐ No ☐

.....

.....

12. Seriousness of the SAE:

Death	☐	Congenitial anomaly	☐
Life threatening	☐	Required intervention to prevent	
Hospitalization-initial or prolonged	☐	permanent impairment / damage	☐
Disability	☐	Others *(specify)*	☐

.....

13. Describe the medical management provided for adverse reaction (if any) to the research participant. (Include infor- mation on who paid, how much was paid and to whom).

.....

.....

14. Outcome of SAE:

Fatal	☐	Recovered	☐
Continuing	☐	Unknown	☐
Recovering	☐	Other *(specify)*	☐

.....

15. Was the research participant continued on the trial? Yes ☐ No ☐ NA ☐

16. Provide details about PI's final assessment of SAE relatedness to trial.

.....

.....

17. Has this information been communicated to sponsor/CRO/regulatory agencies? Yes ☐ No ☐

Provide details if communicated (including date)

18. Does this report require any alteration in trial protocol? Yes ☐ No ☐

19. Provide details of compensation provided / to be provided the participants (Include information on who pays, how much, and to whom).....

.....

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

(Annexure 1.10 (AF 1.10/003/01.0)

Application Form for Human Genetics Testing Research

Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

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

Title of study: .....

.....

.....

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

.....

.....

1. Describe the nature of genetic testing research being conducted.

   (e.g.- screening/gene therapy/newer technologies/human embryos/foetal autopsy)

   .....

   .....

   .....

2. Does the study involve pretest and post-test counselling? If yes, please describe. Yes ☐ No ☐ NA ☐

   .....

   .....

3. Explain the additional safeguards provided to maintain confidentiality of data generated.

   .....

   .....

   .....

4. If there is a need to share the participants' information/investigations with family/community, is it addressed in the informed consent? Yes ☐ No ☐ NA ☐

   If findings are to be disclosed, describe the disclosure procedures (e.g. genetic counseling)

   .....

   .....

   .....

5. Is there involvement of secondary participants? Yes ☐ No ☐ NA ☐

   If yes, will informed consent be obtained? State reasons if not. Yes ☐ No ☐ NA ☐

   .....

   .....

6. What measures are taken to minimize/mitigate/eliminate conflict of interest?

   .....

   .....

   .....

7. Is there a plan for future use of stored samples for research? Yes ☐ No ☐

   If yes, has this been addressed in the informed consent ? Yes ☐ No ☐

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

(Annexure 1.11 (AF 1.11/003/01.0)

Application Form for Socio-Behavioural and Public Health Research

Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

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

Title of study: .....

.....

.....

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

.....

.....

1. Data collection method used in the study

Focus group	☐	Questionnaire/Survey	☐	Observation	☐
Interviews	☐	Documents and records	☐	Ethnographies/Oral history/Case studies	☐
Others *(Specify)*	☐				

....

If it is an interview, will there be audio-video recording of participants' interview? If yes, justify the reasons and storage strategies. Yes ☐ No ☐

.....

.....

.....

2. Type of informed consent used in the study.

Individual consent	☐	Gate-keeper consent	☐	Community consent	☐
Others	☐	*(specify)*.....			

3. Provide details of safeguards to ensure privacy and confidentiality of participants in the event of data sharing.

.....

.....

.....

4. Describe strategies to manage if any patterns of behaviour of self-harm or harm to the society are identified.(e.g.: Suicide or infanticide) Yes ☐ No ☐ NA ☐

.....

.....

.....

5. Are cultural norms/Social considerations/Sensitivities taken into account while designing the study and participant recruitment? Yes ☐ No ☐

6. Is there a use of an interpreter? If yes, describe the selection process. Yes ☐ No ☐ NA ☐

.....

.....

.....

7. Describe any preparatory work or site preparedness for the study Yes ☐ No ☐ NA ☐

.....

.....

.....

.....

.....

.....

.....

8. I. Type of risk related to procedures involved in the study

Invasive ☐ Potentially harmful ☐ Emotionally disturbing ☐ Involving disclosure ☐

Describe the risk minimization strategies.

.....

.....

.....

.....

II. Justify reasons if individual harm is overriding societal benefit. Yes ☐ No ☐ NA ☐

.....

.....

.....

III. Describe how do societal benefits outweigh individual harm.

.....

.....

.....

9. Does the study use incomplete disclosure or active deception or authorized deception? If yes, provide details and rationale for deception. Yes ☐ No ☐

.....

.....

.....

.....

10. Describe the debriefing process that will be used to make participants aware of the incomplete disclosure or deception, including their right to withdraw any record of their participation.

.....

.....

.....

.....

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

(Annexure 1.12 (AF 1.12/003/01.0)

Study completion/Final report format

Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

(Name of the Institution) **IEC 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.*

(Annexure 1.13 (AF 1.13/003/01.0)

Format for Curriculum Vitae for Investigators

Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

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

Name:
Present affiliation *(Job title, department, and organisation)*:
Address (Full work address):
Telephone number: Email address:
Qualifications:
Professional registration *(Name of body, registration number and date of registration):*
Previous and other affiliations *(Include previous affiliations in the last 5 years and other current affiliations):*
Projects undertaken in the last 5 years:

Relevant research training/experience in the area [25] :
Relevant publications *(Give references to all relevant publications in the last five years):*

Signature	Date:

[25] *Details of any relevant training in the design or conduct of research, for example in the Ethics Training, Human participants' protection courses, Clinical Trials Regulations, Good Clinical Practice, consent, research ethics training or other training appropriate to non-clinical research. Give the date of the training*

AF02/003/01.0

Guideline for Filling the Application to be submitted

1. Please keep in mind about the pluralistic nature of the Ethics committee and hence technical terms should be avoided as much as possible within the limited word limits.
2. Please write in legible clear words, preferably typed in the format. Please submit only PDF format in email (iec.lgbrimh@yahoo.com)
3. Please use the annexure for Initial Review (AF 1.0/003/01.0)
4. Please use the protocol format as provided.
5. Please use a guide to ascertain level of risk (point 6(a) in Annexure AF 1.0/003/01.0)
6. Please use format for the Informed Consent Document
7. Please all relevant document as per checklist mentioned in point 12 of Annexure AF 1.0/003/01.0
8. 14 hard copies of the Annexure AF 1.0/003/01.0 with necessary enclosures along with an email as mentioned in the covering letter to be submitted to Ms Manisha Borah, Dept of Psychiatry.
9. The secretariat will revert back with the acknowledgement of receipt and will inform if any necessary submissions needed prior to submission to the IEC.
10. Please go through the ICMR Guidelines 2017 for further needful and revert back to secretariat for any querries/grievances.

Annexure 03/003/01.0

No research can be counted as low risk if it involves:

(i) Invasive physical procedures or potential for physical harm
(ii) Procedures which might cause mental/emotional stress or distress, moral or cultural offence
(iii) Personal or sensitive issues
(iv) Vulnerable groups
(v) Cross cultural research
(vi) Investigation of illegal behavior (s)
(vii) Invasion of privacy
(viii) Collection of information that might be disadvantageous to the participant
(ix) Use of information already collected that is not in the public arena which might be disadvantageous to the participant
(x) Use of information already collected which was collected under agreement of confidentiality
(xi) Participants who are unable to give informed consent
(xii)Conflict of interest e.g. the researcher is also the lecturer, teacher, treatment-provider, colleague or employer of the research participants, or there is any other power relationship between the researcher and the research participants.
(xiii) Deception
(xiv) Audio or visual recording without consent
(xv) Withholding benefits from "control" groups
(xvi) Inducements
(xvii) Risks to the researcher

This list is not definitive but is intended to sensitize the researcher to the types of issues to be considered. Low risk research would involve the same risk as might be encountered in normal daily life.

Annexure 04/003/01.0

1. TITLE:
2. Principal Investigator (Details with Signature):
3. Co Investigator(Details with Signature):
4. Brief Summary/lay Summary including problem statement, expected outcome & application and novelty in current work:
5. Background with rationale for a human study
6. Research question/hypothesis/primary and secondary objectives and end points (if applicable)
7. Methodology: justification for inclusion/exclusion of vulnerable/specific population; sample size justification, type of study/study design, sampling technique, any intervention applied, any tools applied, issues of copyright
8. Duration of study
9. Justification for control/placebo/benefit risk assessment/plan to withdraw and related justification
10. Details of Informed consent procedure
11. Plan to maintain confidentiality and privacy
12. Plan of statistical analysis
13. If risk is more than minimal for the study the an a brief account of managing risk/injury
14. Proposed compensation, reimbursement of incidental expenses and management of research related injury/illnesses during and after the research period
15. Any ancillary care for unrelated illness during the research period
16. An account of data & specimen storage/protection/retrieval and disposal
17. Plans for publication of results
18. Ethical considerations and safeguards for protection of rights of participants

(Please provide details within 1000 words)

Annexure 05/003/01.0

Informed Consent Document (ICD) contains 2 parts: participant Information Sheet (PIS) & Informed Consent Form(ICF). Please refer to Page 49-55 of ICMR Guideline 2017 for a brief review of process. If study involves vulnerable group and involves deception then more elaborated work on ICD may be needed. This is just a template for the ICD for more details please refer to ICMR guidelines and consult appropriate authorities.

Participant Information Sheet may contain the following facts.

INFORMATION FOR PARTICIPANTS OF THE STUDY

Instructions - This is the patient information sheet. It should address the participant of this study stating that the current practice is done for a research.

Depending upon the nature of the individual project, the details provided to the participant may vary.

A separate consent form for the patient/test group and control (drug/procedure or placebo) should be provided as applicable.

While formulating this sheet, the investigator must provide the following information as applicable in a simple understandable language. It should contain the Title of the study, name of investigators for any querry and contact of Member Secretary of IEC for any appeal against violation of ethical principles and human rights. It should contain purpose and method with expected duration and expected frequency of contact. The risks/discomfort/inconvenience to participants along with benefits to participant/community or others needs to be mentioned.

Confidentiality/ reimbursement/ compensation and treatment related matters to be included. The freedom to withdraw from the study should be clearly mentioned.

CONSENT FORM

Title of the project/study:
Participant's name: Address:
The details of the study have been provided to me in writing and explained to me in my own language. I confirm that I have understood the above study and had the opportunity to ask questions. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without the medical care that will normally be provided by the hospital being affected. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). I have been given an information sheet giving details of the study. **Risk and benefit of this project has been explained to me.** I fully consent to participate in the above study.
(I also consent / do not consent to use my stored biological samples for future scientific purposes: Yes/ No – if applicable)
Signature/thumb impression of the participant: _____ Date: _____
Signature of the witness, if applicable: _____ Date: _____
Name and address of the witness:

Signature of the investigator: _____ Date: _____

CONSENT FORM (for participants less than18 years of age)

Parent/Legally acceptable representative (LAR)

Title of the project/study:

Participant's name: Address:

Parent/LAR' s name:

The details of the study have been provided to me in writing and explained to me in my own language. I confirm that I have understood the above study and had the opportunity to ask questions. I understand that my child/ward's participation in the study is voluntary and that I am free to withdraw my child/ward at any time, without giving any reason, without the medical care that will normally be provided by the hospital being affected. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). I have been given an information sheet giving details of the study. **Risk and benefit of this project has been explained to me.** I fully consent for the participation of my child/ward in the above study.

Assent of child/ward obtained (for participants 7 to 18 years of age)

(I also consent / do not consent to use my child/ward's stored biological samples for future scientific purposes: Yes/No – if applicable; but this need to be informed to me and separate permission from the participant be obtained if applicable)

Signature/ thumb impression of the parent/ LAR: _____ Date: _____

Signature of the witness: _____ Date: _____

Name and address of the witness:

Signature of the investigator: _____ Date: _____

ASSENT FORM

(for children above 7 years and below 18 years of age)

Assent form to participate in a clinical research

Child Participant's name: Date of birth/Age:

Parent/LAR' s name: Address:

Title of the project:

The details of the study have been provided to me in writing and explained to me in my own language. I confirm that I have understood the above study and had the opportunity to ask questions. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without the medical care that will normally be provided by the hospital being affected. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). I understand that following completion of study as well as during publication of the results, confidentiality of my identity will be maintained. I have been given an information sheet giving details of the study. **Risk and benefit of this project has been explained to me.** I fully assent to participate in the above study.

(I also assent / do not assent to use my stored biological samples for future scientific purposes: Yes/No – if applicable)

Signature of the child participant : Date:

(If child knows to sign/Thumb impression)

Signature of the parent or guardian : Date:

Name and address of the witness :

Signature of the witness : Date:

Signature of the Investigator : Date:
(Assent form should be accompanied by patient / participant information sheet for children in a simple
language comprehensible to a child of 7-18 years; Language used should be simpler for children in the age group 7-12 years compared to children in the age group >12-18 years)

CONSENT FORM (for participants with vulnerability due to lack of capacity to take decission)

Parent/Legally acceptable representative (LAR)/Nominated Representative

Title of the project/study:

Participant's name: Address:

Parent/LAR' s/ NR's name:

The details of the study have been provided to me in writing and explained to me in my own language. I confirm that I have understood the above study and had the opportunity to ask questions. I understand that my child/ward's participation in the study is voluntary and that I am free to withdraw my child/ward at any time, without giving any reason, without the medical care that will normally be provided by the hospital being affected. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). I have been given anformation sheet giving details of the study. **Risk and benefit of this project has been explained to me.** I fully consent for the participation of my child/ward in the above study.

(I also consent / do not consent to use my patient's stored biological samples for future scientific purposes: Yes/No – if applicable; but this need to be informed to me and separate permission from the participant be obtained if applicable)

Signature/ thumb impression of the parent/ LAR: _____ Date: _____

Signature of the witness: _____ Date: _____

Name and address of the witness:

Signature of the investigator: _____ Date: _____

AF06/003/01.0

To

The Chairperson

Institutional Ethics Committee, LGBRIMH, Tezpur, 784001

Through Director, LGBRIMH

Sub: Application for Ethics Committee clearance for the Research Proposal (Initial/Expediated/Exempted Review/ Protocol amendment/annual status review/continuing review/study completion or termination/submission of SAE or deviation/……..)

Titled……

Dated:

Sir,

I am ……., a student/faculty of ……

I as Principal Investigator at the Site……(name of the site of experiment) would like to submit the Application Form for ……..along with documents as mentioned in the checklist for consideration of the Institutional Ethics Committee, LGBRIMH, Tezpur.

I pledge to take necessary precautions for maintain appropriate ethical considerations and other relevant guidelines in undertaking the proposed work.

Thank you

Name……Course…….Year of admission(If applicable)

Address…….

Phone & email……

(NB: It is necessary to submit 14 copies of whole submission along with Covering letter and mail the whole document to iec.lgbrimh@yahoo.com)

Institutional Ethics Committee

Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

SOP for Board meeting Procedures

LGB/IEC/SOP/ 004/01

Author: Dr. K N Kalita

Checked by: Dr. K Pathak

1. Purpose: The SOP is designed to describe how the IEC, LGBRIMH meetings need to be conducted. The IEC board meeting will be conducted to discuss about ethical issues in the study proposals and decide upon the proposals.

2. Scope: The scope of this SOP is applied to planning, communicating, organizing the regular, ad-hoc/emergency and expedited IEC meetings.

3. Responsibility:

The Chairperson is responsible for calling for the regular meetings, which will be conducted on every quarter. The member secretary has the responsibility of intimating all the members and investigators. Based on the necessity the ad-hoc/emergency meetings can be called for. The request for the same will come through the Director via the Head of respective Departments. The member secretary in consultation with the chairperson will decide on calling for the meeting. The expedited meeting will be conducted as per the procedures laid down in respective SOP.

4. Flowchart

Finalization of date of meeting	Chairman & Member Secretary
Communication to member & investigator	IEC Secretariat
Receipt and scrutiny of submitted document and distribution to members/ reviewers	do
Arrangement for meeting	do
Preperation of agenda	Member Secretary
Conduct of meeting	Chairperson
Minutes preparartion	Member secretary
Post meeting procedures	IEC Secretariat

5. Detailed Instructions

A. The member secretary will finalize the date of meeting in consultation with the Chairperson. Regular meeting will be conducted every quarter. If no meeting is organized in a quarter then that will be intimidated to the members citing reason by secretariat.

B. The invitation for the meeting will be sent to the members 7 days in advance by the IEC Secretariat. The same will be communicated to the investigators.

C. The IEC secretariat will receive, scrutinize and distribute the final copies of proposals to all IEC members.

D. The member secretary will contact the members and confirm their availability for the meeting. Based on their availability, the transport arrangements will be made by the IEC secretariat.

E. The meeting will start as per the timing mentioned in the agenda. The members will be requested to confirm the minutes of the previous board meeting. The chairperson will assess and confirm the required quorum for board meeting (50% +1). No meeting will be conducted without quorum. If no quorum is formed but minimum 5 specified members are available as specified by the ICMR guideline 2017 then a fresh meeting will be conducted by the Chairpersons and functions of the meeting will be conducted as per procedure. The chairperson will request the members to declare any Conflict Of Interest with regard to the proposals to be taken for discussion. List of absentees and participants entering and leaving the discussion will be documented. The investigator will be invited to present their research proposal and asked to provide clarifications. The primary reviewer will lead the discussion. The secondary reviewer will provide comments on ethical and consent related aspects. The investigator will be requested to leave the hall after the presentation and discussion. The member secretary will summarize the important discussion points and recommendations pertaining to the proposal, based on which the members will take a broad consensus or a democratic voting decision about the proposal. Approval will be given for One Year or for full period of study subject to submission of periodic review. The IEC may reverse its positive decision on a study if it receives information that may adversely affect the benefit risk assessment or any misconduct.

F. The minutes of the meeting will be recorded by the Member secretary.

G. The post meeting procedures like circulation of minutes, finalization of minutes and ratification, any protocol exempting review and expedited review will be ratified in full board meetings, issuing suggestion letters and preparing decision letters, prepared by the Secretariat of IEC. The IEC will issue the decision letters to the concerned investigators after obtaining approval from the chairperson with appropriate suggestions, if any. The member secretary will announce the closure of the meeting followed by presenting vote of thanks.

H. The researcher will be given opportunity to reply/clarify to IEC comments or to discuss or present his/her case. The researcher can approach the Director, LGBRIMH for any grievances who also act as an appellate for IEC matters.

6. References

1. ICMR Ethical Guidelines for Biomedical research on Human Participants, ICMR (2017)
2. SOP. IEC. ICMR. NIE 2017 (v02.1)

Annexure 1 (AF 01/004/ 01.0) IEC, LGBRIMH meeting Procedure

Meeting: Full board/expedited	Date:	Time:
Venue:		
Meeting called by: Chairperson		Rapporteur: Member Secretary
Preparation of meeting	Please go through SOP, Minutes, Proposals	Please submit proposals and reviewer forms
Objetive1	Review proposals	
Welcome address	Chairperson	
Conformation of previous meetings	Chairperson	
Declaration of Conflict of Interest by members		
Announcement, if any	Member Secretary	
New Project proposal		
	Project Id/Investigators	Reviewers
Continued review/progress of earlier review		
	Project Id/Investigators	Reviewers
Revised Proposal		
	Project Id/Investigators	Reviewers
Final Report		
Report of ADR/misconduct		
	Project Id/Investigators	
Protocol amendment		
	Project Id/Investigators	
Discussion on SoP etc		
	Applicant/ SOP code	
Any other issue		
Vote of Thanks	Member Secretary	Closure of meeting

Appendix 2 (AF 02/004/ 01.0) IEC, LGBRIMH minutes template

Minutes of Institutional Ethics Committee Meeting held on ----------The following Members were present:

1.
2.
3.
4.
5.
6.
7.
8.
9.
10.
11.
12.
13.

The Following members from IEC Secretariat also attended the meeting:

1
2 The following Investigators attended the meeting for presentation of protocols:

1.
2.
3.
4.
5.

Member Secretary Chairperson

* The concerned investigators/co-investigators were allowed to attend and participate in the discussion on the presentations of their respective protocols only.

Chairperson welcomed all the members and other participants. She then initiated the proceedings.

The minutes of the meeting held on ----------had already been circulated to all Members of the IEC. Since there was no comment on the minutes from any of the Members, it was deemed to have been approved by the Committee. Members of the Committee were then requested to declare any conflict of interest with regard to the proposals listed for review and discussion in the meeting. The Members declared that they had no conflicts of interest with regard to any of the proposals listed; this was noted.

The quorum for initiating the discussion and review of the proposals were verified and found to be in order.

Proposals were then taken up for consideration.

I. <u>New proposals:</u>

The Principal Investigator of the study presented the proposal.

<u>Comments/Suggestions, clarifications:</u>

Conflict of interest:

<u>Decision</u>

II. <u>Annual review of projects/revision/clarification/amendments</u>

The Principal Investigator of the study presented the proposal

Conflict of interest:

<u>Decision:</u>

The meeting concluded with vote of thanks by the member secretary.

Member Secretary Chairperson

Institutional Ethics Committee

Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

Preparing Standard Operating Procedures (SOPs): Recruiting Vulnerable Populations for Research

LGB/IEC/SOP/ 005/01

Author: Dr. K N Kalita

Checked by: Dr. K Pathak

1. Purpose: Vulnerable persons are those individuals who are relatively or absolutely incapable of protecting their own interests because of personal disability; environmental burdens; social injustice; lack of power, understanding or ability to communicate or are in a situation that prevents them from doing so. Some characteristics of vulnerable groups are socially, economically or politically disadvantaged and therefore susceptible to being exploited; incapable of making a voluntary informed decision for themselves or whose autonomy is compromised temporarily or permanently, for example people who are unconscious, differently abled; able to give consent, but whose voluntariness or understanding is compromised due to their situational conditions; or 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.
   Vulnerable populations have an equal right to be included in research so that benefits accruing from the research apply to them as well. When vulnerable individuals are to be recruited as research participants additional precaution should be taken to avoid exploitation/retaliation/reward/credits, etc., as they may either feel intimidated and incapable of disagreeing with their caregivers, or feel a desire to please them. The IEC and researcher must justify the recruitment of these groups and also look after for additional level of safety against exploitation of any kind. They may also advocate for better support system and ancillary care for such groups. This SOP tries to define procedures to be implemented in dealing with these situations arisen due to recruitment of vulnerable population.
2. Scope: it defines characteristics and definitions of vulnerable groups. The list included is not wholesome and it may include groups not included in this SOP but the IEC members opines in such line, additional safeguards to be taken in recruitment of subjects, obligations/duties of different stakeholders including researcher , caregiver/nominated representative/ legal guardian or any such person as defined, IEC members, Institute, sponsors of study. It applies to all research proposals applied for ethical clearance at IEC, LGBRIMH involving vulnerable groups/individuals whether intramural or extramural.
3. Responsibility**: 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.
   IEC Members: During only full committee 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, IECs 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 also in the Informed Consent Document (ICD). Chairperson, IEC should give specific suggestions to researcher and to the sponsors. Secretariat shall do the documentation. IEC 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.
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. 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).

Specific issues of some vulnerable groups:

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 centre and help for law enforcement agencies as additional safety measure for the participants.

Individuals with mental illness/cognitive impairment: According to the Mental Healthcare Act, 2017, "mental illness" means a substantial disorder of thinking, mood, perception, orientation or memory that grossly impairs judgment, behaviour, 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 subnormality 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 the area of 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 a number of 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.

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 in order to achieve the objectives of the research for public good.

Individuals with diminished autonomy due to dependence or being in a hierarchical system: While reviewing protocols that include students, employees, subordinates, defence services personnel, healthcare workers, institutionalized individuals, under trials, prisoners, and others the IEC, LGBRIMH 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 in a position 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.

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/ 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:

1. It is exclusively seen in childhood.
2. Both adults as well as children are involved, but the issues involved are likely to be significantly different in both these populations.
3. 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.
4. Test interventions are likely to be at least as advantageous to the individual child participant as any available alternative intervention.
5. 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).
6. 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 means.
7. 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 varies with growth and maturation from infancy to adulthood.

8. 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.
9. Age appropriate delivery vehicles and formulations (e.g. syrups) are needed for accurate, safe, and palatable administration of medicines to infants and children.
10. 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 IEC 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.
- The IEC 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 society as a whole.
- Consent of the parent/LAR is required when research involves children. Special issues in relation to consent in this regard are
    - The IEC 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 EC 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 so as 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 IEC, should be obtained from children of 7–18 years of age. As children grow, their mental faculties develop and they are able to understand and respond. Respecting the child's reaction, the child is made 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 has to 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 IEC is obtained. Content of the assent form has to 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 definitely 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 IEC should be obtained.

Some issues to be considered while attaining assent:

- 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 has to 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 EC, for example, in behavioural studies of IV drug users where parental consent may not be possible.

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 IEC if there is a research proposal involving these participants. The IEC 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.

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.

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 have to justify their inclusion. IEC members will satisfy them with the justification provided to include these participants and record the same in the proceedings of the IEC meeting. Additional safety measures will be strictly followed by the IEC, LGBRIMH. 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 IEC will carefully determine the benefits and risks of the study and examine risk minimization strategies.

Review Process: the investigator working in the vulnerable groups listed above shall adhere to all the applicable laws and regulations of Government of Assam and Government of India. 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 IEC, LGBRIMH will review proposal and submitted documents and may seek suggestions from reviewer/experts both internal and external. Any clarification sought by IEC, LGBRIMH need to be clarified by the investigator.

References: ICMR Ethical Guidelines for Biomedical research on Human Participants, ICMR (2017)

Annexure 1 (AF 01/005/01.0)

Requirements for Research Involving Children

Investigator : IEC:

Study Title:

RISK DETERMINATION	BENEFIT ASSESSMENT	IEC 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	Approved □ case by case (with special safeguards Not Approved □

	likely to benefit.	
□ 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 IEC 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 IEC 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 2 (AF 02/005/01.0)

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

Investigator : **IEC#:**

IEC#:

Study Title :

Research Involving Pregnant or nursing women, Fetuses & nursing infant

RISK DETERMINATION	BENEFIT ASSESSMENT	IEC 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 promises 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 involves 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 has 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	□	□	□

Signature of reviewer with date:

Annexure 3 (AF 03/005/01.0)

Research Involving Cognitively Impaired & Mentally Ill Adults

Name of investigator **Title of study**

- The purpose of this checklist is to provide support for IEC 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 4 (AF 04/005/01.0)

Research Involving Students, Employees or Residents/Dependents

Name of investigator : **Title of study:**

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:

Institutional Ethics Committee

Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

SOP for Continued Education & Training on Ethical Issues

LGB/IEC/SOP/ 006/01

Author: Dr. K N Kalita

Checked by: Dr. K Pathak

1. Purpose: The SOP is designed to describe how the IEC, LGBRIMH members and the secretariat members will be trained to ensure optimum functioning of the ethical committee.
2. Scope: This SOP is applicable to all members of IEC, researchers, members of secretariat and other relevant agencies/individuals.
3. Responsibility: The Secretariat will ensure about the appropriate training of all concerned individuals. Member Secretary and Chairperson will take appropriate steps in this regard. The Director, LGBRIMH will be coordinated through the Member Secretary and appropriate financial provisions will be followed for training related expenses.
4. Flowchart

Activity	Responsibility	Approving authority
Proposal for training	Member secretary	Chairperson, Director
Training	Members	Appropriate agency
Documentation	Secretariat	Member Secretary

5. Detailed description:
    - At the time of reconstitution of the IEC, the latest SOPs will be circulated to all members of the IEC via e-mail. Members will be encouraged to familiarize themselves with the SOPs before attending the IEC meeting.
    - Member Secretary and other members will be selected at least 3 months and 1 month in advance respectively. Member Secretary designate will be inducted into the IEC as an observer before he/she takes on the mantle in the new IEC. Other member- designates may attend the board meeting as observers before starting their tenure as IEC members.
    - At the time of appointment to the IEC, each member should have a valid GCP (Good Clinical Practice) certificate as a pre-requisite to induction in the IEC as GCP certificate is the universal standard in Clinical Research. The members will be required to update their GCP certification periodically.
    - The Chairperson and/or Member Secretary will conduct a presentation of the TMC IEC SOPs in the first meeting of the newly constituted IEC. Regular trainings will be conducted on the various SOPs through the term of the IEC.
    - In addition to the SOP and GCP training, the IEC Secretariat will organize regular training for the IEC members. An annual training calendar will be prepared by the IEC Secretariat.
    - The topics of training will be finalized by the Chairperson/Member Secretary. The training will be conducted by Chairperson, or any other member of the IEC specialized in a given topic. The IEC may also request a non-IEC member specialized in a topic of importance to impart training to the IEC members. The training programme will be scheduled and spread over the year.

- Topics will be selected to help members understand specific issues like guidelines, regulatory authorities, informed consent, vulnerable groups, conflict of interest, basic principles of ethics etc
- On finalization of the training calendar, the IEC Secretariat will circulate the same to all members of the IEC.
- The IEC Secretariat will also maintain logs of the training and certificates attended by the IEC members.
- Members will also be encouraged to attend training in Research Ethics, Bioethics Conferences, Workshops, Seminars conducted at other organizations. The members should submit the certificates of such Ethic Conferences/Workshops/Seminars to the IEC Secretariat for IEC record.
- Secretariat will do appropriate to liaise with relevant agencies to establish it as a nodal centre for such training for the region.

6. Reference: ICMR Ethical Guidelines for Biomedical research on Human Participants, ICMR (2017)
7. Annexure:
    a. Training Calendar
    b. Training Log

Annexure 1 (AF 01/006/ 01.0) IEC, LGBRIMH Training Calender

Sl no	Training session/topic	Speaker	Date	Target audience
1				
2				
3				

Annexure 2 (AF 02/006/ 01.0) IEC, LGBRIMH Training Log

Topic: Date/time: venue:
Training by/Speaker: target audience:

Sl no	Participant	Designation	Signature
1			
2			
3			
4			

Institutional Ethics Committee

Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

SOP for Conflict of Interest on Ethical Issues in Bio Medical Research

LGB/IEC/SOP/ 007/01

Author: Dr. K N Kalita

Checked by: Dr. K Pathak

1. **Purpose:** The SOP is designed to describe how conflict of interest at various level of the IEC, LGBRIMH members, the secretariat members, researchers, sponsoring agencies including host institution will be trained to ensure optimum functioning of the ethical committee may be influential in the specific area of research and the procedure to deal with such conflicting situations.
2. **Scope:** this will be applicable to IEC members, researchers and any sponsors related there to
3. **Responsibility:** Responsibility for disclosure of related interest will be on the individual concerned in written form. The institute will take measures for training and education of staffs in the area of conflict that may related to financial or non financial (personal, academic including intellectual rights, sociopolitical, cultural, linguistic, religious etc) to mitigate the impact of secondary interest on the primary interests such as patient welfare or validity of research findings etc. IEC will evaluate any conflict of interest related whether financial or non financial. Secretariat will keep the documentation properly.
4. **Detailed description:** Researcher, IEC members, reviewer etc will make a self disclosure of any conflict of interest whether financial or non financial. Non financial issues may be academic for higher grade/pay, award/recognition, publication and authorship, relationship, cultural, linguistic, religious, sociopolitical areas etc. Any such conflict of interest if not self disclosed then it may be disclosed by any of IEC members or staff/student of LGBRIMH about whom if the individual wants anonymity will be ensured.IEC may seek more information from any of the individuals/agencies in the specified area. If Conflict of Interest is inherent in the proposed research then appropriate mechanism to manage it must be attached with the submitted protocol. For IEC members confidentiality and conflict of interest will be an inherent issue and there should be appropriate undertaking in this regard form members.
5. **Reference:** ICMR Ethical Guidelines for Biomedical research on Human Participants, ICMR (2017)
6. Annexure: conflict of Interest of IEC members

ANNEX 2 (AF 02-002/01.0)

CONFLICT OF INTEREST

It has been recognized that the potential for conflict of interest will always exist but faith and confidence are vested in the IEC and its Chairperson to manage the issues of conflict so that the ultimate outcome of protection of human participants is achieved. In accordance of the policy of the IEC, LGBRIMH (IEC) he/she shall not participate in the review, comment or approval of any activity in which he/she have a conflict of interest, except to provide information as requested by the IEC. The Undersigned will immediately disclose to the Chairperson of the IEC any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the committee, and to abstain from any participation in discussions or recommendations in respect of such proposals. If an applicant submitting a protocol believes that an IEC member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol. The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the IEC member(s) in question. The IEC may elect to investigate the applicant's claim of the potential conflict. Examples of conflict of interest cases may be any of the following: A member is involved in a potentially competing research program. Access to funding or intellectual information may provide an unfair competitive advantage. A member's personal biases may interfere with his or her impartial judgment.

Agreement on Confidentiality and Conflict of Interest

In the course of my activities as a member of the IEC, LGBRIMH 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 IEC'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:

Institutional Ethics Committee

Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

Preparing Standard Operating Procedures (SOPs): Review of Protocols

LGB/IEC/SOP/ 008/01

Author: Dr. K N Kalita

Checked by: Dr. K Pathak

1. Purpose

Every research study involving human participants and other forms of studies, before the research is initiated should be reviewed and approved by the IEC. The IEC should evaluate the ethical aspects of the study, which had already approved by the Scientific Advisory Committee of LGBRIMH, other scientific bodies such as ICMR-Task Force/ DST/DBT etc. The IEC will look into the ethical aspects involved in the methodology also. The committee should evaluate the possible risks to the participants with proper justification as well as the expected benefits to participants/community. The adequacy of documentation for ensuring privacy & confidentiality should also be reviewed. The purpose of this Standard Operating Procedure (SOP) is to describe how the IEC members will review an initial submission of the research study for approval using the Reviewers Form (annexed). The Reviewers Form is designed to standardize the review process and to facilitate reporting, recommendations and comments offered to each study for better and smooth discussion in the board meetings. There is also a review form (annexed) for the members of the IEC for each protocols submitted.

2. Scope

This SOP applies to the review of all studies submitted for IEC review and approval of the IEC. The specific points/items in the Reviewers Form must be adequately addressed in the protocol and/or protocol-related documents submitted for the review. Relevant comments made during discussion and deliberation about a study should be recorded in the minutes of the meeting. The decision reached by the IEC will be communicated to the PI.

3. Responsibility

The IEC Secretariat is responsible for receiving, verifying, and managing the hard/soft copies of the received submission. (Refer SOP 003) In addition, the Secretariat should create a study specific file, distribute the packages and study assessment forms to the IEC members for review, and communicate the review results to the investigators. IEC members are responsible for receiving, verifying, and reviewing the protocols.

3.1 Responsibility of Reviewer: The Members Secretary may engage a primary and a secondary reviewer to look into the nuts and bolts of the study proposed considering scientific rigor and ethical concerns and put it before the full board meeting through the Member Secretary. They may communicate with the investigators regarding any information needed in email keeping the IEC Secretariat in the loop (cc:iec.lgbrimh@yahoo.com). The secretariat will give atleast 3 working days to reviewers. If any query is made then the investigators will also try to reply in 3 days in the same loop. Any modification suggested in the annexed format for review may be communicated with secretariat in email and the secretariat will keep track of it and may put it for discussion in the full board meeting or may allow with comment form a board constituted for early disposal of the event.

3.2 Responsibility of the Members: The members need to acknowledge the receipt of the package and cross check the contents. If any part is missing the same may be communicated with the Secretariat within 3 days of receipt of the package. They should also notify about their availability for the meeting in advance at least by 2 days. The members have to bring the package on the date of meeting and submit it to the secretariat for appropriate disposal. If a member cannot deposit the documents on said day for any reason or the member is absent on the day of meeting then it will be responsibility of the member to submit it to the secretariat at earliest for safe disposal. In case any document is shared over e mail

regarding proposals then it is expected that the members will tackle the issue of the electronic waste disposal as per relevant documents of Govt of India.

4. Flowchart

Activity	**Responsibility**
Call for meeting	Chairperson
Communication with IEC Member & Investigator	IEC Secretariat
Receipt of document & acknowledgement	Do
Check for completeness	Do
Categorization of review	Member Secretary
Circulating documents to members	IEC Secretariat
Review individual proposals for facilitation of discussion	Assigned Primary/Secondary reviewer
Review	Members
Full Meeting	Full IEC & investigators
Collect documents from members	IEC Secretariat
Minute preparation	Member Secretary
Communication to investigators	IEC Secreteriat

5. Detailed Instructions: The Proposal is reviewed by the member designated as Reviewers according to the guidelines given the SOPs and in the Reviewer Form for facilitating discussion. The primary reviewer will facilitate the whole review while the secondary reviewer will discuss the relevant issues of the proposal. The investigators may be asked about any issue in advance as described before. While in full board meeting any member may make specific query to the investigator directly or to the facilitator of the discussion.

Distribution of the proposal documents

a. The IEC Secretariat receives the documents to be reviewed by the IEC from the Principal Investigator / Co – Investigator in the standard submission templates given in the SOPs

b. The Member Secretary categorizes the type of review (Full Board, Expedited, Exemption) and gives guidance to the Secretariat in scrutinizing the submitted documents

c. The Member Secretary will assign technical primary/Secondary reviewers among the Members of the IEC for leading the discussion during the IEC meetings. The Primary reviewer will review the whole study proposal and secondary reviewer will review the ethical aspects and consent related issues in the proposal. However the proposals will be submitted to all the Members for review for obtaining diverse opinion related to ethical conduct of research.

d. The scrutinized documents will be circulated to the IEC Members along with the reviewers form and agenda

e. If any primary reviewer/s is / are not attending the meeting, his/her comments will be obtained along with the reviewers' form before the meeting date for including in the discussion. They may be allowed for specific comments over electronic platform with permission from the Chairperson and this will be kept in record.

f. Please Refer SOP 003/01 for further details.

5.1 Issues for Primary and Secondary Reviewer: The designated reviewer will acknowledge the receipt over email regarding appointment and communication will be kept to minimum on the allotted research matter. The reviewer will ascertain the content submitted and categorize according to following categories (Initial review with or without issues related to expedited review/exempted from review, resubmission of corrected version, protocol amendment, termination of study, reporting of SAE, annual report submission or extension of study period. In some type of research studies like multistep hybrid studies where findings of some initial work may be needed for continuing the research proposals there may be need of Protocol amendments that may include variation in methodology in areas of sample size, sampling techniques, change in Informed Consent Document, Case Record Form or any change in the tools utilized or investigation proposed, protocol deviation or emergence of adverse reactions. Such changes need to be informed to the IEC with appropriate justification in prescribed format. The member Secretary will examine these from case to case basis and may call for emergency full board meeting or may allow the appropriate modifications as permitted in specific categories mentioned in SOP 003. Appropriate reviewer form (annexed) may be used for this purpose and any additional comments should be made in writing. SOP 005 may also need to be referred for specific issues of vulnerable groups.

5.2 The chairman will allow discussion on each proposal as per agenda prepared by Member Secretary and will ensure smooth conduct of the meeting. The proceedings to me kept on record and kept in safe custody by Secretariat staffs. Member may use the Review Form (annexed) for record which needs to be handed over to the secretariat at the end of the meeting. If a member is unable to attend the meeting in person he/she may hand over the review form to the secretariat with signature and if Chairman allows such member may be allowed to participate over video conference mode. However the member will be considered absent and his/her vote will not be counted if consensus needs to be formed on basis of votes. In general an overall consensus will be obtained for each proposal through appropriate discussion among the members.

6. References

1. ICMR Ethical Guidelines for Biomedical research on Human Participants, ICMR (2017)

7.1 Appendix AF 01/008/01.0 Reviewer Form

(This copy will be attached with the Detailed Research Proposal for comment of Reviewer for smooth discussion in Board meetings. Any conflict of interest must be informed to Secretariat apriori)

Name of the Reviewer:

Proposal Title: Proposal Id:

Investigators:

Type of Proposal: Academic Course related/……..

(Please Tick and add comments wherever applicable)

- Any comment on the research question/hypothesis
    - Validity: Yes/No/No comment
    - Scientific rigor: praiseworthy/acceptable/below average
    - Impact of work/justice: individual benefit/benefit to group/ enhance to scientific knowledge
    - Any other comment:
- Methodology:
    - Approval from Scientific Advisory Committee: Yes/No (all documents attached)
    - Any comment on sample size/sampling technique/ selection of subjects/statistics applied
    - Any other comment:
- Respect for individual autonomy:
    - Informed Consent Document: Participant Information Sheet: adequate/ can be better
    - Autonomy to withdraw at any point of time: yes/No
    - Measures for data and biological sample safety and confidentiality addressed: yes/no
    - Any other comment:
- Beneficence and non malefacience/ Risk- benefit assessment:
    - Benefit: individual/group/society/enhancement of scientific knowledge
    - Any potential risk: physical/psychological/social/ moral/economic
    - Risk mitigation strategy: adequate/ not adequate/any comment
    - Too beneficial/Benefit overshadows risks/Risks overshadow benefits/equivocal/too risky (Considering the mitigation strategies too)
    - Any other comment:
    - Any Specific issue with vulnerable population:
    - Any comment on publication ethics:
- Legal issues addressed (specific law/guideline): Yes/No (Any Comment)
- Dissemination of information to participants & scientific bodies: Yes/No (any comment)
- Level of risk: Less than Minimal Risk/Minimal Risk/Minor increase over minimal risk or low risk/more than minimal risk or high risk

7.2Appendix AF 02/008/01.0 Decision letter of IEC, LGRIMH template

Institutional Ethics Committee

Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

Preparing Standard Operating Procedures (SOPs): Review of Study Progress Reports (Continuing Review/Annual Report)

LGB/IEC/SOP/ 009/01

Author: Dr. K N Kalita

Checked by: Dr. K Pathak

1. Purpose

The purpose of continuing review is to 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 003.

2. Scope

This SOP applies to conducting continuing review of research studies 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, IEC may choose to review the study more frequently.

3. Responsibility

It is the responsibility of the IEC Secretariat to send reminders (Appendix) to PIs regarding the submission of Continuing Review Application/Annual Status Report. All the approved studies must atleast be reviewed annually. The IEC 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 IEC meeting wherein the project is finally approved. IEC 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 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 IEC. 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 IEC 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.

4. Flow chart

Activity	Responsibility
Fixing date for annual/continuing review	IEC Secretariat
Notify investigators	Do
Manage Continue review package	Do
Verify contents of package	Do
Agenda preparation	Do
Review process	IEC Members
Communicate IEC decision to investigator	IEC Secretariat
Store original documents	do

5. Detailed Instructions:

5.1 Determine the date of continuing review: The secretariat will look through the master file of projects approved by the IEC for the due date of continuing reviews. Continuing review of the study should not be conducted through an expedited review.

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

5.3 Manage continuing review application upon receipt

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

b. Upon receipt of the Continuing Review Application, the Secretariat of the IEC will perform the following: Verify the contents of the package ; Continuing review applications will be checked by the IEC Secretariat for completeness before submission to IEC .

5.4. 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 IEC. 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) along with other necessary documents as mentioned in the SOP, however the same will be communicated by the Member-Secretary in the IEC 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 IEC 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.

5.5. Prepare meeting agenda: 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 IEC

5.6. Review Process

a. The IEC members will use the Continuing Review/Annual Report Application Form (AF 1.3/003/01.0) to guide the review and deliberation process. The IEC members could arrive at any one of the following decisions at the IEC meeting: Noted and the project can be continued without any modifications/Revisions recommended -Studies for which modifications have been suggested by the IEC might not proceed until the conditions set by the IEC have been met. Studied should be amended and submitted to IEC for amendment as per format/as per suggestion (AF1.4/003/01.0)/disapproved.

b. these decision of IEC will be accorded and kept in record by Member Secretary in minutes.

5.7 Store original documents: The IEC secretariat will file the documents pertaining to continuing review in master file of the concerned research study.

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

6.References

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, (Geneva 2000)www.who.int/tdr/publications/publications

2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996-http://www.ich.org/LOB/media/MEDIA482.pdf

3. ICMR Ethical guidelines, 2017

Institutional Ethics Committee

Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

Preparing Standard Operating Procedures (SOPs): Review of amendments of protocols and related documents

LGB/IEC/SOP/ 010/01

Author: Dr. K N Kalita

Checked by: Dr. K Pathak

1. **Purpose:** The purpose of this procedure is to describe how protocol amendments or any other amendments are reviewed by the IEC

2. **Scope:** This SOP applies to amended study protocols/ documents, tools and letters that are submitted for IEC approval. Amendments made to protocols or any other amendments related to the study may not be implemented until reviewed and approved by the IEC

3. **Responsibility:** It is the responsibility of the IEC secretariat to manage protocol amendments/documents and letters.

Receipt of the Amendment Package:
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 Form (AF 1.4/003/01.0).
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 IEC Secretariat follows the same procedure of circulation of the received documents to the IEC 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.

e. The procedures of board meetings as in SOP 003 is followed and the decision of the IEC 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. Modification suggested is also communicated in writing specifically. IEC Secretariat does this in a week time. If modification is suggested then the investigator is asked to resubmit within 2 weeks of IEC secretariat communication and the matter may be placed in full board or expedited meeting as appropriate by the Member Secretary.

f. Storage of Documents: File the amendments in the corresponding research protocol file, as per the SOP for documentation and archival.

g. 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. The Sub Committee may even take opinion of members in telecommunication modes for saving resources and for time constraints.

Reference: ICMR Guideline 2017

Institutional Ethics Committee

Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

Preparing Standard Operating Procedures (SOPs): Review of Serious Adverse Event Reporting

LGB/IEC/SOP/ 011/01

Author: Dr. K N Kalita

Checked by: Dr. K Pathak

1. Purpose

The purpose of this SOP is to provide instructions on the review and follow-up reports of serious adverse event (SAE) and unexpected events for any active study approved by the IEC.

Unanticipated risks are sometimes discovered during the course of studies. Information that may impact on the risk/benefit ratio should be promptly reported to and reviewed by the IEC to ensure adequate protection of the welfare of the study participants.

The unanticipated risks may as well include any event that in the investigator's opinion, may adversely affect the rights, welfare or safety of subjects in the study.

2. Scope

This SOP applies to the review of SAE and unexpected events reports submitted by investigators, Data Safety Monitoring Board (DSMB), sponsor/funding agency, local safety monitor, IEC/SAC members, participants or other concerned stakeholders including Director and institute fraternity.

3. Responsibility

The primary responsibility of the IEC is to review and address SAE and unexpected events involving risks to subjects or others as well as ethics complaints. In addition, the Committee is authorized to offer mediation under appropriate circumstances.

IEC should also make sure that researchers are made aware of the policies and procedures concerning reporting and continuing review requirements.

The Member Secretary is responsible for first screening the assessment of the reports and seeing whether they need a review of full Board, Chairperson, other qualified IEC members or experts.

4. **Flowchart**

Activity	Responsibility
Reporting of SAE	Investigator/IEC/SAC/other stackholders
Examination/ review of reports/determine severity	Member secretary (may constitute Board)
Meeting/ Expedited or Full called	IEC Secretariat
Review-discuss & action taken	IEC members & Chairperson
Communication to Investigator	IEC Secretariat
Any Grievance	Chairperson (appellate authority: Director)

5. **Detailed Instruction**: The Investigators should directly report any SAE to Secretariat within 3 working days of occurrence in writing in appropriate format (AF 1.6 or 1.9/003/01). The Investigator should inform the sponsor about the occurrence of the SAE within 24 hours. There should be remedial measures done at earliest.

Reference: ICMR Guideline 2017

Institutional Ethics Committee

Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

Preparing Standard Operating Procedures (SOPs): Review of Record Keeping & Archieving

LGB/IEC/SOP/ 012/01

Author: Dr. K N Kalita

Checked by: Dr. K Pathak

1. Purpose: This SOP describes the procedure of record keeping and archiving along with disposal of documents related to IEC functions.
2. Scope: This SOP will apply to handling of all documents both hard and soft in the IEC which may be administrative or Proposal related.
   The documents that may be included in the list are
   a) Administrative documents: Constitution and Composition of IEC; Appointment Letters; Signed recent CVs of members; Signed confidentiality and conflict of Interest documents, training records of IEC members, Financial records of IEC, Registration and accreditation documents; copies of national and international guidelines and applicable laws and regulations; regulatory notifications, registration related documents; meeting related documents; agenda and minutes; all communications received and made by IEC; appraisal report of members; any grievances; SOPs
   b) Proposal related documents: One hard copy and soft copy of initial research proposal and all related documents; decision letters; any amendment submitted for review and approval; regulatory approvals; SAE and AE Reports; Protocol deviations and violations; progress reports; continuing review activities; site monitoring reports; all correspondences between IEC and investigators; record for premature termination; final reports, publications etc
3. Responsibility: The record keeping and achieving will be responsibility of dedicated staff. The staff should be trained and should be well versed with Confidentiality and Intellectual Property Related Issues. Appropriate oath should be taken from the staff in written format. The staffs should be well versed with docketing of documents and management of official documents including the official red taped file both in hard and soft formats. The Director will make appropriate arrangement for infrastructure and staff support. The office staff should be well trained and due to complexity of the job/task involved interdepartmental transfers should be kept to minimum.
4. Procedure for Administrative Documents: IEC secretariat will keep track of all documents as mentioned in 2(a) above. These documents will also need to be kept in knowledge of the Director. IEC Secretariat will do necessary ground work for constitution and maintenance of the IEC. The outcomes of meetings will be communicated with the Director. It can be done in both hard and soft formats. Any communication done in soft format will also be kept in hard format for record. The IEC Secretariat will maintain the Official File of LGBRIMH relating to the IEC. For formation of IEC and formats as per the SOPs will be used. IEC Secretariat will do the necessary work for its registration and accreditation at appropriate level. It will maintain the documents related thereto both in soft and hard format and may need to store it in appropriate Cabinets and also in the Cloud Space. IEC Secretariat will do the laision with the technical person for updating the mandated details in the Website of LGBRIMH like member details, contact details, SOPs, notification for meetings etc. IEC Secretariat will do the communication with the members, Director, Investigators for issues related to board meetings, official needs such as registration etc, notification for SOPS , infrastructures, grievances, financial issues, proposal related issues etc. Member Secretary will clarify other stake holders wherever needed and guide the Secretariat. IEC Secretariat will maintain Log of both incoming and outgoing documents and appropriate tag and stag it. The secretariat may utilize various offline and online electronic tools

for facilitation and storing and archiving of documents including minutes etc. The Minutes of meeting may also be shared with members electronically for comments in real-time taking care of confidentiality through appropriate encryption. All these events will be done with approval of Chairperson. For financial issues like remuneration Govt of India guidelines will be followed. This will be done with approval of Director. Financial concurrence will be done with the Accounts Section by IEC Secretariat. Annual Budget will be prepared and the receipt of expenditure etc will be handed over to accounts section quarterly. The Budget will include routine administrative costs, training expenditure, remunerations. Secretariat will make requisition for needed office materials including electronic equipments and peripherals to the Nazarat Section quarterly. IEC Secretariat will be responsible for its audit by relevant agencies (regulatory/finance/academic/internal) on written request. The matter will be communicated to the Director in writing by the Secretariat. IEC Secretariat will keep log of all items received in a register with date and date of expiry/condemnation and audit etc. This will be done in conjunction with the Internal Audit Section of the institute. Secretariat will also keep a register of visitors and will try to form a network of related bodies of the region and keep record of such events.

IEC Secretariat will keep the administrative documents active till the IEC is active and accordingly it can be archived. Archived files will be kept in separate cabinets for minimum 5 years. Financial records will be handed over annually with a back for 5 years. SOPs when modified will be kept in achieved with appropriate tagging. The SOPs will not be discarded and can be accessed for archive on written request of any stack holders. There may be effort to make these documents in digital achieve. These administrative documents are mostly public documents and will be covered under the relevant laws and regulations.

5. Procedure for Proposal Related Documents: It is the responsibility of IEC Secretariat staff to ensure that all study files are prepared, maintained, and kept securely for a period of 5 years or mentioned in the proposal (whichever is more) after the closure of the project/proposal (under a proper system that ensures confidentiality and facilitates retrieval at any time).

   Active study files maintenance & archival of closed files: A Study Master File is the file comprising all essential documents and correspondence related to the study/protocol. Study master files should be established at the time of initial submission in the IEC Secretariat. The study files are assigned unique identifiers (serial project ID no/EC Ref No.) All documents related to the study file are gathered, classified and combined together appropriately. All active files are kept in a secured file cabinet with controlled access. Only authorized individuals' i.e. IEC Members/Secretariat will have access to the files. The study files are maintained in an easily accessible and secure place for at least 5 years after the study closure.

   All closed study files (Completed study) are separately archived. IEC Secretariat staff will arrange for the closed project files to be archived once the completion/status reports are reviewed by the IEC. The completed/closed project files will be stored in archive boxes that

are clearly labeled with the project number/EC Ref No and title, Principal Investigator and disposal date. The archive boxes will be sent to a secure, dry location. The access to the files should be restricted to the IEC and the regulatory authorities. The details of the archiving location should be recorded in a location register stored in the IEC Secretariat. This register should record the project number and title, Principal Investigator and the disposal date. These can be maintained on appropriate online/offline electronic tools as mentioned above in Para 4. The staffs will be trained on file maintenance, record and archiving.

6. Disposal of closed files and copies of protocols and documents submitted for IEC review: The study master file will be maintained in the IEC Secretariat for a period of 5 years following closure of the study. After completion of the archival period the closed files will be shredded and disposed off in the shredding facility after informing the study PI over email.

   However, all the copies of the research projects and documents submitted for IEC review will be shredded by the authorized IEC personnel after the IEC meeting without any notification to the Principal Investigator. If a PI proposes to get the proposal copies back, the same can be given after getting a written request. However the completed and signed reviewers form will be filed in the master study file. A logbook of disposed documents of the closed files will be maintained.
7. Accessibility/ Retrieval: Master file will be made available for inspection and copying by authorized representatives of regulatory authorities after receiving the request in writing. The Director being the appellate authority will have the access to the documents.

   In case any investigator needs a copy of any document from the master file, he/she should make a written request. (Appendix). The IEC staff will furnish a copy of the required document within a week with the IEC Secretary's consent. The IEC will issue a copy of the documents on formal written request. Archived boxes may be retrieved from storage by the IEC as per need. For administrative purposes, the IEC Secretariat can retrieve archived file(s) without requiring the Chairperson's approval. For this purpose the Member Secretary can authorize a staff member of the IEC secretariat to physically retrieve a file. Whenever an item is retrieved from the archives, the date, item and person retrieving the item should be documented, together with the date returned to the archives.

   Final Disposal of Master files: The master files will be disposed off by the IEC secretariat after the archival period of 5 years or more as mentioned in the proposal. A formal written off register (Appendix) will be maintained, providing details of the documents being written off / disposed off after notification to IHEC in IEC meeting and the PI. The Secretariat will do liaison with the condemnation committee of institute in this regard.

Appendix 01/012/01.0 Log of Items & auditing/condemning

Sl no	Item	Demand date/No. (Sign Date)	Received by (sign date)	Docket/numbering (Sign Date)	Audit (Sign Date)
1	Table	XX 01012020	YY01022020	ZZ05022020	BB31032020
2	Chair				

Appendix 02/012/01.0 Log for incoming & outgoing documents

Sl no	Document name	Received from	Date	Remark/sign

Sl no	Document name	Sent to	Date	Remark/sign

Appendix 03/012/01.0 List of Visitors

Sl no	Name & address	Date	Purpose	Remark/sign

Appendix 04/012/01.0 List of Register of Proposals (active)

Sl no	IEC Ref No	Title	Investigator	IEC approval date	Remark	

Appendix 05/012/01.0 List of Closed Proposals

Sl no	IEC Ref No	Title	Investigator IEC appro Date	Date of Compltn (IEC approved)	Remark	

Appendix 06/012/01.0 Log book of documents disposed after IEC meetings

Sl no	Document	Authorized disposer	Remark/sign

Appendix 07/012/01.0 Document Request Form

IEC Ref No
Proposal Title
Requesting Person Name & Designation
Date
Documents requested
Purpose
Requesting persons signature with date
Permission of IEC Secretariat: Yes/No Signature of Member Secretary with Date

Appendix 08/012/01.0 Master Register of proposals submitted for Review

Sl no	IEC Ref No	Title	Investigator	Initial Review Date	Decision	Contd Review date	Decision
					approved		complt
					Pproved with suggestion		aproved
					rejected		Approved with suggestion

Institutional Ethics Committee

Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

Preparing Standard Operating Procedures (SOPs): Management of Premature Termination/Suspension/Discontinuation of Research Proposal

LGB/IEC/SOP/ 013/01

Author: Dr. K N Kalita

Checked by: Dr. K Pathak

1. Purpose: The purpose of this SOP is to describe the procedure for management of the premature termination/suspension/discontinuation of a research study by the IEC. Research studies are usually terminated as per the recommendation of the IEC, PI, sponsor or other authorized bodies wherein subject enrollment and subject follow-up are discontinued before the scheduled completion of the study.

2. Scope : This SOP applies to any study approved by IEC that is being recommended for termination/suspension/discontinuation before its scheduled completion.

3. Responsibility: It is the responsibility of the IEC to terminate any study that the IEC has previously approved when the safety or benefit of the study participants is doubtful or at risk, also to review the termination suggested by PI, Sponsor or other authorized bodies. The secretariat is responsible for management of the premature termination/ suspension/discontinuation process.

4. Flowchart:

Activity	Responsibility
Receive study discontinuation/termination/suspension report	Secretariat
Review/ discuss the report at	IEC
Notify investigator	Secretariat
Store document	Do

5. 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 IEC members/Chairperson can prematurely terminate the study if protocol non compliance/violation is detected and IEC 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.

The secretariat will inform the PI to prepare and submit a protocol termination package along with Premature Termination Report (available at IEC office and also shared at time of submission of initial review application)

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 (Appendix 1.7/003/01.0) signed and dated by the PI and/or other material (letter from Principal Investigator/sponsor etc)

The Secretariat will check the completeness of the information

The Secretariat will receive and acknowledge the reports.

Review and discuss the Termination / suspension/discontinuation report:

IEC 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 IEC 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 IEC approvals for such studies would be terminated. The same will be ratified during the next full board meeting.

Notify the PI:

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 14days 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.

Store the Report:

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.

6.Reference

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, (Geneva 2000)
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

Institutional Ethics Committee

Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

Preparing Standard Operating Procedures (SOPs): Management of Site Monitoring

LGB/IEC/SOP/ 014/01

Author: Dr. K N Kalita

Checked by: Dr. K Pathak

1. Purpose: The purpose of this SOP is to provide procedures as to when and how a study site should be visited and monitored of its performance or compliance to national and international ethical guidelines.

2. Scope: This SOP applies to any visit and/or monitoring of any study sites as stated in the IEC approved study protocols that identify the place(s) where the study and/or laboratory procedures are being carried out or performed. The site visits can be either 'Routine' or 'For Cause'. The examples of 'For Cause' monitoring are High number of Protocol deviation/violation' large number of proposals at same site or by same investigator, large number of SAE, high recruitment rate, complaints received from participants, any adverse media report, adverse information received from any other sources, non compliance with IEC directions, misconduct, any other cause as decided by IEC. Routine site visits be done atleast once in six months.

3. Responsibility: It is the responsibility of the IEC Members to perform or designate some qualified persons to perform on its behalf on-site inspection of the research projects it has approved. The IEC members or Secretariat in consultation with the Chairperson may initiate an on-site evaluation of a study site for cause as and when if required.

4. Flowchart

Activity	Responsibility
Study site selection	IEC members/ subcommittee
Procedure before visit	IEC member
Procedure during visit	IEC Member/subcommittee
Procedure after visit	do
Full board meeting	IEC Members

5. Detailed Instructions

Selection of study sites: The site visits can be either 'Routine' or 'For Cause'. See Para 2.

From the study data base/master file, routine monitoring at 6 month interval is done. Member Secretary may form a subcommittee for the same. The IEC approval will have a comment about the routine monitoring.

Before the visit: The IEC Secretariat will communicate with investigator for the same. Investigators shall facilitate inspection of the required documents/records by the IEC and any other designated person. Secretariat shall make the appropriate travel arrangements. Review team will examine files for the study and site & make appropriate notes. Review committee will copy some parts of the files for comparison with the site files.

During the visit: A checklist (annexure) helps assessment. The team will review (a)the informed consent document to make sure that the site is using the most recent version, (b)review randomly the participant files to ensure that participants are signing the correct informed consent, (c) observe the informed consent process, if possible; (d)observe laboratory and other facilities necessary for the study at the site; (e) review the IEC files for the study to ensure that documentation is filed appropriately; (f) collect views of the study participants; (f) debrief the visit report/comments; (g)get immediate feed back.

After the visit: The IEC representative/team will write a report/comment (Annexure) within 1 week describing the findings during the audit & forward a copy of the site visit to the 'site monitoring' file for Full Board review. Secretariat then manages the document with proper tagging and staging.

Present the inspection results to the Full Board: The report is put in agenda f full board meeting and discussed appropriately. IEC Secretariat communicates with stakeholders and keeps track of these events.

6. References

- World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
- International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
- ICMR Guideline 2017.

Appendix 01/014/01.0 Checklist for monitoring site visits

IEC Ref No:	Date of the Visit:	
Study Title:		
Investigators:		Phone:
Institute:	Address:	
Sponsor etc:	Address:	
Total number of participants:	Total participants enrolled:	
Are site facilities appropriate? □ Yes □ No	Comment:	
Are Informed Consents recent? □ Yes□ No	Comment:	
Any adverse events found? □ Yes□ No	Comment:	
Any protocol non-compliance /violation? □ Yes□ No	Comment:	
Are all Case Record Forms up to date? □ Yes□ No	Comment:	
Are storage of data and investigational products locked? □ Yes□ No	Comment:	
How well are participants protected? □ Good □ Fair □ Not good	Comment:	
Any outstanding tasks or results of visit? □ Yes□ No	Give details:	
Duration of visit: …….hours	Starting from:	Finish:
Name of IEC Members / Subcommitte		
Completed by:		Date:

Institutional Ethics Committee

Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

Preparing Standard Operating Procedures of Reporting of Protocol deviation/violation

LGB/IEC/SOP/ 015/01

Author: Dr. K N Kalita

Checked by: Dr. K Pathak

1. Purpose

To provide instructions for taking action and maintaining records that identify investigators/institutes who fail to follow the procedures written in the approved protocol or to comply with national / international guidelines for the conduct of human research, including those who fail to respond to the IEC's requests.

2. Scope

This SOP applies to all IEC approved research protocols involving human subjects.

3. Responsibility

The designated member of the Secretariat is responsible for collecting and recording the non-compliance list (AF 1.5/003/01.0) from the study team, sponsor/monitors or IEC or its subcommittee.

4. Flowchart

Activity	Responsibility
Information about Protocol deviation/violation	IEC Members/sponsor/monitor/study team
Calling for discussion either subcommittee/fullboard	Member Secretary
Notify Investigator	IEC Secretariat
Keep record & follow up	Do

5. 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 IEC 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 IHEC's request for information/action.

c. *Note*: The Board 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.

The IEC's Decision:

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

a. Suspends or

b. Terminates approval of a current study or

c. Refuses subsequent applications from an investigator cited for non-compliance.

Notify the investigator:

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

Keep records and follow 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.

References:
ICMR Guideline 2017

Institutional Ethics Committee

Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

Preparing Standard Operating Procedures of Dealing with Participants' Requests/Complaints

LGB/IEC/SOP/ 016/01

Author: Dr. K N Kalita

Checked by: Dr. K Pathak

1. Purpose : The IEC considers protection of the rights and welfare of the human subjects participating in a clinical research approved by the IEC as its primary responsibility. Informed Consent Documents reviewed by the IEC inform the study participant that queries regarding their rights as a participant in the study may be addressed to the IEC, Member Secretary, and the IEC address and phone number/email are provided over and above the information provided by the research investigator. This SOP provides guidelines for dealing with and accommodating requests by participants regarding their rights as a participant or to resolve their complaints in any approved research study.
2. Scope :This SOP applies to all requests concerning the rights and well being of the research participants participating in studies approved by the IEC.
3. Responsibility
It is the responsibility of the IEC Member Secretary to provide the required information to the research participants/ research participant's representatives, in case of any queries asked from them. It is the responsibility of the Member Secretary/Chairperson to initiate the process of giving information to the participants or identifying and addressing any injustice that has occurred, if any complaints received from research participants.
4. Flowchart

Activity	Responsibility
Receipt of query/complaint from participant	Investigator/IEC
Provide information to participant	Member Secretary
Initiation of Process to identify Problem	IEC Secretariat
Deliberation to attend at solution	IEC
Communication with complainant	IEC Secretariat
Record of events	do

5. Detailed Instructions: When the IEC Members/secretariat receives an enquiry or request from any participants or his/her representative in any form of communications (Phone/letter/email)

The request will be recorded in Participant Request Form (Appendix). Member Secretary will inform the Chairperson within 2 days. Chairperson or any of his designate will provide the information required by the participant. The Chairperson will direct the Member Secretary to consider matter within 2 weeks for discussion at full board meeting or to call for a emergency meeting of 2 or more members for discussion or to appoint a subcommittee of 3 or more members for 'due analysis' in order to resolve the matter. The chairperson/member secretary/subcommittee will asses the situation and will facilitate or initiate a dialogue between the complainant and investigator in order to resolve the matter. The IEC will insist on factual details to determine the reality between truth and individual perception.final decision will be informed to the participant by IEC Secretariat. Information and actiona taken will be signed with date by the secretariat. In the next meeting of IEC, the issue will be kept in agenda. The record file will be kept in the 'study file' and also in a separate 'Response File" by the Member Secretary and will be kept in a log for prompt retrieval in any need.

Annexure: AF 01/016/01.0 Participant Request Record Form

Date Received:
Received by:
Request from:

Telephone call No……
Fax No……
Letter / Date…… …
E-mail / Date……
Walk-in / Date / Time……
Other, specify ……

Participant's Name:
Contact Address:
Phone:
Title of the Study:
IEC Ref No:
Starting date of participation:
Request/ Complaint:
Action taken:
Outcome:

Signature of the Chairperson----------Date----------

Signature of the Member Secretary ----------Date----------

Institutional Ethics Committee

Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

Preparing Standard Operating Procedures of Review of Study Completion/Final Reports

LGB/IEC/SOP/ 017/01

Author: Dr. K N Kalita

Checked by: Dr. K Pathak

1. Purpose: The purpose of this SOP is to provide instructions on the review of Study Completion/Final Report for every study previously approved by the IEC.

2. Scope**:** This SOP applies to the review of the Study Completion Report which is a mandatory review of each investigator's activities presented to the IEC as a written report of study completed. Although IEC provides a Study Completion/Final Report Form (AF 1.12/017/01.0) to the investigator, additional information (letter format, form provided by the Sponsor, etc.) may be submitted to provide adequate and sufficient information.
3. Responsibility: The study completion report should be submitted by the study PI in the prescribed formats .It is the responsibility of the IEC members to review the study completion report and notify it or request for further information, if necessary.
4. Flowchart

Activity	Responsibility
Submission of Study Completion Report	Investigator
Check submitted documents for completion	IEC Secretariat
Circulate among IEC Members	Do
Include in next meeting agenda	Do
Present report in next IEC Meeting	Investigator
Review process	IEC members
Communicate with investigator	IEC Secretariat
Store original documents & closing of study file	do

5. Detailed Instructions: Before each board meeting

a. The IEC 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 IEC Secretariat will review the report for completeness before submission to the IEC Members.
d. The Member Secretary should keep the study completion reports on the agenda for IEC meeting.

Before and during board meeting

a. IEC 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 IEC meeting.
d. If appropriate to the discussions, the chairperson may call for consensus to accept it or request further information or take any other action.

After the board 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 IEC 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 IEC secretariat within 30 days. This update will be tabled in the full board meeting of IEC.

c. Once the report is accepted by IEC, the Secretariat will file the report in the study master file.

d. The IEC 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.

e. 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.

6. References

World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, (Geneva 2000)

International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996

ICMR Guideline 2017

Institutional Ethics Committee

Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

Preparing Standard Operating Procedures of Constitution of Data Safety Monitoring Board(DSMB)

LGB/IEC/SOP/ 018/01

1. Purpose: The Data Safety Monitoring Board (DSMB) is a unit of the IEC comprising of members of varied expertise from the hospital, supported by IEC staff with a primary responsibility to review serious adverse events (SAE), safety reports and annual status reports of the projects approved by the IEC. This unit reports to the IEC. It is essentially responsible for monitoring IEC approved projects, to ensure patient safety and assess data during the course of the study in a manner that contributes to the scientific and ethical integrity of the study. It will to enhance the quality of the ongoing research which has been approved by IEC by safety review, periodic monitoring and annual review.
2. Scope: This SOP describes the formation and functions of DSMB.
3. Responsibility: it is a 5 member- committee with affiliated members of IEC along with staff of IEC Secretariat. The member secretary will propose the names of IEC members to be included and they will get appointed by the Director. The appointment will be for 2 years which is non extendable. The member secretary will be an ex officio member. The DSMB has following responsibilities- Assess and evaluate Serious Adverse Event reports (SAEs) on all trials being conducted at LGBRIMH**,** Monitor the overall progress of institutional clinical trials/studies and ensure adherence to protocol specific procedural requirements, Ensure that the safety of participants, validity of data and projected accrual goals are maintained, Provide regular reports (monitoring) to the Institutional Ethics Committee, Creation, development, revision and implementation of guidelines for the DSMB which is needed to be vetted by the IEC, Continuing education and training programs to ensure that DSMB members are qualified to perform their specific duties. They will do these routine works. The chairman of IEC can constitute separate subcommittee in consultation with secretariat for SAE evaluation, site monitoring, protocol deviation, study final reports etc as mentioned in respective SOPs. DSMB will do these activities routinely and can be engaged by the IEC in full meeting for these specific purposes too. This will provide double layer to the safety and ethical considerations of the studies conducted. The secretariat will keep record of membership details, confidentiality certificates, conflict of interest declarations (as in SOP/002) etc and make it available for the IEC Secretariat.

References:

ICMR Guideline 2017

Institutional Ethics Committee

Lokopriya Gopinath Bordoloi Regional Institute of Mental Health, Tezpur

Preparing Standard Operating Procedures of Inspection, Assessments and Audit of IEC

LGB/IEC/SOP/ 019/01

1. Purpose: This SOP outlines the procedure for the self-assessment of the IEC members/staff and internal audit of the IEC to maintain high standards of research.

2. Scope: This SOP is applicable to the IEC members and staffs.

3. Responsibility: Chairpersons, Member Secretaries and IEC staff will be responsible for the assessment and audit of IEC.

4. Detailed Instructions:

Assessment of IEC members and IEC Secretariat

• The Chairperson will perform assessment of the IEC members annually. This assessment will cover regularity in attendance to IEC 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 IEC annually.

Evaluation forms will be circulated to individual members and the respective IEC staff via email and a copy of the same will be maintained in the IEC records.

Internal Audit

On receipt of written/ mailed communication regarding audit, the IEC 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.

Audit Procedure

*The audit involves review of IEC records, minutes, membership files, protocols, IEC correspondence etc.

*The internal audit report will be prepared by the auditors. A signed copy of the report will be forwarded to the IEC Member Secretary.

Correction of deficiencies observed at audit

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

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

5. Annexures:

1. AF01/019/01.0 IEC Evaluation Form of Chairman
2. AF02/019/01.0- IEC Evaluation Form of IEC Member Secretary/Members
3. AF03/019/01.0- IEC Evaluation Form of Staff
4. AF04/019/01.0- IEC Audit NABH Checklist
5. AF05/019/01.0- IEC Internal Audit Checklist

Annexure: AF01/019/01.0 IEC Evaluation Form of Chairman

1. Mention the person who is doing evaluation: ……../Self
2. No. of meetings attended of total: ……..of……Subcommittee meeting……
3. No of full protocols reveiewed:…….expedited……
4. Training completed:……. Last date of training……
5. Any training session conducted:…….
6. Specific input in area of Specialization: ……..
7. Preparedness for IEC meetings: Poor/Average/ Good
8. Contribution to IEC: poor/average/good
9. Communication to IEC Secretariat: poor/average/ good
10. Any suggestions/feedback:……..

Signature with Date

Annexure: AF02/019/01.0- IEC Evaluation Form of IEC Member Secretary/Members

1. Mention the person who is doing evaluation: ……../Self
2. No. of meetings attended of total: ……..of……Subcommittee meeting……
3. No of full protocols reviewed:……..expedited……
4. Training completed:……. Last date of training……
5. Any training session conducted:…….
6. Specific input in area of Specialization: ……..
7. Preparedness for IEC meetings: Poor/Average/ Good
8. Contribution to IEC: poor/average/good
9. Participation in IEC activities/mmeting
10. No. subcommittee meetings attended:……..
11. Communication to IEC Secretariat: poor/average/ good
12. Any suggestions/feedback:…….

Signature with Date

Annexure AF03/019/01.0- IEC Evaluation Form of Staff

1. Name of Staff evaluated:……
2. Number of Proposal submission examined:…….
3. Maintenance of communication among IEC: Poor/average/good
4. Drafting of agenda and minutes efficiently :poor/average/good
5. Maintenance of IEC record/roster: poor/average/good
6. Training attended:……
7. Communication with Investigators:…….
8. Maintenance of communication with Directors' office:……
9. Maintenance of follow up work: poor/ average/ good
10. Ability to help investigator: poor/average/good
11. Feedback:……

Member Secretary Sign with Date

AF04/019/01.0- IEC Audit NABH Checklist (Downloaded version from Internet as prototype for any accrediting body)

AF05/019/01.0- IEC Internal Audit checklist

Auditors:
Date of Audit Conducted: ……IEC Name:……..
Audit can be for infrastructure and documents

1. Document related maintenance of Infrastructure: Log Book/ Register
2. Documents related to IEC formation:……..
3. Document related to Membership requirements: CV/Training/appraisal/appointment/resignation/termination
4. Documents related to IEC registration: Authorization letter/ToR/Certficate of Registration of organization & IEC/CT01
5. Maintenance of SOPs…….
6. Agenda preparation
7. Minutes preparation
8. Documents related to proposals…….
9. Master file of proposals: Active study/ closed study
10. Proposal related documents:……..
11. Communication from IEC Secretariat: Investigator/IEC members/ Regulatory body ……..
12. Addressal of grievances: Participant/ Investigators
13. Maintenance of financial records