INSTITUTE OF CHILD HEALTH
INSTITUTIONAL ETHICS COMMITTEE FOR BIOMEDICAL AND HEALTH RESEARCH (IECBMHR)

11, Dr. Biresh Guha Street, Kolkata – 700017
Phone: 033-2290-5686/09073687795;
Email: iecbmhrich@gmail.com

STANDARD OPERATING PROCEDURES (SOP)

VERSION 2

EFFECTIVE DATE: 05th DECEMBER 2022

COPY NUMBER: 02

Approved by:
Signature of Chairperson, IECBMHR ICH

Accepted by
Signature of Director, ICH:

CONTENTS

PREAMBLE

INTRODUCTION

In 2019, the **INSTITUTIONAL ETHICS COMMITTEE FOR BIOMEDICAL AND HEALTH RESEARCH-INSTITUTE OF CHILD HEALTH** was established by the ICH Governing Body resolution and subsequent policy statement issued by the Director of ICH.

The IECBMHR -ICH is composed of medical/scientific professionals and non-medical/ non-scientific members working together in a committee that safeguards the rights, safety, and well-being and confidentiality of all participants involved in biomedical research, thereby providing public assurance of that protection.

The IECBMHR -ICH is committed towards providing the best possible ethical reviewing of all research proposal submitted under its scope.

It is now registered with the Department of Health Research, Ministry of Health and Family Welfare, Government of India vide provisional certificate No. File No. - EC/NEW/INST/2019/316 dated 30.11.2021(Ref.: https://naitik.gov.in).

SCOPE

The IECBMHR-ICH reviews biomedical (clinical) research protocols following local, national and international ethics guidelines in biomedical research.

The scope of research is biomedical research on human participants between 0-18 years of age carried out in the premises of Institute of Child Health, situated at 11, Dr. Biresh Guha Street, Kolkata – 700017, under the supervision of a senior researcher (called the principal investigator) with experience and training in conducting clinical research and knowledge of Good Clinical practice and Biomedical ethics or in collaboration with researchers in institutes of eminence.

The Standard Operating Procedures (SOPs) written in this booklet describe the procedures for the ethical review of biomedical research protocols established by the IECBMHR-ICH, and intends to demonstrate compliance of the procedures to the requirement of guidelines put forth in the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017 by ICMR; and applicable standards mentioned in the New Drugs and Clinical Trial Rules, 2019, CDSCO, Government of India.

The booklet describes the procedures established for operating and maintaining all components of the standards for ethical reviewing with the aim of achieving and continually improving on the desired quality level in every activity and service of the committee.

The document control system of the committee has a provision to update the booklet through amendments to various sections, and amendments are documented for the amendment sheet provided in the SOP for SOPs.

MANDATE OF THE COMMITTEE

- All academic research projects or studies on human subjects that will be conducted in this Institution (ICH, Kolkata) must be approved by this committee prior to study initiation The IECBMHR shall also review and monitor ongoing projects from time to time.

- Dissertation or thesis, research work of faculty, students (medical, nursing, paramedical, &allied sciences) of this Institute will be reviewed and monitored by this committee.

- It will provide ethics consultation to investigators proposing to embark on clinical research and to physicians involved in patient care but not necessarily conducting research who request for such service.

- In evaluating protocols and ethical issues, the IECBMHR is aware of the diversity of laws, culture and practices governing research and medical practices in India and various countries around the world.

- It attempts to inform itself where possible of the requirements and conditions of the various localities where proposed research is being considered.

- The IECBMHR is guided in its reflection, advice and decision by the ethical principles expressed in Declaration of Helsinki (Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964, and its amendments at 64th WMA general Assembly, Fortaleza, Brazil, October 2013).

- The IECBMHR will work according to its current established Standard Operating Procedures based on, International Conference on Harmonization - Good Clinical Practices (ICH-GCP) Guidelines,1996; New Drugs and Clinical Trial Rules, 2019; ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants,2017; ICMR National Ethical Guidelines for Biomedical Research Involving Children, 2017 and other international, national and local guidelines and their amendments as applicable from time to time.

RESPONSIBILITIES OF THE INSTITUTIONAL ETHICS COMMITTEE

- The Committee's primary responsibilities will be protection of safety, rights and confidentiality of the research participants.

- The Committee will keep all information submitted to them confidential specially the proprietary information.

- The Committee will maintain concise but clear documentations of its views on the scientific and ethical aspects of the research proposal.

- The Committee will review the progress of each research project at appropriate and specified intervals, but not less than once a year and will also review the final report of the studies approved by them.

- The Committee will participate in activities that promote ethical research in the institution and community

- The Committee will participate in and organize programs aimed at educating and training community members, members of the public, investigators, IEC members in ethical research.

- The vicarious responsibility of the committee towards compliance with guidelines lies with the Chairperson. Each member is accountable for ensuring that protocols reviewed meet regulatory compliance in all essential aspects.

JURISDICTION OF IECBMHR

IECBMHR shall receive, review, approve (or otherwise) and monitor research proposals involving human study volunteers in the following Institutions: Institute of Child Health, 11, Dr. Biresh Guha Street, Kolkata. This includes both intramural and extramural research by faculty and students.

Administrative Requirements: All proposals originating from ICH or other institutions must be routed to the IECBMHR through the Director, ICH after obtaining an NOC from his office

Jurisdiction: Approval given to studies
The validity of approval of the IECBMHR –ICH is restricted for studies to be carried out
- within the physical premises of ICH and/or
- in settings expressly approved by the IECBMHR

Approval given by ethics committee of another institution to carry out a study shall not be valid for carrying out the same study at ICH, Kolkata

Validity of approval given to multi-centric studies by the IECBMHR –ICH
For centres other than ICH, Kolkata, investigators need to obtain approval from their own centres also.

Jurisdiction and validity of approval
Research proposals submitted to the **IECBMHR –ICH** by researchers from Institutions other than ICH, Kolkata, above will be considered on a case-by-case basis.

In such cases, researchers must adhere to the following conditions:
a. For research involving data collection from ICH, Kolkata, by researchers other than those from ICH, Kolkata,
i. Letter of introduction from their respective Head of the institution
ii. Letter of consent from research guide
iii. Letter from Head of the institution and / or Guide describing the need for collecting data from ICH, Kolkata,
iv. Approval letter from the researcher's institutional ethics committee (if there is no ethics committee functioning in the researcher's institution, approval from any institutional ethics committee from the researcher's city of work / approval from an independent ethics committee) and
v. All other documents required for scrutiny by **IECBMHR –ICH**

b. For researchers from ICH, Kolkata, involving data collection from outside institutions
i. Letter from Head of the institution and / or Guide describing the need for collecting data outside ICH, Kolkata,
ii. Approval letter from the researcher's collaborative institutional ethics committee (if there is no ethics committee functioning in the researcher's institution, approval from any institutional ethics committee from the researcher's city of work / approval from an independent ethics committee)
iii. All other documents required for scrutiny by **IECBMHR –ICH** for scrutiny of study protocols
iv. Samples from participant for research projects approved by **IECBMHR –ICH** shall be collected from ICH, Kolkata, or its approved sites only

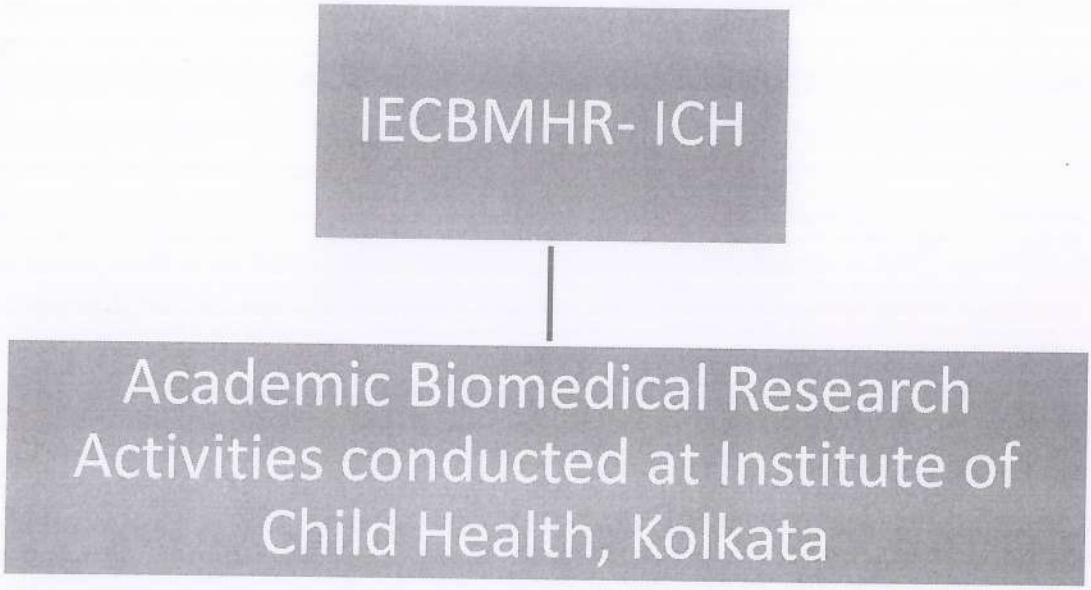
c. For multicentric studies, where ICH, Kolkata is one of the centres
i Letter of invitation from Principal investigator of nodal/ coordinating center inviting investigator at ICH to participate in the study
ii Approval letter from the institutional ethics committee of nodal/ coordinating center or any centre

iii All other documents required for scrutiny by **IECBMHR –ICH** for scrutiny of study protocols including site specific protocols

BUSINESS ADDRESS OF ETHICS COMMITTEE
Room 122, Ground Floor, Main Building,
Phone: +91-033-22905686
Fax: +91-033-22893242
E mail: iecbmhrich@gmail.com
Mon-Fri: 11.00 – 15.00, Sat: 10.00-12.00

Flowchart: Jurisdiction and Independence of IECBMHR-ICH

The Ethics Committee is functionally autonomous. Its activities (as listed in this SOP) lie outside the administrative jurisdiction of the Director, ICH, Kolkata



AMENDMENT SHEET

(SOPs of ICH IECBMHR)

Sl No.	Page	Section	Date of amend ment	Reasons for amendment	Signature of Member	Approved by Chair

DETAILS OF SUPERSEDED SOPs

Name of Authorized Signatory	Version	Effective Date	Date of becoming Obsolete	Major Changes
Dr. Phalguni Dutta	Version 2.0	05.12.2022	NA	• Form 3G Assessment form-revised • Form 4H-Audit checklist-revised • Form 2C-Template for Biodata-Revised as per DHR template
Dr. Phalguni Dutta	Version 1.0	18.11.2019	04.12.2022	NA

Preparation of Standard Operating Procedures
SOP Code: SOP 01/V2

Reviewed By

Name and Position in IECBMHR	Signature
Dr. Phalguni Dutta Chairperson	
Dr. Surupa Basu Member Secretary	
Dr. Arunaloke Bhattacharyya Clinician	
Prof. Jaydeep Choudhury Clinician	
Dr. Supriyo Choudhury Basic Medical Scientist; Clinical Pharmacologist	
Mr. Tamal Chatterjee Legal expert	
Ms. Anasuya Basu Layperson	
Ms. Kaberi Mukherjee Theologian	

Approved By

Name and Position in IECBMHR	Signature
Dr. Phalguni Dutta Chairperson	

TABLE OF CONTENTS:

Supersedes	01
Version	02
Authored By	SOP Team
Version Date	30 September 2022
Approved By	Dr. Phalguni Dutta
Effective Date	05 December 2022

1. OBJECTIVE

The purpose of this Standard Operating Procedure (SOP) is to define the process for writing, reviewing, circulating, amending and storing SOPs of the Institutional Ethics Committee for Biomedical and Health Research (IECBMHR) of Institute of Child Health Hospital, Kolkata. The SOPs should provide clear, unambiguous instructions so that the related activities of the committee are conducted in accordance with Indian laws and relevant national and international guidelines.

2. SCOPE

This SOP applies to any item in the IECBMHR-ICH SOP and their amended versions as published and distributed by the IECBMHR-ICH.

3. RESPOSIBILITY

The IECBMHR-ICH Chair is responsible for ascertaining the need for new SOPs and amendments to existing ones based on changes in international and national guidelines and policies or requests from various stakeholders including IECBMHR-ICH Members.

The IECBMHR-ICH Chair is responsible for designing an SOP Team, which drafts new SOPs and amends them as needed. The team is responsible for proposing design and format as well as the substantial contents of the SOP. The Chair will review and approve the SOPs. He/ She signs and dates the approved SOPs.

IECBMHR-ICH members are responsible for consensus action on the proposed SOP, the outcome of which is approved by the IECBMHR-ICH Chair. The IECBMHR members will receive and sign and date the new approved SOPs. They will maintain a file of all SOPs received. They will return the obsolete SOPs to the IECBMHR Secretariat.

The IECBMHR-ICH Secretariat Staff is responsible for storing and distribution. The Member Secretary shall ensure that all approved SOPs are distributed to all members of the IECBMHR and to the administrative head of the Institute **within 30 calendar days** of its approval for their records.

- Maintain on file all current SOPs and the list of SOPs
- Maintain an up-to-date distribution list for each SOP distributed to the IECBMHR members
- Maintain a record of the investigators to whom SOPs are distributed
- Ensure that all the IECBMHR members and involved administrative staff have access to the SOPs
- Ensure that all the IECBMHR members and involved staff are working according to current versions of the SOP
- Maintain on file all past SOPs of the IECBMHR
- Assist in the formulation of the SOP procedure

DETAILED INSTRUCTIONS

4. IDENTIFY THE NEED FOR NEW OR AMENDING SOP

Any member of the IECBMHR/ Secretariat/ administrative staff/ or investigators who would like a revision or notices an inconsistency/ discrepancy has any suggestions on how to improve the existing SOPs or requests to design an entirely new SOP can put forth his request by using the request form **IECBMHR – ICH 1-F** for revision of an SOP. Revision of an SOP made as a formal request will be submitted to the IECBMHR Chairperson.

The Chairperson will inform all the IECBMHR members about this request in a regular full-board IECBMHR meeting. If the IECBMHR members agree to the request, an appropriate member/ consultant will be appointed by the Chairperson and designated the task to proceed with the revision process/ formulation process of the SOP.

If the IECBMHR members do not agree, no further action will be taken. The Chairperson will inform the person/IECBMHR member who made their request for modification of the SOP.

Minor one line revisions will be recorded by hand in the relevant SOP (only in the copy of SOP with the Secretariat) when any change is necessary as perceived by the IECBMHR members with the approval of the Chairperson. This will be logged in **IECBMHR – ICH 1-D, Amendment Sheet.** If the changes are more than 10 lines per page, printed amendments will be incorporated and a revision number and date will be given before print. Otherwise, printed amendments will be done during the annual revision of the collective SOPs.

DESIGN, FORMAT AND LAYOUT

5. COMPILED SOPs

a. **Cover Page:** The first page of the compiled SOP document will be in "Arial" font with font size of 18 bearing the name of the IECBMHR, registration number with designated authority, address and logo of the Institute of Child Health in font size 18. It will have the version number, effective date and copy number followed with the signatures of the Chairperson in Font 18(**Form IECBMHR – ICH 1-A, Template of first page of the compiled SOP document set**).

b. **Second page**: This will carry the list of all individual SOPs and their respective codes

c. **Third – Sixth Page**: This will bear a brief introduction of the Institutional Ethics Committee for Biomedical and Health Research and its Scope, Mandate and Responsibilities

d. **Seventh Page**: SOP Amendment Page which will log all the minor revisions of the SOPs till the next version is printed (**Form IECBMHR – ICH 1-D, Amendment Sheet Format**).

e. **Eight Page**: This will document the History of the SOPs with the list of Superseded SOPs (**IECBMHR – ICH 1-E, Document History of SOP**)

f. **The Appendices** will include the following: **Glossary, References, List of Acronyms**
   - **Glossary**, which is an alphabetical list, with meanings, of the technical terms in the SOP
   - **References**, which lists the instruments use to draft the Guideline such as other SOPs, guidelines, or policies

6. INDIVIDUAL SOP

a. Each SOP will be prepared according to the standard template

b. First Page: The SOP is introduced by a cover page **(IECBMHR-ICH Form 1-B: SOP Cover Page)** laid out as:
   i. Title with SOP Code
   ii. Name of Reviewers with signature: Reviewed, and Approved by
   iii. Table of contents with page numbers
   iv. Number and Date of the previous version: if not applicable, the date of previous issue is indicated by "N/A" (not applicable)
   v. Number and date of Current version
   vi. Name of the authors/editors
   vii. Approval information such as approving authorities and offices and date
   viii. Institutional contact details (address, telephone numbers, facsimile number, email address) with logo, version number and effective date in present as header of every page of the SOP
   ix. Footer with details including revision number and date, and page number

c. An SOP follows the format:
   i. **Number and version**, which follows the SOP on coding SOPs. A unique code number with the format SOP xx/vy will be assigned to each. SOP item by the Secretariat. "xx" will be a two-digit number assigned specifically to each activity based SOP."V" refers to version of the SOP and "y" will be a number identifying the version. The current version of the SOPs would be the **fifth one;** hence it will be denoted as"v5". The first SOP of the current version would be ICH IECBMHR SOP01/v1 i.e. it is SOP number 01 of version 01.
   ii. **Title**, which is descriptive of contents and self explanatory (present in header)
   iii. **Objectives**, which defines the purpose and intended outcome
   iv. **Scope**, which defines the extent of coverage of the SOP and its limitations
   v. **Responsibilities**, which delineates tasking and accountabilities for SOP implementation
   vi. **Detailed instructions**, which elaborates the steps outlines in the workflow
   vii. **Workflow**, when necessary, which provides a graphic representation of the essential steps to implement the SOP
   viii. **Forms**, which are documents to be filled out or accomplished by different parties as required by the SOP, with a **list of forms**

ix. **References**, which lists the instruments use to draft the Guideline such as other SOPs, guidelines, or policies

x. **Appendices**, which provide elaborations or clarifications of specific sections including glossary and list of abbreviations

d. The text matter of all SOP documents will be "Arial" font with font size of 11. The margins of each page of the body of the document shall be "moderate". The alignment of the text of the document will be "Left" with single line paragraph spacing.

e. Each page of the SOP will bear a header and footer in the same font of "Arial" with font size of 11.The SOP number with version will be on the right hand corner of the header. The left hand corner will bear the Institute's logo. The title of the SOP will be in the centre subtended by the name of the Ethics Committee and name of the Institute. The footer will bear the author name and approving authority's name. In the centre will be the Revision Number and Revision Date (if any). The right hand corner will bear the version number of the SOP and page number as "Page number M-of total N".

7. WRITING AND REVIEW OF NEW SOP

a. SOPs are issued by the IECBMHR-ICH in order to facilitate transparent, clear, and systematic implementation of its functions.

b. New SOPs may be issued in not less than **three-year intervals**; unless regulations on which these documents are based have significantly changes in the interim.

c. Existing SOPs are reviewed every three (3) years; unless situations or circumstances dictate more frequent review and revision or when the regulations on which these documents are based have significantly changed in the interim.

d. Any amendment or revision must be written and submitted to the IECBMHR-ICH Chair for compilation and processing by respective parties, such as IECBMHR-ICH Members, in preparation for the next round of SOP review.

e. A request for amendment or revision is accomplished by filling out ***Form IECBMHR – ICH 1-F: Request for Revision of an SOP.*** The IECBMHR-ICH Chair is responsible for initial review of the request, procurement of relevant information, recommendation of further action as follows:

- Confirm need for amendment or revision, forward to SOP Team
- Request further information
- Forward to content expert for opinion

f. When the need for a new SOP has been identified and agreed on, the IECBMHR-ICH Chair will organize the writing process whereby a draft will be written by SOP Team designated by himself/ herself. The draft is regarded as a consensus issuance by the SOP Team, and may be a result of consultation with other stakeholders prior to completion.

Note: Minor one line revisions, which may arise out of discussions held during meetings or when any change is necessary as perceived by the IECBMHR members, will be recorded by hand in the relevant SOP (only in the copy of SOP with the Secretariat), with the approval of the Chairperson. This will be logged in ***IECBMHR – ICH 1-D, SOP Amendment Sheet***. If the changes are more than 10 lines per page, printed amendments will be incorporated and a revision number and date will be given before print. Otherwise, printed amendments will be done during the bi-annual revision of the collective SOPs.

8. APPOINT THE SOP TEAM

The Chairperson will constitute an SOP team consisting of the Member-Secretary and two or more members of the IECBMHR who have a thorough understanding of the ethical review process. The SOP writing team will carry out the subsequent steps

9. LIST THE RELEVANT SOPs

- Write down step by step all the procedures of the IECBMHR
- Organize, devise and, name each process
- Make a list of SOPs with coding reference

10. PRESENTATION OF NEW/REVISED SOP TO THE IECBMHR-ICH

a. The draft version is submitted by the SOP Team to the IECBMHR-ICH Chair

b. The IECBMHR-ICH Chair presents the new/revised SOP to the IECBMHR during its regular meeting and presides over deliberation.

11. DECISION OF IECBMHR-ICH ACTION ON NEW/REVISED SOP

a. The IECBMHR-ICH members will deliberate on the proposed draft and arrive at a consensus action.

b. If a consensus cannot be achieved, the matter is put to a vote. *Favourable action by voting* requires a vote of **two-thirds plus one** of the members present in the meeting

c. Action can be deferred if recommendations for further amendments or revisions are lodged, in which case, the IECBMHR-ICH Chair will supervise the documentation of requested amendments or revisions and call for a subsequent meeting, **no more than thirty (30) days** from the date of this meeting.

12. APPROVAL OF NEW/REVISED SOP FOR IMPLEMENTATION

a. Upon favourable action by IECBMHR-ICH, the SOP is approved by the IECBMHR-ICH Chair.

b. The approval is indicated by the dated signature of the Chairperson, IECBMHR-ICH on the cover page of the document.

c. The **effective date** of the document is reckoned as the date when the Chair signs the document. The approved SOPs will be implemented from the effective date

d. The printed copy of the approved SOPs will be distributed to IECBMHR-ICH Members and ICH authorities (Hospital Director, Chief Administrative Officer) **within thirty (30) days** of approval by the IECBMHR-ICH Chair. This will be recorded in the ***Form IECBMHR-ICH 1C: Log of SOP Recipients***

e. An electronic copy of the SOP will be published as soon as possible in the ICH website.

13. MAINTAINING CONFIDENTIALITY WORKFLOW

a. One (1) complete originally signed set of current SOPs is maintained by the IECBMHR-ICH Secretariat Staff, which can be reproduced as needed. The Member Secretary will discuss the approved SOPs with the administrative staff and instruct them to implement it accordingly.

b. In case of amended or revised SOP documents, the old version will undergo archiving procedure by the Secretariat Staff. The word "OBSOLETE" is stamped on all pages of one complete set of the old version, after which it is stored separately from the current version.

c. Superseded versions are indicated in the **IECBMHR – ICH 1-E:** ***Document History of SOP*** of the new version by the Secretariat Staff prior to storage.

14. PREPARING STANDARD OPERATING PROCEDURES (SOPS) FLOWCHART

ACTIVITY	RESPONSIBILITY
Identify the need for new/revised SOP ↓	IECBMHR-ICH Chair on the request of any IECBMHR member/ Stakeholder
Design SOP format, coding and layout ↓	SOP Team
Write new/review existing SOP ↓	SOP Team
Present new/revised SOP to the IECBMHR-ICH ↓	IECBMHR-ICH Chair
Decide on IECBMHR-ICH action ↓	IECBMHR-ICH Members
Approved new/revised SOP ↓	IECBMHR-ICH Chair
Accepted new/revised SOP ↓	Director, ICH
Distribute and store new SOP ↓	Secretariat Staff

Stamp old version as OBSOLETE and document in Document History of SOP	Secretariat Staff

15. LIST OF FORMS

IECBMHR – ICH 1-A	Template of first page of the compiled SOP document set
IECBMHR – ICH 1-B	Template cover page of each SOP
IECBMHR – ICH 1-C	Log of SOP recipients
IECBMHR – ICH 1-D	SOP Amendment Sheet format
IECBMHR – ICH 1-E	Document History of SOP/ Details of Superseded SOPs
IECBMHR – ICH 1-F	Request for Revision of an SOP

INSTITUTIONAL ETHICS COMMITTEE FOR BIOMEDICAL AND HEALTH RESEARCH - INSTITUTE OF CHILD HEALTH

IECBMHR Registration Number: XXXXXXXXXX

11, Dr. Biresh Guha Street, Kolkata – 700017
Phone: 033-2290-5686/09073687795;
Email: instecich@gmail.com

STANDARD OPERATING PROCEDURES (SOP)

VERSION aa

EFFECTIVE DATE: XX/YY/ZZZZ

COPY NUMBER: bb

Approved by
Signature of Chairperson, IECBMHR ICH:

Accepted by
Signature of Director, ICH:

Template cover page of each SOP

Title: XXXXX
SOP Code: XX/VY

Reviewed By

Name and Position in IECBMHR	Signature
XXXXXXXXXX	XXXXXXXXXX
XXXXXXXXXX	XXXXXXXXXX
XXXXXXXXXX	XXXXXXXXXX
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Approved By

Name and Position in IECBMHR	Signature
XXXXXXXXXX	XXXXXXXXXX

Accepted By

Name and Position in ICH	Signature
XXXXXXXXXX	XXXXXXXXXX

LOG OF SOP RECIPIENTS

S. No.	Name of recipients	Designation	SOP Copy No.	Date of receipt
1				
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AMENDMENT SHEET

(SOPs of ICH IECBMHR)

Sl No.	Page	Section	Date of amend ment	Reasons for amendment	Signature of Member	Approved by Chair

DOCUMENT HISTORY OF THE SOP

Author	Version	Effective Date dd/mm/yyyy

DETAILS OF SUPERSEDED SOPs

Name of Authorized Signatories	Version	Effective Date	Date of becoming Obsolete	Major Changes

Constitution, Composition, Terms of Appointment, functions, role and responsibility of IECBMHR Members
SOP Code: SOP 02/V2

Name and Position in IECBMHR	Signature
Dr. Phalguni Dutta Chairperson	
Dr. Surupa Basu Member Secretary	
Dr. Arunaloke Bhattacharya Clinician (Pediatrician)	
Prof. Jaydeep Choudhury Clinician (Pediatrician)	
Dr. Supriyo Choudhury Basic Medical Scientist; Clinical Pharmacologist	
Mr. Tamal Chatterjee Legal expert	
Ms. Anasuya Basu Layperson	
Ms. Kaberi Mukherjee Theologian	

Reviewed By:

Approved By:

Name and Position in IECBMHR	Signature
Dr. Phalguni Dutta Chairperson	

Accepted By:

Name and Position in ICH	Signature
Prof. Apurba Ghosh Director	

Request for Revision of an SOP

Please complete this form whenever a problem or a deficiency in an SOP is identified and submit to the IECBMHR-ICH Chair for processing.

SOP Code	**SOP Title**
Reason for request (citing details of problems or deficiency in current document):	
Description of requested changes	
Revision Requested by: (Name and signature)	**Date: (dd/mm/yyyy)**

Recommendations by IECBMHR-ICH ☐ Revision requirement confirmed, forward to SOP Team ☐ Request further information (state) ☐ Forward to content expert for opinion	
Name of IECBMHR-ICH Chair	Dr Phalguni Dutta
Signature	
Date	

TABLE OF CONTENTS:

Supersedes	01
Version	02
Authored By	SOP Team
Version Date	30 September 2022
Approved By	Dr. Phalguni Dutta
Effective Date	05 December 2022

1. OBJECTIVES

The SOP describes the organizational framework for the structure and composition of the Institute of Child Health- Institutional Ethics Committee for Biomedical and Health Research (ICH- IECBMHR). This Standard Operating Procedure (SOP) describes the Terms of References (TOR), which provide the framework for constitution, responsibilities, and activities of the IECBMHR. This SOP also describes and provides the procedures, templates, and forms that are related to the nomination, appointment, training, and compensation of members of the Committee, as well as identifying the persons who should read, agree to, sign and date these forms. Privacy and confidentiality documentation is likewise decided. The SOP also describes the collective responsibility of the committee to carry out periodic self assessments and financial audit.

2. SCOPE

The SOP applies to the stated functions of the ICH-IECBMHR, as it carries out its task of providing an independent review of research protocols involving human participants that are submitted to the IECBMHR by consultant-physicians, biomedical scientists, resident and fellow-trainees, students, hospital staff and employees of the ICH for all academic biomedical and health research done within the hospital/ institution or in approved sites or as multi-centric research activities. The committee will review research protocols that fall in the ambit of academic clinical and biomedical health research funded by various agencies.

Studies which are categorized as academic studies either sponsored by pharmaceutical entities or others, including investigator initiated academic studies, will be reviewed by the Institute of Child Health - Institutional Ethics Committee for Biomedical and Health Research (ICH- IECBMHR).

This SOP describes the basic ethical principles and values on which the ICH-IECBMHR is based, the composition and appointment of the IECBMHR members and the duties and responsibilities of IECBMHR personnel, including attendance, training and disclosure of conflict of interest. It also outlines the collective function of the committee in periodic self assessment and financial audit review. The Head of the Institute who is the appointing authority of the IECBMHR members and staff shall also abide by this SOP.

3. RESPONSIBILITIES

IECBMHR has responsibility within the institution with the following objectives:

- To ensure the competent review and evaluation of all ethical aspects of research projects received, to ensure compliance with the appropriate laws and safeguard welfare of subjects.
- Clinical ethics consultation
- Education of professional, administrative, and support staff about ethical issues
- Creation, developing revising and implementing ethical guidelines (SOPs)
- Initiate studies in ethics
- Self assessment and improvement in services

The Institution's Governing Body is responsible for constituting and establishing the ICH-IECBMHR under the authority of the Director. The Director is responsible for appointing the IECBMHR Chair, its Members and Secretariat Staff, and providing the terms of reference for these appointments in accordance with prevailing hospital policies, guidelines, and regulations.

It is the responsibility of the ICH-IECBMHR Chair, Members and Secretariat Staff to study, comprehend, comply with, and respect the procedures and guidelines set forth by the ICH-IECBMHR.

It is the responsibility of all newly appointed ICH-IECBMHR Chair and Members (including the Chair) to read, understand, accept, and sign the required appointment forms at the start of their appointment or reappointment to the IECBMHR. Refusal of any member to sign such agreement may be a ground for his/her disqualification from the Committee.

It is the responsibility of new IECBMHR to undergo training during the course of his/her appointment. Likewise, existing IECBMHR personnel have to continuously update themselves and be trained on relevant knowledge and skills. To this end, the ICH administration is responsible for allocating an annual budget for specific training and other educational activities for the IECBMHR Members.
It is the responsibility of the Chair and IECBMHR members and the Secretariat to read, understand, follow and respect the SOP set by this Ethics Committee.

4. CONSTITUTION AND FUNCTIONS

a. Organizational Structure of the IEC-ICH

Invite Member to the IECBMHR ↓	Chair
Send members the following forms: □ IECBMHR **Form 2A: *Member Notification and Appointment;*** □ IECBMHR **Form 2B: Non-Medical *Member Notification and Appointment;*** □ IECBMHR **Form 2-C:*Curriculum Vitae*;** □ IECBMHR **Form 2-D: *Confidentiality Agreement and Conflict of Interest Disclosure*** and □ IECBMHR **Form 2-E: *Training Record*** ↓	Secretariat Staff
Return accomplished and signed forms ↓	Member
Recommend members with signed conforme ↓	Chair
Appoints member of the IECBMHR	Director

i. The Director appoints the IECBMHR Chair and all members. The Chairperson will be the head of the committee. All other members will be of equal ranking.

ii. Only the Director has the authority to dissolve the IECBMHR after due process.

iii. Appointment terms for a member

- The Chairperson and IECBMHR members can suggest names of potential members but the final decision will remain with the Director of the Institute.
- Members must disclose in writing any interest or involvement-financial, professional or otherwise- in a project or proposal under consideration.
- The IECBMHR will decide the extent to which members that might have a conflict of interest may participate in bringing out an advice/decision. Members will be required to sign a confidentiality agreement at the start of their term.

iv. Conditions of appointment

Members and Independent consultants will be appointed to the IECBMHR if they accept the following conditions.

- Willingness to publicize his/her full name, profession and affiliation.
- Willingness to record reimbursement received for work and expenses incurred, related to the IECBMHR assignment and make these records available to ECBMHR and or general public on request
- Willingness to sign the Confidentiality and Conflict of Interest Agreements regarding meeting, deliberations, applications, information on research participation and related matters.

b. Composition of ICH-IECBMHR

i. The composition of this IECBMHR will be as per the **ICMR guidelines for Biomedical research involving human participants, 2017 and relevant sections of the New Drugs and Academic studies Rules, 2019.**

ii. The IECBMHR shall have **at least 7** and a **maximum of 15** members. To the end that a quorum will be met during regular IECBMHR meetings it is highly encouraged that there should be five (5) other members serving at any one time in the Board. The voting rights shall dwell with such members.

1. Chairperson (who will be a member not affiliated to the Institution)
2. Member Secretary (who is affiliated to the institution)
3. One or more persons from basic medical science area (preferably one clinical pharmacologist)
4. One or more clinicians from various Institutes (pediatricians and neonatologists)
5. Legal expert
6. Social scientist/ representative of non-governmental agency/ philosopher/ ethicist/ theologian

7. One or more lay person from community

iii. The IECBMHR is a multidisciplinary and multi-sectoral in composition. The members should be a mix of medical and non-medical, scientific and non-scientific persons including one layperson and one woman member at least to represent the different points of view. The IECBMHR will have representation that is varied in terms of age, gender and social background.

iv. Members are selected according to their personal capacities; based on their interest, background, ethical, and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the work of ICH-IECBMHR. The members representing biomedical scientists and clinicians should have postgraduate qualification and adequate training in their respective fields and aware of their role and responsibilities as committee members.

v. All members are appointed for a fixed term of three (3) years, with no prejudice to the possibility of reappointment. Reappointment for another term may be given by the Director in consultation with the Chairperson and the Member Secretary.

vi. The Director has the responsibility of appointing the Chair and the Members of the IECBMHR.

vii. To ensure continuity of policy structures of the Committee, it is encouraged that after the initial appointment of three years, **at least one-fourth** of the membership of the Committee should be reappointed.

viii. The IECBMHR members, in its first meeting, choose among themselves the Member Secretary. A Vice-Chair may be appointed in the absence of a Chair.

ix. The IECBMHR may be supported in its deliberation of specific protocols by Independent Consultants (see **ICH SOP 02-7, Selection of Independent Consultants**). They will attend the meeting in the capacity of 'Observer' and will not have right to vote.

c. Resignation, Disqualification, and Replacement of Members

i. A member may resign his/her position by submitting a letter of resignation to Director **at least 30 calendar days** prior to the next scheduled meeting. The member may or may not assign reasons for resignation. The resignation will become effective from the day it is approved by the Chairperson in a formal meeting. It has to be accepted by the Director, ICH.

ii. A member may not be reappointed if found non-compliant to assigned duties and responsibilities herein stated.

iii. A member who has resigned or members who will not be reappointed will be replaced by new members upon recommendation by the Director.

iv. Should the Member Secretary resign or be disqualified, the IECBMHR members will elect a replacement for another term in consultation with the Director.

d. General Duties and Responsibilities of ICH-IECBMHR Members and Staff

i. ICH-IECBMHR members and personnel should submit their properly signed and updated Curriculum Vitae [Form 2-C], which will be filed at the ICH-IECBMHR Membership File (which the CV, the Terms of Appointment, and copies of Training Certificate of each member)

ii. Members are required to sign ICH-IECBMHR Form 2-D: Confidentiality Agreement and Conflict of Interest Disclosure at the start of their term. The confidentiality agreement protects the privacy and confidentiality of all parties whose information may be disclosed to the IECBMHR in the course of its work

iii. Members should be willing to publish their full name, profession, and affiliation to the ICH-IECBMHR upon request.

iv. Members must commit to record and make available, upon request or demand, all financial relationships, and any conflict of interest within or related to the IECBMHR

v. Members must attend IECBMHR Meetings and participate in discussions and deliberations so that appropriate decisions can be arrived at.

e. Specific Duties and Functions of ICH-IECBMHR Personnel

i. ICH-IECBMHR Chair

- Oversee the whole operations of the ICH-IECBMHR
- Preside over monthly meetings
- Oversee the IECBMHR protocols reviewed by Members and assign primary reviewers to review protocols submitted to the IECBMHR
- Prepare the budget and propose membership
- Represent ICHBMHR in national and international ethics fora
- Ensure IECBMHR compliance with international, national, and institutional policies governing human subject research and human subject protection.
- Recommend updates in IECBMHR policies and procedures in accordance with emerging national and international policy trends
- Recommend policy amendments and changes
- Prepare new IECBMHR documents as needed
- Maintain and update IECBMHR manual of policies and standard operating procedures
- Supervise the issuance of all IECBMHR communication in respect of IECBMHR decisions and actions
- The Chairperson will sign documents and communications related to IECBMHR functioning.
- During IECBMHR meetings, declare any conflict of interest in general and for specific protocols for review

- Recommend to the appointing body any new Member of the IECBMHR in case of vacancy
- Initiate and schedule site visits as needed
- Act on suggestions, complaints, and queries from stakeholders
- The Chairperson will delegate his/ her responsibilities to appropriate individuals in accordance with IECBMHR SOPs.
- In case of anticipated absence, the Chairperson will nominate a committee member as Acting Chairperson. The Acting Chairperson will have all the powers of the Chairperson for that meeting.

ii. ICH-IECBMHR Secretary

- Assist the IECBMHR Chair in overseeing the review of protocols by IECBMHR Members and may, in the absence, on unavailability, of the Chair, assign primary reviewer/s for a submitted protocol
- Oversee preparation and accuracy of the agenda and minutes of the meeting
- Supervise the preparation of communication pertinent to protocol review-related actions to the Principal Investigator
- Perform other IECBMHR-related tasks that may be assigned to him/her by the IECBMHR Chair
- Recommend the development, implementation, and monitoring of IECBMHR policies and procedures to the IECBMHR Chair
- Manage the IECBMHR office under the supervision of the IECBMHR Chair
- Ensure the basic training, orientation, and continuing education of IECBMHR members and staff
- Inform research investigators regarding IECBMHR application processes
- Assist the IECBMHR Chair in budget planning and the preparation and submission of midyear and annual reports to be submitted to the Hospital Director
- Upon directive from the IECBMHR Chair, schedule and lead the IECBMHR in Site Visits or similar activities
- During IECBMHR meetings, declare any conflict of interest in general and for specific protocols for review
- Participate in Site Visits and similar activities as needed
- Perform other IECBMHR-related tasks that may be assigned to him/her by the IECBMHR Chair

iii. ICH-IECBMHR Member

- Make timely and thorough review and decision regarding protocols given to him/her for evaluation (**See SOP 03: *Protocol Review*** for timelines)
- Familiarize him/herself with the SOPs of the IECBMHR, his/her terms of reference, and the international and national guidelines on research ethics

- Participate actively in the monthly meetings and other IECBMHR meetings. It is expected that a member will have at least 75% attendance during the period of appointment because attendance is vital and integral to the effectiveness of the IECBMHR as a review Committee.
- Participate actively in the review of the progress reports, final reports, and other amendments presented during the IECBMHR meeting.
- Participate in Site Visits and similar activities as needed.
- Maintain confidentiality of the documents and deliberations of IECBMHR meetings.
- During IECBMHR meetings, declare any conflict of interest in general and for specific protocols for review.
- Participate in required training as stipulated in **SOP 02 – 6: *Training of IECBMHR Members and Personnel*** with proof of attendance in such training activity submitted to the Secretariat.
- Submit updated and signed curriculum vitae at the start of each calendar year.
- Refer to the IECBMHR Chair any suggestion, complaint, or grievance of research participants, PIs, and/or sponsors for appropriate discussion during the monthly IECBMHR meeting
- Do other IECBMHR-related duties that may be requested of him/her by the Chair.

iv. ICH-IECBMHR Secretariat Staff

- Manage protocol submissions
- Organize an effective and efficient tracking procedure for each protocol received
- Prepare and distribute protocol files for review
- Maintain the ICH-IECBMHR Active Files and Archives, ***Submission Log*** **[IECBMHR –ICH FORM 5-N]**, References and other document files, especially their security and confidentiality
- Organize IECBMHR meetings (see **SOP 03-5: *Conduct of Full Committee Meetings***)
- With the IECBMHR Secretary, prepare and maintain meeting agenda and minutes
- Facilitate requisition and procurement of office supplies and materials
- Inform the IECBMHR members and personnel about training workshops and arrange for the latter's participation in such workshops
- Organize the preparation, review, revision, and distribution of SOPs and guidelines
- To perform any other functions as instructed by Member Secretary/ Chairperson.
- The administrative staff of the Secretariat will be appointed by the IECBMHR and they will be supervised by the Member Secretary.

5. CONFIDENTIALITY/CONFLICT OF INTEREST AGREEMENT WORKFLOW

ACTIVITY	RESPONSIBILITY
Prepare *IECBMHR -ICH Form 2-D: Confidentiality Agreement and Conflict of Interest Disclosure*	Secretariat Staff

↓	
Accomplish *IECBMHR -ICH Form 2-D: Confidentiality Agreement and Conflict of Interest Disclosure* ↓	Chair, , Secretary, Members, Secretariat Staff
Store Documents	Secretariat Staff

a. *DETAILED INSTRUCTIONS:*

Preparation of Confidentiality Agreement (CA) and Conflict of Interest (COI) disclosure forms of the ICH-IECBMHR for Panel Members: The ICH-IECBMHR Secretariat provides a copy of IECBMHR-ICH Form 2-D: *Confidentiality Agreement and Conflict of Interest Disclosure* to new members of the ICH-IECBMHR panel as soon as they are appointed; these are renewed annually.

b. Accomplishment of Forms

i. A copy of IECBMHR-ICH Form 2-D: *Confidentiality Agreement and Conflict of Interest Disclosure* must be filled out and signed by all ICH-IECBMHR personnel. A COI does not necessary disqualify a person from becoming a member of the ICH-IECBMHR for as long as he/she declares it beforehand, understands his/her responsibility as a ICH-IECBMHR member (that is, to provide an unbiased review of a protocol for the protection of research participants), and declines from participating in protocol deliberations when his/her COI could affect the result of board decisions

ii. The ICH-IECBMHR personnel reads, signs the forms, and dates his/her signature on the forms then submits them to the ICH-IECBMHR Secretariat Staff

iii. The ICH-IECBMHR Secretariat Staff accepts the signed/unsigned form, makes duplicate copies of each, and files the originals together with the letter from the Director about the member's appointment, his/her CV and terms of reference, in the ICH-IECBMHR Membership Files.

iv. The Secretariat Staff gives a copy of each signed and dated form to the ICH-IECBMHR Member who must keep them in his/her own personal files

c. Storage of Signed Form in the ICH-IECBMHR Membership Files

i. The Secretariat Staff keeps one (1) copy of the signed and dated **IECBMHR-ICH Form 2-D: *Confidentiality Agreement and Conflict of Interest Disclosure*** in the ICH-IECBMHR Membership File

ii. This form is required to be updated when appointment is renewed.

6. TRAINING OF ICH-IECBMHR MEMBERS AND PERSONNEL WORKFLOW

ACTIVITY	RESPONSIBILITY
Set training requirements ↓	Chair
Find available training, seminars, lectures, workshops /	Members/Secretariat Staff

in clinical research and good clinical practice and SOPs. One training every year at the minimum should be provided.

ii. An individual selected as a new member of the IECBMHR will be required to attend at least one meeting as an 'Observer' before being inducted as a member of the IECBMHR. Member Secretary or an IECBMHR member will provide an introductory training to the new member. The new IECBMHR members would be encouraged to undergo online EC training programme too.

d. Training of the Secretariat

i. The IECBMHR Member Secretary along with other members will train the Secretariat on SOPs. There will be initial training and at least one training session per year on SOPs. The competency of staff in computers and communication skills will be evaluated and ensured initially at the time of appointment by the Member Secretary and Chairperson.

e. Storage and Filing

i. The IECBMHR members' performance is evaluated once a year using **IECBMHR-ICH Form 2-E:** ***Training Record*** to document the training/workshop/conference activities in chronological order. The Chairperson should does self-assessment once a year

ii. The Secretariat Staff makes a copy of the form and files the copy in the ICH-IECBMHR Membership File.

7. SELECTION OF INDEPENDENT CONSULTANTS WORKFLOW

ACTIVITY	RESPONSIBILITY
Invite Independent Consultants to the ICH-IECBMHR ↓	ICH-IECBMHR Chair
Sign conforme and **IECBMHR-ICH Form 2-D: Confidentiality Agreement and Conflict of Interest Disclosure** ↓	Independent Consultant
Appoint the roster of Independent Consultants ↓	ICH-IECBMHR Chair Chief, Medical Professional Staff
Store roster of Independent Consultants in the Independent Consultants File	Secretariat Staff

a. The invitation includes the responsibilities and functions of the Independent Consultant as follows:

i. Accomplish the following forms when requested:

- **□IECBMHR –ICH Form 2-F:** ***Service Agreement for Independent Consultants***

- **IECBMHR-ICH Form 2-D:** ***Confidentiality Agreement and Conflict of Interest Disclosure***

ii. Review assigned protocols that concern his/her specialty using the **IECBMHR-ICH Form 3-G: Assessment Form**

iii. Attend the ICH-IECBMHR meeting when invited where deliberations on said protocols will be made or alternatively, submit results of review to the ICH-IECBMHR Secretariat Staff, if unable to attend the meeting.

iv. Return all protocol-related materials to the ICH-IECBMHR Secretariat Staff after review

v. Submit an updated and signed CV annually.

b. Confirmation of Invitation

i. The Independent Consultant signifies agreement to the invitation by signing the conforme attached to the letter of invitation

ii. The signed conforme is submitted to the ICH-IECBMHR

c. Appointment of Independent Consultants

i. Any member of the ICH-IECBMHR recommends to the IECBMHR Chair a roster of Independent Consultants who have been invited and who have accepted the invitation

ii. The Director is informed of the appointment of an Independent Consultant. The Director is regularly updated on the current roster of Independent Consultants.

iii. The appointment is for three (3) years

iv. Appointment may be terminated by either resignation of the consultant, or by the ICH-IECBMHR Chair

d. Storage of Roster of Independent Consultants

i. The ICH-IECBMHR Secretariat Staff files the appointment-related documents in the Independent Consultants File

ii. The Independent Consultant's File contains the appointee's CV and the originally signed conforme representing the terms of reference of appointment

8. COMPENSATING MEMBERS AND CONSULTANTS WORKFLOW

ACTIVITY	RESPONSIBILITY
Recommend Honorarium ↓	ICH-IECBMHR Chair
Approved Honorarium ↓	Director
Communicate Honorarium Information to Personnel and Independent Consultants	Secretariat Staff

a. Recommendation of Honorarium

i. The ICH-IECBMHR Chair initiates the recommendation of honorarium, or increase thereof, after a dialogue with ICH-IECBMHR Members and subsequent approval by the Hospital Director

ii. The compensation for IECBMHR members covers a fixed amount for review of protocols, henceforth referred to as "Reviewers' Fee".

iii. The amount of reviewers' fee is determined and fixed by an existing memorandum issued and approved by the Hospital director

iv. Only the IECBMHR members who actually reviewed a submitted protocol and participated in the deliberation towards its ultimate approval or disapproval will receive a share of the reviewers' fee.

v. The compensation may or may not include a fixed amount for attending meetings and other ICH-IECBMHR related-activities

vi. The fee of independent consultant will be a fixed amount (Rs.1, 500.00) that covers initial review and subsequent review of submitted documents for approval by the Committee.

vii. The recommendation for the honorarium of IECBMHR members and Independent Consultants will be submitted to the Director through submission of the IECBMHR budget.

b. Approval of Honorarium

i. The Director may approve or disapprove the recommendation

ii. Approval or disapproval will be indicated in the approval of the IECBMHR budget or amendment thereof

c. Communication of Honorarium Information

iii. The ICH-IECBMHR Members are informed of the honorarium package both upon appointment and whenever there are changes subject to the governing rules and regulations.

iv. ICH-IECBMHR personnel and Independent Consultants acknowledge the information upon receipt of notification

9. Financial Policies and Procedures

ACTIVITY	**RESPONSIBILITY**
Recommend Honorarium ↓	ICH-IECBMHR Chair
Approved Honorarium ↓	Director
Communicate Honorarium Information to Personnel and Independent Consultants	Secretariat Staff

a. Purpose: The obligation of IECBMHR is to comply with the financial management for ethics committee functioning as well as internal financial policies, procedures and processes that have been established to execute effective EC operations. The SOP shall enable the committee to maintain financial transparency regarding its activities and functioning.

b. Scope: This SOP covers the procedures for receiving payments and disbursement, maintaining financial records, audit reports and declarations, and IECBMHR budget allocation. It also defines the

responsibilities of accounts manager and the head of the institute in the financial management of IECBMHR.

c. **Responsibility:** It is the responsibility of the Member Secretary to coordinate with the Accounts Manager of the Institute to inform regarding the financial requirements of the IECBMHR. The IECBMHR secretariat will receive payments for services offered and keep a record, which will be promptly handed over to the accounts department. The Accounts manager or his designee will perform and maintain the records of the financial transactions with the approval of the Head of the institute. In addition, it will maintain the accounts of the IECBMHR and generate audit reports as and when necessary and will participate in budget allocation. All financial decisions regarding revenue and expenditure will be approved by the Head of the Institute, in consultation with the Chief Accountant.

d. Budget Planning and Preparation

i. A budget is prepared at the beginning of a financial year (April month of each year) and represents the best estimation by the IECBMHR office of what is needed to carry out the proposed activities of the EC.

ii. A complete budget includes direct and indirect costs.

iii. Direct costs that are paid in cash include meeting refreshments, purchasing stationary and supplies and local travel. Direct costs that are paid in kind include salary for existing staff, professional membership fees, honorarium to members, and purchase of office furniture and equipments.

iv. Indirect or overhead costs include the ongoing expenses of operating an office (e.g. costs associated with facilities and basic utilities), repair of office equipment, administration fees, and basic communication devices.

v. The complete budget details all direct and indirect costs associated with the EC (cash and in kind), classified in such a way that all stakeholders understand what costs will be covered and by whom.

vi. The EC budget is an integral part of the hospital's financial management and must be developed with ICH accounts department and the head of the Institute. The HOI must provide written approval of an expenditure plan and related budget for internal and external funding opportunities.

e. Expenditures: IECBMHR practice regarding specific expenses that is commonly made is outlined below. Expenses not listed below will be managed on a case –by –case basis.

i. Salaries: Employees may be directly compensated for their time spent working on administrative jobs related to IECBMHR office functioning.

ii. Professional Membership Fees: All members will receive professional fees towards travel and other expenses in every EC meeting. The HOI will take a decision regarding the fee structure in consultation with the Chief Accountant.

iii. Equipment: Funding to purchase equipment and the costs associated long term storage and maintenance costs, will be discussed and managed on a case –by -case basis.

iv. Consulting fees: Where possible, the expertise needed to complete a particular assignment of EC may be hired against agreed consulting fees.

v. Travel: Reasonable local travel costs shall be reimbursed on actual.

vi. Conference attendance & travel: Travel and registration costs for attending conferences, workshops and training will be funded at the sole discretion of the HOI.

vii. IECBMHR Registration and Accreditation Expenditures: Necessary registration and accreditation related expenditures of IECBMHR will be drawn from IECBMHR account with the approval of HOI.

f. Procedures:

i. All financial EC transactions will be assigned a unique account number for tracking expenses by the accounts department. All expenses must be charged directly to the EC account wherever possible.

ii. All bills for payment in cash (minor) must be forwarded with filled in voucher to the accounts manager only after it is approved by the member secretary.

iii. All direct expenses made in cash (minor) must be forwarded for reimbursement with filled in voucher to the accounts manager only after it is approved by the member secretary.

iv. All bills generated for payment of consultation fees/ honorarium / purchase of equipment and other major expenses must be forwarded to the accounts manager only after it is approved by the Director of the Institute.

v. Out of pocket expenses towards attending a training programme/ conference in ethics can be reimbursed on providing valid receipt of payment and proof of attendance. Travel costs must be approved in advance.

vi. To order supplies/ equipments/ furniture for the IECBMHR office, the member secretary or a designate must forward to accounts manager either 1) an invoice/quote from the supplier or 2) detailed information about the specific item to be purchased. It is the responsibility of the member secretary to ensure that all details regarding the materials and supplies to be purchased are correct and to get the matter approved by the Head of Institute.

g. Revenue: The IECBMHR receives revenue in cheque or bank transfer for the services offered from the sponsors of the research study.

i. The IECBMHR Secretariat will receive the IECBMHR fees as cheque in the name of the designated account or bank transfer, with a letter in duplicate from the PI to the Member Secretary outlining the details and mode of payment.

ii. The IECBMHR Secretariat will immediately transfer the cheque with the original letter to the Accounts manager or his designate. The accounts manager will receive the same with his initials signed and dated on the duplicate letter. The Secretariat will retain the same for records. In case of

bank transfer, the Accounts manager will sign on the duplicate letter as an acknowledgement of the transfer of IECBMHR fees to the Institute's account.

iii. The Accounts manager will keep copies of all such transactions and maintain the account for revenue of IECBMHR.

h. Audit Reports: An audit report of IECBMHR account will be obtained by the Head of the Institute, with a copy forwarded to the IECBMHR secretariat for records.

10. Periodic Self Assessment, Root Cause Analysis and IECBMHR Annual Report

ACTIVITY	**RESPONSIBILITY**
Periodic Self Assessment (Twice a year) ↓	Secretariat Staff
Reviewed in Full Board Meeting ↓	ICH-IECBMHR Chair
System failures addressed, RCA and CAPA done; documented ↓	Primary Members
Follow up and Improvements discussed in Full Board Meeting ↓	ICH-IECBMHR Chair
Annual report published (end of calendar year) Copy to Director, ICH	Secretariat Staff

a. Periodic Self Assessment

i. ICH IECBMHR conducts self evaluation twice a year. Evaluation is done by the IECBMHR Secretariat under the supervision of the Member Secretary

ii. The evaluation is done using three broad approaches: Evaluation of Structure, Process and Outcome with the help of Checklist (Form 2J: Checklist for Periodic Self Assessment)

iii. Statistical analyses of the checklist parameters are performed to review the performance of the IECBMHR.

iv. The self assessment review is discussed in the full board IECBMHR meeting and system failures are identified

v. The Chair after discussion with members suggests means of corrections and improvement if necessary. This is recorded in the minutes of the meeting.

b. Root Cause Analysis

i. System failures identified through periodic self assessments are subject to corrective action following root cause analyses (RCA). Preventive actions are taken when applicable. The Chair appoints one or two primary members for the purpose.

ii. Members perform CAPA (Correction action and Preventive Action) which are documented in the Non-Compliance (NC) log (Form 2K: NC with RCA and CAPA).

iii. The log is sent to the Chair for review and approval.

iv. CAPA may be discussed in the next IECBMHR meeting under the instruction of the Chair.

v. Steps for improvement may be undertaken to reduce recurrent system failures and increasing efficiency of the IECBMHR as suggested by members. These shall be recorded in the minutes of the meeting.

c. Publication of Annual Report

i. IECBMHR Secretariat will prepare an annual activity report of the IECBMHR for submission to the Director of the Institute.

ii. The Annual Report is placed for review at the first meeting of the calendar year.

iii. It includes the following elements:

- A quantitative evaluation of the activities of the committee in a year
- The list of the proposals reviewed in a year
- Status of each study proposal

11. LIST OF FORMS

Nomenclature	Subject
IECBMHR Form 2A:	Medical / Scientific Member Notification and Appointment
IECBMHR Form 2B	Non Medical / Lay Member Notification and Appointment
IECBMHR Form 2C:	Curriculum Vitae
IECBMHR Form 2D:	Confidentiality Agreement and Conflict of Interest Disclosure
IECBMHR Form 2E:	Training Record
IECBMHR Form 2F:	Service Agreement for Independent Consultants
IECBMHR Form 2G:	IECBMHR Budget (Financial Year)
IECBMHR Form 2H	Records of Income (Financial Year)
IECBMHR Form 2I	Records of Expense (Financial Year)
IECBMHR Form 2J:	Checklist for Periodic Self Assessment
IECBMHR Form 2K:	NC/ CAPA Record
IECBMHR Form 2L	Renewal of Appointment

No.:ICH/...../20..... Date: .....

Name, Qualification,
Designation
Address

Subject: Letter of Engagement for the post of .....

Dear Dr. .....,

As per our discussions we are pleased to issue your letter of engagement as ....., Institutional Ethics Committee For Biomedical and Health Research -Institute of Child Health, Kolkata with effect from.....
Brief term & conditions are as mentioned bellow:

SCOPE: The Institutional Ethics Committee For Biomedical and Health Research -Institute of Child Health is engaged in to protect potential participants in research, taking into account potential risks and benefits for the community in which the research will be carried out and to promote high ethical standards in research for health. In order to achieve the above objective, the Institutional Ethics Committee For Biomedical and Health Research -Institute of Child Health is engaging you as .....

NATURE:

- You shall be engaged as .....
- You shall be attending all the meetings of Institutional Ethics Committee For Biomedical and Health Research -Institute of Child Health, Kolkata.
- The date of the meeting will be intimated to you through electronic mail from the office of the Secretariat, Ethics Committee.
- In case of any urgent requirement of Ethics Committee you are expected to co-operate with all the other members of the Committee.
- You shall well versed with the System of Procedure (SOP) of Institutional Ethics Committee For Biomedical and Health Research -Institute of Child Health.

RESPONSIBILITY:

- Be accountable for detailed review of the protocol and other study-related documents, in reference to-
  1. Scientific aspects, considering particularly the study rationale, objectives, research design, the nature of intervention, the statistics proposed, and
  2. Ethical aspects- benefit-risk analysis, protocol specified SAE reporting and management strategy, medical management of SAE and compensation for study-related injury, and disclosure in informed consent document
- Ensure through continuous review that the study is conducted as per the protocol, ethics guidelines and regulatory provisions, as applicable.

TENURE: Your engagement shall be with us as ..... for a period of 3(Three) Years, with effect from ..... to .....

EMOLUMENTS: In consideration of the services rendered by you, you shall be paid a consolidated fees of Rupees 3,000/- (Rupees Three Thousand Only) per Meeting, which will be subjected to tax deduction at source as applicable. You shall be responsible for any applicable tax on all your personal income and shall indemnify and hold harmless the Ethics Committee for any liability in this connection.

PLACE OF MEETING: Place of Meeting shall be at Seminar Hall- Institute of Child Health, Kolkata. However, you may be required to go anywhere within the country as and when needed if the Ethics Committee so desire based on the requirement. Short term relocation will also be applicable to you.

REPORTING: You will report to Member Secretary/ Chairperson of Institutional Ethics Committee For Biomedical and Health Research -Institute of Child Health, Kolkata or any other Supervisor duly authorized by competent authority as and when required.

Confidentiality of Information: You will not, during the continuance of this engagement and thereafter, disclose, divulge or communicate to any interested or other persons, whatsoever any information relating to the committee's technical knowhow, practice or any other information of a confidential character. You will treat information obtained by you during the course of your engagement with the Committee, either directly or form the other associates of the Committee, as strictly confidential. Such information may include without limitation, the Committee's finances, mode of operation, information relating to research, development, secret, contact names, address, phone numbers, email ids etc.
You shall not divulge/share any administrative /Organizational matter of the committee with any outsiders which may be your personal privilege to know by virtue of being an associate of this committee or any such other information, the disclosure of which in the opinion of the organization, is likely to be prejudicial to the interests of the committee.
Further you shall not divulge to anyone else any information relating to hardware, software, database, strategies, finance, methodologies, future plans, drawings and diagrams of Institutional Ethics Committee for Biomedical and Health Research-Institute of Child Health, Kolkata.

REGISTRATION OF DEGREE:

(a) Your engagement is being done keeping in view your express representation to the Hospital and validation of qualification, experience and registration documents that you have valid registration of the basic medical degree with the concerned State Medical Council.
(b) You shall maintain the validity of the aforesaid registration(s) during the entire Term of your engagement and renew the same from time to time at your cost, expense and sole responsibility. In the event, you fail to maintain the validity and/or renew the registration (s) within stipulated periods as prescribed under any applicable regulation the engagement will cease to be valid and the Ethics Committee at its sole discretion would be liberty to forthwith terminate this engagement without notice.

(c) If you hold or subsequently acquire any post-graduation or higher degree/diploma and/or super specialization you will ensure its registration thereof in terms of specific legislation/ regulation as applicable and keep the Hospital duly informed and shall submit all supporting documents in relation thereto within 30 days of obtaining requisite degree/ diploma /certificate.

EXCLUSIVITY: Your engagement with Institutional Ethics Committee For Biomedical and Health Research as a .....is on the condition that you will be working ONLY and EXCLUSIVELY with Institutional Ethics Committee, no way with the Institute of Child Health, Kolkata and any Breach of Contract in this regard may lead to legal action.

MISCONDUCT: At any time during this engagement if you found guilty of misconduct or any wilful breach or continuous negligence of the terms of this engagement or dereliction of the duties and/or instruction given to you from time to time by the Member Secretary and/or Chairman, the Chairman may without prejudice to any other action as may be called for, without any notice or payment in lieu of any notice, put an end to and determine the engagement of you with the Ethics Committee, without prejudice to above. You shall be deemed to have brought about such a situation by your misconduct compelling the Ethics Committee to put an end to your engagement and you shall, therefore, continue to be liable for all losses and/or damages to the Ethics Committee.

Further the Hospital authority shall have the right to seek such remedies at law or in equity against you including but not limited to terminate this association forthwith without any notice. In this case, the cost of such loss of the Organization will also be recovered from you.

TERMINATION:

(a) This engagement can be terminated by giving 1 (One) month of notice.
(b) This engagement shall be terminated with immediate effect upon the occurrence of any of the following:

1. death of the concerned;
2. providing false, inaccurate or incomplete information to the Ethics Committee regarding your educational background, registration.
3. your conduct is considered by the Ethics Committee as detrimental to its interest or in violation of one or more terms of this engagement letter, code of conduct of the Ethics Committee or you fail or refuse to carry out your obligations herein;
4. expiry of Registration certificate issued by Medical Council of India and/or WB State Medical Council as the case maybe and the same being not renewed within stipulated period as prescribed in terms of any specific regulation or otherwise;
5. commit any act of gross misconduct
6. commit any serious breach or repeat or continue to commit a material breach of the terms of your association with the Ethics Committee;
7. are guilty of conduct tending to bring yourself or the Ethics Committee into disrepute;
8. are convicted of a criminal offence, other than a road traffic offence for which you are not convicted to a term of imprisonment whether immediate or suspended
9. are found in an act of moral turpitude or to have indulged in violations of any laws, rule or regulations as applicable generally or in respect of the Ethics Committee.
10. refuse or fail to carry out your duty and/ or obligations; commit or be guilty of sexual harassment.
11. refuse or fail to carry out your obligations without reasonable cause.

We take this opportunity to congratulate you on your engagement with the Institutional Ethics Committee for Biomedical and Health Research-Institute of Child Health, Kolkata and look forward to a long term mutually beneficial relationship. You are requested to sign and return the duplicate copy of this letter as token of your acceptance and collect your Hard Copy of

engagement letter from the office of the Member Secretary, of Institutional Ethics Committee For Biomedical and Health Research -Institute of Child Health, Kolkata.

Your previous agreement with us will be declared null and void after acceptance of this letter.

You are required to submit the following documents time of joining & collect your letter:

a) Your Graduate, post graduate and Other degrees and other Academic & Work Related Testimonials
b) 2 recent Photographs with MCI Registration.
c) List your professional attachment
d) Your Date of Birth Certificate/Passport Copy
e) Your PAN card copy & Voter's ID card
f) Your professional indemnity Insurance certificate and other documents you may want to submit.

Thanking You,
Yours faithfully,

For Institutional Ethics Committee For Biomedical and Health Research - Institute of Child Health, Kolkata.

_____

Director, ICH

Accepted
I have read all the terms and conditions of this letter of engagement on contract and confirm my acceptance of the same.

_____

Name .....
Date:

<dd-mm-yyyy>

<Name, Qualification,
Designation
Address>

No.:
Date: DD/MM/YYYY

Name, Qualification,
Designation
Address

Subject: Letter of Engagement for the post of .....

Dear .....,

Apropos our discussions we are pleased to issue your letter of engagement as....., **Institutional Ethics Committee for Biomedical and Health Research-Institute of Child Health, Kolkata** with effect from DD/MM/YYYY, Brief term & conditions are as mentioned bellow:

SCOPE: The Institutional Ethics Committee for Biomedical and Health Research of Institute of Child Health is engaged in to protect potential participants in the research, taking into account potential risks and benefits for the community in which the research will be carried out and to promote high ethical standards in research for health. In order to achieve the above objective, the Institutional Ethics Committee for Biomedical and Health Research for Biomedical and Health Research of Institute of Child Health is engaging you as .....

NATURE:

- You shall be engaged as .....,
- You shall be attending all the meetings of Institutional Ethics Committee for Biomedical and Health Research of Institute of Child Health, Kolkata.
- The date of the meeting will be intimated to you through electronic mail from the office of the Secretariat, Ethics Committee.
- In case of any urgent requirement of Ethics Committee you are expected to co-operate with all the other members of the Committee.
- You shall be well versed with the Standard Operating Procedures (SOPs) of The Institutional Ethics Committee for Biomedical and Health Research of Institute of Child Health.

RESPONSIBILITY:

- Be accountable for detailed review of the protocol and other study-related documents, in reference to-
  1. Ethical review of the proposal, Informed Consent Documents with the translations
  2. Evaluate benefits and risks from the participants perspective and opine whether benefits justifies the risks

3. Serve as a patient/participant/societal/community representative and bring in ethical and societal concerns
4. Assess on societal aspects if any

- Ensure through continuous review and monitoring that the study is conducted as per the protocol, ethics guidelines and regulatory provisions, as applicable.

TENURE: Your engagement shall be with us as Lay Person for a period of 3(Three) Years, with effect from DDD/MMM/YYYY to DDD/MMM/YYYY.

EMOLUMENTS: In consideration of the services rendered by you, you shall be paid a consolidated fees of Rupees 3,000/- (Rupees Three Thousand Only) per Meeting, which will be subjected to tax deduction at source as applicable. You shall be responsible for any applicable tax on all your personal income and shall indemnify and hold harmless the Ethics Committee for any liability in this connection.

PLACE OF MEETING: Place of Meeting shall be at Seminar Hall, Institute of Child Health, Kolkata. However, you may be required to go anywhere within the country as and when needed if the Ethics Committee so desire based on the requirement. Short term relocation will also be applicable to you.

REPORTING: You will report to the **Chairperson/Member secretary, Institutional Ethics Committee for Biomedical and Health Research - Institute of Child Health, Kolkata,** or any other Supervisor duly authorized by competent authority as and when required.

Confidentiality of Information: You will not, during the continuance of this engagement and thereafter, disclose, divulge or communicate to any interested or other persons, whatsoever any information relating to the committee's technical knowhow, practice or any other information of a confidential character. You will treat information obtained by you during the course of your engagement with the Committee, either directly or form the other associates of the Committee, as strictly confidential. Such information may include without limitation, the Committee's finances, mode of operation, information relating to research, development, secret, contact names, address, phone numbers, email ids etc.
You shall not divulge/share any administrative /Organizational matter of the committee with any outsiders which may be your personal privilege to know by virtue of being an associate of this committee or any such other information, the disclosure of which in the opinion of the organization, is likely to be prejudicial to the interests of the committee.
Further you shall not divulge to anyone else any information relating to hardware, software, database, strategies, finance, methodologies, future plans, drawings and diagrams of **Institutional Ethics Committee for Biomedical and Health Research-Institute of Child Health, Kolkata.**

REGISTRATION OF DEGREE:

(a) Your engagement is being done keeping in view your express representation to the Committee and validation of qualification, and experience

(b) If you hold or subsequently acquire any post-graduation or higher degree/diploma and/or super specialization you will ensure its registration thereof in terms of specific legislation/ regulation as applicable and keep the Secretariat duly informed and shall submit all supporting documents in relation thereto within 30 days of obtaining requisite degree/ diploma /certificate.

EXCLUSIVITY: Your engagement with Institutional Ethics Committee for Biomedical and Health Research as a ..... is on the condition that you will be working ONLY and EXCLUSIVELY with Institutional Ethics Committee for Biomedical and Health Research, no way with the Institute of Child Health, Kolkata and any Breach of Contract in this regard may lead to legal action.

MISCONDUCT: At any time during this engagement if you found guilty of misconduct or any wilful breach or continuous negligence of the terms of this engagement or dereliction of the duties and/or instruction given to you from time to time by the Member Secretary and/or Chairman, the Chairman may without prejudice to any other action as may be called for, without any notice or payment in lieu of any notice, put an end to and determine the engagement of you with the Ethics Committee, without prejudice to above. You shall be deemed to have brought about such a situation by your misconduct compelling the Ethics Committee to put an end to your engagement and you shall, therefore, continue to be liable for all losses and/or damages to the Ethics Committee.

Further the Hospital authority shall have the right to seek such remedies at law or in equity against you including but not limited to terminate this association forthwith without any notice. In this case, the cost of such loss of the Organization will also be recovered from you.

TERMINATION:

(a) This engagement can be terminated by giving 1 (One) month of notice.
(b) This engagement shall be terminated with immediate effect upon the occurrence of any of the following:

1. death of the concerned;
2. providing false, inaccurate or incomplete information to the Ethics Committee regarding your educational background.
3. your conduct is considered by the Ethics Committee as detrimental to its interest or in violation of one or more terms of this engagement letter, code of conduct of the Ethics Committee or you fail or refuse to carry out your obligations herein;
4. commit any act of gross misconduct
5. commit any serious breach or repeat or continue to commit a material breach of the terms of your association with the Ethics Committee;
6. are guilty of conduct tending to bring yourself or the Ethics Committee into disrepute;
7. are convicted of a criminal offence, other than a road traffic offence for which you are not convicted to a term of imprisonment whether immediate or suspended
8. are found in an act of moral turpitude or to have indulged in violations of any laws, rule or regulations as applicable generally or in respect of the Ethics Committee;
9. refuse or fail to carry out your duty and/ or obligations; commit or be guilty of sexual harassment.
10. refuse or fail to carry out your obligations without reasonable cause.

We take this opportunity to congratulate you on your engagement with the Institutional Ethics Committee for Biomedical and Health Research, Institute of Child Health, Kolkata and look forward to a long term mutually beneficial relationship. You are requested to sign and return the duplicate copy of this letter as token of your acceptance and collect your Hard Copy of engagement letter from the office of the Member Secretary, of Institutional Ethics Committee for Biomedical and Health Research, Institute of Child Health, Kolkata

Your previous agreement with us will be declared null and void after acceptance of this letter.

You are required to submit the following documents time of joining & collect your letter:

a) Your Graduate, post graduate and Other degrees and other Academic & Work Related Testimonials
b) 2 recent Photographs.
c) List your professional attachment
d) Your Date of Birth Certificate/Passport Copy
e) Your PAN card copy & Voter's ID card

Thanking You,
Yours faithfully,

For Institutional Ethics Committee for Biomedical and Health Research, Institute of Child Health, Kolkata

_____

Director, ICH

Accepted
I have read all the terms and conditions of this letter of engagement on contract and confirm my acceptance of the same.

.....
Date: .....

FORMAT FOR BIODATA

1. Name:
2. Address (full work address):
3. Telephone number: E-mail-ID:
4. Present affiliation (Job title, department, and organisation):
5. Affiliation with host institute: **Yes/ No**
6. Qualification (starting from highest):

COURSES/SUBJECT	ORGANIZATION	YEAR

7. Previous and other affiliations (Include previous affiliations in the last 5 years and other currentaffiliations):

AFFILIATION	DESIGNATION	DURATION

8. Role in proposed Ethics Committee (Dual Role if any):

9. Suitability as per the role:

10. Additional Questions (if applicable):
    a. **Chairperson**: Previous EC experience: **Yes/ No**
    b. **Member Secretary**: Knowledge and experience in clinical research and ethics: **Yes/ No**
    c. **Lay person**: Not pursued a career in a medical science/ health related career in last 5 years:

    Yes/ No

    d. **Other EC Members:** Previous EC Experience: **Yes/ No**

11. Relevant research training/experience in the area*:

Name of Ethics Course/ Training	Organized By	Date	Duration of Training	Attach Agenda/ Topics Covered

12. Relevant publications and additional information (if any):

Signature: **Date:**

* *Details must primarily include training in ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017, GCP Guidelines (if applicable), New Drugs and Clinical Trials (NDCT) Rules, 2019, EC Functions & SOPs and relevant regulations of the country.*

FORMAT FOR BIODATA

1. Name:
2. Address (full work address):
3. Telephone number: E-mail-ID:
4. Present affiliation (Job title, department, and organisation):
5. Affiliation with host institute: **Yes/ No**
6. Qualification (starting from highest):

COURSES/SUBJECT	ORGANIZATION	YEAR

7. Previous and other affiliations (Include previous affiliations in the last 5 years and other currentaffiliations):

AFFILIATION	DESIGNATION	DURATION

8. Role in proposed Ethics Committee (Dual Role if any):

9. Suitability as per the role:

10. Additional Questions (if applicable):
    a. **Chairperson**: Previous EC experience: **Yes/ No**
    b. **Member Secretary**: Knowledge and experience in clinical research and ethics: **Yes/ No**
    c. **Lay person**: Not pursued a career in a medical science/ health related career in last 5 years:

    Yes/ No

    d. **Other EC Members:** Previous EC Experience: **Yes/ No**

11. Relevant research training/experience in the area*:

Name of Ethics Course/ Training	Organized By	Date	Duration of Training	Attach Agenda/ Topics Covered

12. Relevant publications and additional information (if any):

Signature: **Date:**

* *Details must primarily include training in ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017, GCP Guidelines (if applicable), New Drugs and Clinical Trials (NDCT) Rules, 2019, EC Functions & SOPs and relevant regulations of the country.*

INSTITUTE OF CHILD HEALTH
INSTITUTIONAL ETHICS COMMITTEE FOR BIOMEDICAL AND HEALTH RESEARCH
11, Dr. Biresh Guha Street, Kolkata 700017,
Telephone No. 033 2290 5686, 9073687795
Email: iecbmhrich@gmail.com Website: www.ichcal.org

CONFIDENTIALITY AGREEMENT AND CONFLICT OF INTEREST DISCLOSURE

The following terms and conditions covering Confidentiality and Conflict of Interest arising in the discharge of a ICH-Institutional Ethics Committee Member's functions are hereby stipulated in this Agreement for purpose of ensuring the same high standards of ethical behaviour necessary for the IECBMHR to carry out its mandate. This agreement binds the Undersigned to assess research studies and protocols involving human subjects in order to ensure that the same are conducted in a humane and ethical manner, with the highest standards of care according to the applied national and local laws and regulations, institutional policies and guidelines.

CONFIDENTIALITY

The undersigned as a member of the IECBMHR is based on individual merits and not as an advocate or representative of a territory or community nor as a delegate of any organization or private interest;

Whereas, the fundamental duty of an IECBMHR member is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions under review;

Whereas, the IECBMHR must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of research participants;

The undersigned, as a member of the IECBMHR, is expected to meet the same high standards of ethical behaviour 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 IECBMHR. 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 and 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 IECBMHR.

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 the Institute's policies and any contractual obligations they may have to third parties.

CONFLICT OF INTEREST

- It is recognized that the potential for conflict of interest will always exist. There is concomitant faith, however, in the ability of the ICH-IECBMHR to manage these conflict issues, in such a way that the ultimate outcome of the protection of human subjects remains.

- It is the policy of the IECBMHR that no member may participate in the review, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the ICH-IECBMHR

- The Undersigned will immediately disclose to the ICH-IECBMHR Chair any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the Board, and to abstain from any participation in discussion or recommendations in respect of such proposals

- If an applicant submitting a protocol believes that a ICH-IECBMHR 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 Chair. The request must contain evidence that substantiates the claim that a conflict of interest exists with the ICH-IECBMHR Member(s) in question. The Board may elect to investigate the applicant's claim of the potential conflict

- When a member has a conflict of interest, the member should notify the Chair and may not participate in the ICH-IECBMHR review or approval except to provide information requested by the Board.

AGREEMENT ON CONFIDENTIALITY AND CONFLICT OF INTEREST

In the course of my activities as a member of the ICH-IECBMHR, I will be provided with confidential information and documentation referred to as the "Confidential Information". I shall take reasonable measures to protect the Confidential Information, subject to applicable legislation, not to disclose the Confidential Information for any purpose outside the Board'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 Board duties) to the Chair upon termination of my functions as a member.

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

I have read and accept the aforementioned terms and conditions as explained in this Agreement.

_____
(Printed name & signature)
Date:

Noted by:

Dr.Phalguni Dutta
Chair, ICH-Institutional Ethics Committee, BMHR
Date:

Institutional Ethics Committee For Biomedical and Health Research, Institute of Child Health, Kolkata					
Budget Estimate for the year: April YYYY to March YYYY					
CATEGORY			**BUDGET**	**ACTUAL**	**UNDER / OVER**
Total Income					
Total Expenses					
Income					
Institutional Ethics Committee Fees					
Expenses					
Fees					
Honorarium (members)					
Audit fees					
Fees for consultancy					
Registration & Accreditation Fees					
Salary (Secretariat Staff)					
Refreshment (Meeting)					
Training Workshop					
Attending outside Training/ Conference/ etc					
Travelling					
Postage & Telegraph					
Printing					
Telephone					
Purchasing Stationary					
Purchase of office furniture					
Purchase of equipments					
Repairing of office equipments					
Miscellaneous Expenses					

			TOTAL	TOTAL	TOTAL

RECORD OF INCOME (FINACIAL YEAR)

S. No	Date of Receipt	Project No	Short Title/ Code	PI	Sponsor Name	Cheque No	Date of Issue	Amt INR	Type of Meeting/ Submission Type	Remarks if any

RECORD OF EXPENSES (FINACIAL YEAR)

S. No	Date of expenditure	Head of expenses	Amt INR	Approved By	Remarks if

REVIEW CHECKLIST FOR PERIODIC SELF ASSESSMENT OF IEC

A1. Evaluation of structure - IECBMHR composition and qualifications

IECBMHR MEMBER CHARACTERISTICS	
Number of IECBMHR Members	
TOTAL	
By affiliation	
ICH Staff (Academic/ Non-Academic)	
Non- Affiliated to ICH	
By expertise	
Physician (MD)	
Scientist	
Social Scientist/ Ethicist/Theologian	
Lawyer	
Lay Person	
By gender distribution	
Male	
Female	
Age	
Mean (Min-Max)	
Reviewers of Protocol	

A2. Evaluation of Structure - IECBMHR workload & number of meetings & protocols/documents reviewed

	Meetings	Date
1.	Regular/Special	
2.		
3		
4.		
5.		
6.		

	Non Regulatory Stud (IIT/ Academic/Thesis)	
	Convened	Expedited
New Study		
Resubmitted Study		
Amendment Study		
Continuing Study		
Study reporting deviation		
Study Reporting AE/SAE		
Discontinued/ Terminated Study		
Closed Study		

Year: xxxx		
Total no of projects reviewed by IECBMHR		
Type of Study	Phase I	

REVIEW CHECKLIST FOR PERIODIC SELF ASSESSMENT OF IEC

	Phase II	
	Phase III	
	Phase IV	
	Phase II/III	
	Observational/ Others	

B1. Evaluation of Process – Timelines of protocols review

New Non-Exempt Study			
Days from Protocol Submission to Investigator Notification	Xx days	Average (SD)	Median (min-max)
	Convened Review		
	Expedited Review		
Total Days From Submission to Final Approval	Xx days		
	Convened Review		
	Expedited Review		
Number of Times a New Study is Amendment	None	N(%)	
	1	N(%)	
	2	N(%)	
	>2	N(%)	
Amended Study			
Total Days From Submission to Final Approval	Xx days		
	Convened Review		
	Expedited Review		

C1. Evaluation of Outcome – Ethical Issues notified to researcher

REVIEW CHECKLIST FOR PERIODIC SELF ASSESSMENT OF IEC

Number of New Non-Exempt Studies with Issues Requested for Revisions [Note: A study may have more than one issue (as shown on IRB initial review & meeting)]		
Research Question		
Objectives		
Risk & Benefit		
Study Design		
Research Methodology		
Sample Size		
Inclusion/ Exclusion Criteria		
Recruitment Process		
Specimen Data Collection (Amount/Procedure)		
Statistical & data analysis		
Privacy and Confidentiality		
Informed Consent (Document +Process]		
Participant Information Sheet		
Informed Consent Form		
Assent Form		
AV Consent Form		
Study Documents		
Related study documents (IB, Advertisement etc)		
Case Record Form		
Research facilities		
Trial Agreement		
Budgeting		
Insurance		
Compensation		

B2. Evaluation of Outcome – Decision on projects submitted at the end of Year xxxx

Year xxxx	Projects Reviewed	Under Process	Approved	Approved after Defer	Deferred	Disapproved
Academic						
Thesis						

D. Annual Evaluation:

Total active (ongoing) projects of IECBMHR as on 31st December xxxx

Year	Pharmaceutical	Academic	IIT	PGT Thesis	Year Wise Total Active
YYYY					
YYYY					
YYYY					
YYYY					
YYYY					
Total Active					

REVIEW CHECKLIST FOR PERIODIC SELF ASSESSMENT OF IEC

INSTITUTE OF CHILD HEALTH
INSTITUTIONAL ETHICS COMMITTEE FOR
BIOMEDICAL AND HEALTH RESEARCH
11, Dr. Biresh Guha Street, Kolkata 700017
Telephone No.: (033 2290 5686, 9073687795)

Instructions:

1. Person observing non-conformity shall fill-in sections 1, 2, 3.
2. Assigned Reviewer (Internal EC Auditor) shall fill-in sections 4, 5, 6 and will be approved by Chair.
3. Chair shall fill-in sections 7, 8 and 9

NC № NC- nnn/ yy	**Non-conformity/Corrective & Preventive Action Report (NC/CAPA R)**	Date NC Found:
Section where NC is found:		
1. DETAILS: Nonconformity raised as a result of:		
☐ Internal audit	☐ Customer complaint	☐ Incident_____☐ Others
☐ Process non-conformity	☐ Suggestion (improvement)	
2. REFERENCES: Documents used or referred-to (e.g. manuals, procedures, flowcharts, standards, records …)		
3. NON-CONFORMITY: Description of nonconformity, suggestion, complaint or incident.		
Detected or Observed by:	Affiliation:	
4. IMMEDIATE ACTION: Immediate remedial action		
Proposed by:	Date:	Implementation date:
5. INVESTIGATION: Cause of nonconformity:		
Investigated by:	Date investigation started:	
	Date investigation finished:	

6. CORRECTIVE/PREVENTIVE ACTION: (Preventive action is only required for **potential non-conformities**). Fill ONLY EITHER "Corrective Action" OR "Preventive Action"	
Corrective Action:	Preventive Action:

Proposed by:	Date: Proposed implementation date:

7. VERIFICATION OF VALIDITY OF CORRECTIVE "or" PREVENTIVE ACTION:

☐ Addresses the root cause? ☐ Prevents recurrence? ☐ Valid ☐ Invalid. Issue new NC CAPA R Remarks: _____	☐ Addresses the root cause? ☐ Prevents occurrence? ☐ Valid ☐ Invalid. Issue new NC CAPA R Remarks: _____
Signature: (Internal Auditor) / Date:	Signature: (Internal Auditor) / Date:

8. FOLLOW-UP OF IMLEMENTATION CORRECTIVE/PREVENTIVE ACTION TAKEN:

Implementation of corrective action is: ☐ Implemented ☐ Not implemented. Issue new NC CAPA R Remarks: _____	Implementation of preventive action is: ☐ Implemented ☐ Not implemented. Issue new NC CAPA R Remarks: _____
Signature: (Chair) / Date:	Signature: (Chair) / Date:

9. VERIFICATION OF EFFECTIVENESS OF IMPLEMENTED CORRECTIVE/PREVENTIVE ACTION:

Corrective action is: ☐ Effective ☐ Not effective. Issue new NC CAPA R Remarks: _____	Preventive Action: ☐ Effective ☐ Not effective. Issue new NC CAPA R Remarks: _____
Signature: (Chair) / Date:	Signature: (Chair) / Date:

RENEWAL OF APPOINTMENT

<dd-mm-yyyy>

<name and designation>

Dear <name and designation>

Dear Sir/ Madam,

We are pleased to inform you that your membership for the post of Chairman / Member Secretary / Member of IECBMHR has been further renewed for a period of three years effective from..... Kindly accept.

Thank you and our best regards.

Respectfully yours,

_____

Director, ICH

CONFORME:

_____

(Title, Name, Surname) & Signature

Date (dd/mm/yyyy)

Submission & Proposal Review with Preparation of Agenda And Conduct of IECBMHR Meetings
SOP Code: SOP03/V2

Reviewed By

Name and Position in IECBMHR	Signature
Dr. Phalguni Dutta Chairperson	
Dr. Surupa Basu Member Secretary	
Dr. Arunaloke Bhattacharyya Clinician	
Prof. Jaydeep Choudhury Clinician	
Dr. Supriyo Choudhury Basic Medical Scientist; Clinical Pharmacologist	
Mr. Tamal Chatterjee Legal expert	
Ms. Anasuya Basu Layperson	
Ms Kaberi Mukherjee Theologian	

Approved By

Name and Position in IECBMHR	Signature
Dr. Phalguni Dutta Chairperson	

TABLE OF CONTENTS

Supersedes	01
Version	02
Authored By	SOP team
Version Date	30 September 2022
Approved By	Dr. Phalguni Dutta
Effective Date	05 December 2022

1. OBJECTIVE

The purpose of this Standard Operating Procedure (SOP) is to describe how the Secretariat of the Institutional Ethics Committee for Biomedical and Health Research (IECBMHR) manages protocol submissions to the IECBMHR.

2. SCOPE

The ICH-IECBMHR reviews global or local academic studies conducted on participants 0 – 18 years of age by institution's training residents & fellows, physicians or other employees and researchers who may wish to collaborate with investigators affiliated to ICH. The IECBMHR will accept protocols for ethics review for studies to be done outside the ICH premises following review. In certain cases (collaborative research) deemed appropriate by the Chair and expressly approved by the Committee (e.g. community-based studies or research studies by training residents, fellows or consultants), the conditions outside the purview of the above conditions may be relaxed e.g. research in adults.

The committee will approve *academic clinical trial*s where the clinical trial in respect of the permitted drug formulation is intended solely for academic research purposes for a new indication or new route of administration or new dose or new dosage form; and
(ii) the clinical trial referred to in clause (i) has been initiated after prior approval by the Ethics Committee for clinical trial; and (iii) the observations generated from such clinical trial are not required to be submitted to the Central Licensing Authority; and (iv) the observations of such clinical trial are not used for promotional purposes.

The SOP applies to IECBMHR actions from the time of initial submission to the filing of the original study protocol package in the Active Study File cabinet and the preparation of copies of the package for distribution to the reviewers and deliberations during Committee meeting.

3. RESPONSIBILITIES

It is the responsibility of the Secretariat Staff to manage study protocol package submission and process the submission.
It is the responsibility of the IECBMHR Chair to decide whether the study protocol is for full Committee (convened) or expedited review. It is the responsibility of the IECBMHR Secretary to inform the members of their assigned task, and to ensure that the deliberations and discussions are adequately documented during the meeting.
It is the responsibility of the members to check the completeness of the study protocol package delivered to them, systematically review the study protocol, write their comments after each item listed in the study protocol assessment and informed consent assessment form, include consideration of relevant guidelines when doing the review, and present findings in the full Committee meeting (for full review study protocol).

The Principal Investigator (PI) is responsible for submitting a complete set of documents to the ICH-IECBMHR.

4. INITIAL REVIEW WORKFLOW

ACTIVITY		RESPONSIBILITY
Receive and manage study protocol submissions ↓		IECBMHR Secretariat Staff
Receive the proof of payment of institutional fee (deposited in the ICH Trust Fund) with the submitted protocol (if applicable) ↓		IECBMHR Secretariat Staff
Classify submission as expedited or full committee review ↓		IECBMHR Chair
Send study protocol package to members with **IECBMHR- ICH Form 3-A: *Application Form for Initial Review*;**		IECBMHR Secretariat Staff
Review the protocol and return accomplished **IECBMHR- ICH Form 3-GA+ Form 3-GB: *Study Protocol Assessment Form and Informed consent Assessment Form*** to the Secretariat Staff ↓		IECBMHR members
FULL COMMITTEE REVIEW	**EXPEDITED REVIEW**	
Include the protocol in the agenda of the next full Committee meeting ↓	Send study protocol package to with **IECBMHR- ICH Form 3-C: *Application Form for Expedited Review*;**	Secretariat Staff
Deliberates on Committee action on the protocol ↓		IECBMHR Members
1) If approved: send approval letter to PI **2) If minor modification/s:** send notification with recommendation to P.I., then process resubmission by expedited review **3) If major modification/s:** send notification with recommendation to P.I., then process resubmission by full Committee review **4) If disapproved**: send notification of decision with justification to PI ↓		Secretariat Staff
	Include in the agenda of the next IECBMHR meeting under the Expedited Review ↓	Secretariat Staff
	Present review findings during full Committee meeting	Chair

DETAILED INSTRUCTIONS:

a. Receipt and Management of Study Protocol Submission

i. A study protocol is the developed study plan for conducting an academic research study. It is created to protect the well-being of the participants and to establish the intent of the study to answer specific questions or needs. It defines the nature of study participants, the tests to be conducted, the procedures to be used, the time frame of the study and the interventions to be given to participants.

ii. A study protocol package for initial review must be received together with duly signed and accomplished forms and documents (as applicable) as enumerated in **IECBMHR- ICH Form 3-A: *Application Form for Initial Review*; Form 3-D: *Application Form for genetic studies' Review*; Form 3-E: *Application Form for Socio-Behavioural studies' Review***

iii. The Secretariat Staff ensures completeness of submitted forms and documents using the above checklist.

iv. The Secretariat Staff receiving the study protocol assigns a Study No. to the package and stamps in onto all the forms and documents submitted.

v. The Secretariat Staff signs **IECBMHR- ICH Form 3-A: *Application Form for Initial Review or any other as per the categorization of study type*;** to document the receipt of study protocol package and gives one copy of duly signed form to the P.I. or designated representative submitting the package, and attaches another duly signed form to the study protocol package.

vi. The Secretariat Staff logs the submission numbers as IECBMHR/nnn/yyyy using **IECBMHR-ICH Form 5-N: *Submission Log***.

vii. Payment of the institutional fee if applicable must be made before the protocol package is submitted. Review of protocol will be done only on presentation (by the Principal Investigator or a representative) to the IECBMHR Secretariat of an official receipt from the ICH. Accounts section showing full payment of the institutional fee.

1. The payment will be made in the name of ICH Trust Fund, for the sole purpose of the money received being used for research purposes of the institution and the maintenance of the daily operational expenses and training activities of the ICH-IECBMHR.

2. Research protocols by training residents and fellows, and academic studies conducted by in house researchers for review by the IECBMHR will be exempted from payment of the prescribed institutional fee.

3. Others may be eligible for exemption on a case to case basis.

b. Classification of Submission

i. The Principal Investigator can submit research proposal to the Institutional Ethics Committee office for review and approval under any of the 5 sections mentioned below:

- ☐ Initial Review Application
- ☐ Initial Review Application for Thesis/ Dissertation
- ☐ Resubmission of Protocols with corrections
- ☐ Protocol Amendment
- ☐ Continuing Review of Approved Protocols
- ☐ Protocol Termination

ii. The ICH-IECBMHR Chair classifies the study protocol review pathway as either **Expedited Review** or **Full Committee Review** filtered through the following criteria for Expedited Review:

- ☐ The research poses no more than minimal risk.
- ☐ The study does not involve vulnerable populations.
- ☐ The study does not involve the collection of stigmatizing information.
- ☐ The study uses anonym zed or archived samples.
- ☐ Continuing review of academic researches that do not involve further recruitment of participants.
- ☐ Continuing review of studies previously classified under expedited review
- ☐ Study protocol amendments that are administrative in nature and do not affect the study protocol.

iii. Study protocols that do not meet the criteria for expedited review are classified under full Committee review.

iv. Some studies may be **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 behavior when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person;
- quality control and quality assurance audits in the institution;
- comparison of instructional techniques, curricula, or classroom management methods;
- consumer acceptance studies related to taste and food quality; and
- public health programmes by government 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)

c. Initial Study Protocol review for Thesis/ Dissertation

i. Student's research project for thesis/ dissertation received by the Secretariat Staff ***twenty (20)*** *calendar days before the full Committee meeting are included in the agenda* along with **IECBMHR-ICH Form 3H Thesis/ Dissertation Submission Forms and Checklist**

ii. Reviewer is given **ten (10) calendar days** before the next scheduled meeting within which time he/she must review make comments on and evaluate the study.

iii. The review of the study protocol and informed consent documents must be in accordance with the National Ethical Guidelines for Biomedical and Health Research involving Human Participants, ICMR 2017; and National Ethical Guidelines for Biomedical Research involving Children, ICMR 2017 and other local, national, and international guidelines applicable.

iv. Review of elements is as entailed in the next page

d. Study Protocol Review

i. Studies that do not qualify for expedited review and received by the Secretariat Staff ***twenty (20)*** *calendar days before the full Committee meeting are included in the agenda.*

ii. Reviewers accomplish **IECBMHR- ICH Form 3-GA+B:** ***Protocol Assessment Form and Informed consent Assessment Form*** completely and comprehensively, and check for completeness of the documentation and information about the PI, study site, and other documents (Basic and Study Specific) as required by the study protocol under review such those listed in **SOP 02-4.a:** ***Receipt and Management of Study Protocol Submissions*** applicable to the study

iii. Reviewer is given **ten (10) calendar days** before the next scheduled meeting within which time he/she must review make comments on and evaluate the study.

iv. The review of the study protocol and informed consent documents must be in accordance with the assessment points and elements detailed in **IECBMHR- ICH Form 3GA+B:** ***Protocol Assessment Form and Informed consent Assessment Form.***

v. In addition to the review elements described above, the reviewers should ensure study protocol compliance with the National Ethical Guidelines for Biomedical and Health Research involving Human Participants, ICMR 2017and National Ethical Guidelines for Biomedical Research involving Children, ICMR 2017 regarding the following matters:

1. It is acknowledged that some populations require special protection because of characteristics or situations that render them vulnerable. Research with children falls in the category of research in vulnerable groups. Children should not be included in research unless:
(a) the research is necessary to promote the health of the population represented and
(b) the research cannot be performed on legally competent persons

2. The following elements are essentially reviewed:

A. Scientific design and conduct of the study

- Is the project original and innovative? Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools or technologies for this area?
- Is this an attempt to validate, prove or disapprove the validity of existing knowledge?

- Appropriateness of study design, work plan and structure to achieve the stated objectives: Are the conceptual or clinical framework, design, methods and analyses adequately developed, well integrated, well reasoned and appropriate to the aims of the project?
- Relevance of the work in the context of contemporary translation or clinical research:
- Does this study address an important research question or is it a predominantly service proposal?
- If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced?
- What will be effect of these studies on the concepts, methods, technologies, treatments, services, or preventive interventions that drive this field?
- Appropriateness of the study design in relation to the objectives of the study;
- The statistical methodology (including sample size calculation), and the potential for reaching sound conclusions with the smallest number of research participants;
- The justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants and the concerned communities;
- The justification for the use of control arms;
- Potential of the work that would be conducted to lead into a larger and high impact study;
- Criteria for prematurely withdrawing research participants, and criteria for suspending or terminating the research as a whole;
- The adequacy of provisions made for monitoring and auditing the conduct of the research, including the constitution of a Data Safety Monitoring Board;
- Investigator's capability, availability of infrastructure and scientific environment to conduct the study within the time frame and carry it forward;
- The adequacy of the site, including the support staff, available facilities, and emergency procedures;
- Study Reporting and publication of the research.

B. Risk Benefit Analysis

- Is there a balance between benefit and risk in the study?
- Is the participant exposed to risk or harm as a direct or indirect consequence of the research procedure?
- Are the procedures over and above the routine standard of care for the patient?
- Is the harm occurring from participation physical (pain due to procedure), psychological (fear of separation from parents) or social (missing going to school)?
- Is there a direct benefit to the child participant such as possibility of recovery, amelioration of pain, reduction in disease severity?
- Is the benefit indirect such as understanding about a disease process etc.?
- Payments for participation should not be considered benefit
- Risk assessment needs to be done for procedures that are over and above those procedures that the child would any way undergo during normal care and may hence vary from situation to situation and child to child
- Determinants of risk are age and developmental status, underlying medical condition, and cumulative risks during research (e.g. single X-ray vis a vis multiple X-rays in a short span)

- Risks may be classified as Less than minimal risk, minimal risk, low risk (minor increase over minimal risk), and high risk (risk over and above low risk)
- Review plans for risk management including withdrawal criteria with rescue medication or procedures.
- Advice regarding minimization of risk/discomfort wherever applicable.
- Are there adequate provisions must be made for monitoring and auditing the conduct of the research, including the constitution of a Data and Safety Monitoring Board (DSMB) if applicable(for example in academic research)

C. Care and Protection of Research Participants

- Required qualifications and experience of the investigators' for the proposed study;
- Any plans to withdraw or withhold standard therapies for the purpose of the research, and the justification for such action;
- Plans to withdraw subjects from the study by the investigator ;
- Medical care to be provided to research participants during and after the course of the research;
- Adequacy of medical supervision and psycho-social support for the research participants;
- Steps to be taken if research participants voluntarily withdraw during the course of the research;
- Criteria for extended access to, the emergency use of, and/or the compassionate use of study products;
- Arrangements, if appropriate, for informing the research participant's general practitioner or family doctor, including procedures for seeking the participant's consent to do so
- Description of any plans to make the study product available to the research participants following the research and description of any financial costs to research participants
- Rewards and compensations for research participants (including money, services, and/or gifts);
- Provisions for compensation/treatment in the case of the injury/disability/death of a research participant attributable to participation in the research [as per institutional policy/ICMR guidelines/existing national legislation (CDSCO)].
- Insurance and indemnity arrangements.

D. Informed Consent

Researcher must obtain voluntary written informed consent from the prospective participant for any biomedical and health research involving human participants.

Requisites

- The participant must have the capacity to understand the proposed research, be able to make an informed decision on whether or not to be enrolled and convey her/his decision to the researcher in order to give consent.
- The consent should be given voluntarily and not be obtained under duress or coercion of any sort or by offering any undue inducements.
- In the case of an individual who is not capable of giving voluntary informed consent, the consent of Legally Acceptable Representative (LAR) must be obtained.
- It is mandatory for a researcher to administer consent before initiating any study related procedures involving the participant.
- It is necessary to maintain privacy and confidentiality of participants at all stages.

Essential information for prospective research participants

- Before requesting an individual's consent to participate in research, the researcher must provide the individual with detailed information and discuss her/his queries about the research in the language she/he is able to understand. The language should not only be scientifically accurate and simple, but should also be sensitive to the social and cultural context of the participant.
- The ICD has two parts – patient/participant information sheet (PIS) and the informed consent form (ICF). Information on known facts about the research, which has relevance to participation, is included in the PIS. This is followed by the ICF in which the participant acknowledges that she/he has understood the information given in the PIS and is volunteering to be included in that research.
- Adequate time of at least 20 minutes should be given to the participant to read the consent form, if necessary discuss it with family and friends, and seek clarification of her/his doubts from the researchers/research team before deciding to enroll in the research.

Essential Elements of PIS:

- Statement that the study involves research and explanation of the purpose of the research
- Statement that the study is approved by IECBMHR
- Expected duration of the Subject's participation and total number of subjects that will be accrued on the study.
- Description of the procedures to be followed, including all invasive procedures
- Description of any reasonably foreseeable risks or discomforts to the subject
- Description of any benefits to the Subject or others reasonably expected from research. If no benefit is expected, subject should be made aware of this.
- Disclosure of specific appropriate alternative procedures or therapies available to the Subject.
- Statement describing the extent to which confidentiality of records identifying the Subject will be maintained and who will have access to Subject's medical records
- Trial treatment schedule(s) and the probability for random assignment to each treatment (for randomized studies)
- Statement describing the financial compensation and medical management as under:
  - In case of any injury occurring to the subject during the studies, free medical management shall be given as long as required or till such time it is established that the injury is not related to the academic research; whichever is earlier
  - In the event of a study related injury or death, the sponsor ICH(the parent institute where study is being conducted) shall provide financial compensation for the injury or death
- An explanation about whom to contact for studies related queries in the event of any injury and rights of Subjects.
- The anticipated prorated payment, if any, to the subject for participating in the study. In particular IECBMHR review payments to determine that:
  - The amount of payment and the proposed method and timing of disbursement neither is coercive nor presents undue influence.
  - A description of acceptable and unacceptable payment arrangements for the organization, researcher, and those referring research participants, if applicable.
- Subject's responsibilities on participation in the study

- Statement that participation is voluntary, that the subject can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the Subject is otherwise entitled
- The identity of the research team and contact persons with addresses and phone numbers (for example, PI/Co PI for queries related to the research and Chairperson/ Member Secretary/ or helpline for appeal against violations of ethical principles and human rights)
- Any other pertinent information

Additional elements, which may be required

- Statement of foreseeable circumstances under which the Subject's participation may be terminated by the Investigator without the Subject's consent.
- Additional costs to the Subject that may result from participation in the study.
- The consequences of a Subject's decision to withdraw from the research and procedures for orderly termination of participation by Subject.
- Statement that the Subject or Subject's representative will be notified in a timely manner if significant new findings develop during the course of the research which may affect the Subject's willingness to continue participation will be provided;
- Any alternative procedures or courses of treatment that might be as advantageous to the participant as the ones to which she/he is going to be subjected;
- A Statement that the particular treatment or procedure may involve risks to the subject (or embryo or fetus, if the subject may become pregnant), which are currently unforeseeable
- Approximate number of Subjects enrolled in the study
- A full description of the process for obtaining informed consent, including the identification of those responsible for obtaining consent
- Adequacy, completeness and comprehension of written and oral information to be given to the research participant's parent, and, when appropriate, their LARs
- Clear justification for the intention to include research participants who cannot consent, and a full account of arrangements made to obtain their consent /authorization/consent of LAR;
- Assurances that research participants will receive information that becomes available during the course of the research relevant to their participation including their rights, safety, and well-being;
- Provisions made for receiving and responding to queries and complaints from research participants or their representatives during the course of a research project;
- If test for genetics/ stem cell research and HIV is to be done, counseling for consent for testing must be given as per national guidelines;
- Storage period of biological sample and related data with choice offered to participant regarding future use of sample, refusal for storage and receipt of its results;
- When the written consent is not possible because the parent/legal guardian is illiterate, thumb impression of parent/LAR can be taken after ensuring its documentation by an unrelated witness. Audio-visual documentation may be needed for the procedure in the presence of the witness in certain studies;
- Provision for ongoing consent in situations as mentioned under "**Fresh or re-consent**";

- If there is a possibility that the research could lead to any stigmatizing condition, for example HIV and genetic disorders, provision for pretest-and post-test counseling
- Insurance coverage if any, for research-related or other adverse events
- Foreseeable extent of information on possible current and future uses of the biological material and of the data to be generated from the research.
- Other specifics are as follows:
    - period of storage of the sample/data and probability of the material being used for secondary purposes.
    - whether material is to be shared with others, this should be clearly mentioned.
    - right to prevent use of her/his biological sample, such as DNA, cell-line, etc., and related data at any time during or after the conduct of the research.
    - risk of discovery of biologically sensitive information and provisions to safeguard confidentiality.
    - post research plan/benefit sharing, if research on biological material and/or data leads to commercialization.
- Publication plan, if any, including photographs and pedigree charts

Fresh or re-consent is taken in following conditions:

- Availability of new information would necessitate that participant understands ongoing and renewed risks and benefits and provides consent on a continuous basis while in the study.
- Also there may be certain conditions for which fresh consent or re-consent is required:
    - When long term follow-up or study extension is planned later.
    - When there is a change in treatment modality, procedures, site visits, data collection methods or tenure of participation which may impact the participant's decision to continue in the research;
    - If the child is now above18 years of age, or the LAR has changed.
    - Before publication if there is possibility of disclosure of identity through data presentation or photographs.
    - For use of stored biological samples if not anonymized.
    - In emergency situations when no surrogate consents can be taken. Examples include research involving neonatal resuscitation, life threatening emergencies etc. In such situations, the parents/ care givers may not be in a situation to give consent. However, once the child has been stabilized, a deferred consent must be taken.
    - When a research participant regains consciousness from unconscious state or is mentally competent to understand the study. If such an event is expected, then procedures to address it should be spelt out in the informed consent form.

Revised Informed Consent Form

- When the Investigator / CRC receive updates to the Investigator's Brochure, Safety Reports, or protocol amendments, he/she should also review the informed consent to determine if it should be revised to reflect the new information.
- No changes to the study procedures that are a result of the protocol amendment will be implemented until the IECBMHR approval of the amendment is received.
- If the consent form is changed as a result of a protocol amendment, the PI/CTC will ensure that the revised consent is approved by the IECBMHR.

- The PI/ Co I will explain the changes to the subject and will provide the subject with the revised consent form for review and signature.
- If the subject decides to continue in the study and signs the consent form, the investigator will provide the subject with a copy of the revised consent and will place the original in the separate file.

If incorrect version of ICF used:

- If the Investigator discovers that an outdated version of the consent form was used for a subject whose participation in the study has not been completed, he/she will:
- Contact the subject and explain the reason for re- consenting the subject the correct version.
- Instruct the subject to sign the consent with current date while signing and dating the correct version (i.e., do not back-date the consent form).
- Maintain both signed versions of the consent in the separate file.
- Write an explanatory memo in the file so that future auditors will understand why two signed informed consent documents for the same subject are present in the file. If the investigator is unable to contact the subject, the explanatory memo should also document the dates and methods by which the attempts to reach the subject were made.

Waiver of consent

- research cannot practically be carried out without the waiver and the waiver is scientifically justified
- retrospective studies, where the participants are de-identified or cannot be contacted;
- research on anonymized biological samples/data;
- certain types of public health studies/surveillance programmes/programme evaluation studies;
- research on data available in the public domain; or
- Research during humanitarian emergencies and disasters, when the participant may not be in a position to give consent. Attempt should be made to obtain the participant's consent at the earliest

Procedures after the consent process

- After consent is obtained, the participant should be given a copy of the PIS and signed ICF unless the participant is unwilling to take these documents. Such reluctance should be recorded.

E. Audio Visual Consent

A-V consent is mandatory only in cases of vulnerable populations and with research on new chemical entities (as per Third Schedule of the New Drugs and Clinical Trial Rules, 2019). However, IECBMHR will have the discretionary power to exercise A-V consenting in studies where participants are vulnerable and exposed to high risk.

All the elements of A-V consent documentation and process are enlisted in the websites www.cdsco.nic.in and www.cdsaindia.in

- The audio visual consenting process should be no less than 30 minutes duration.

- If the participant is unable to give consent for medical or legal reasons, the A-V consent should be taken from the legally acceptable representative (LAR) and the process recorded.
- If the participant/LAR is illiterate then an impartial witness is needed. This person should also be in the frame for the entire duration of the consent process.
- AV recording should be done of assent process wherever applicable
- Separate recordings one for assent and one for consent process should be done.
- Good quality infrastructure (designated room, Camera, Laptop) should be available
- Participant/ LAR (where applicable) should be made to sign the A-V consent before recording the informed consent process
- Entire consenting should be captured in the frame including the signing process.
- One CD (preferably) for each participant should be stored in locked cabinets; hard disk should be password protected.

F. Assent

Assent means a minor's affirmative agreement to participate in research. Mere failure to object should not be interpreted as assent. A child's refusal must be respected. The earliest age at which assent is recommended is set at 7 years. However, the assent process should be developmentally appropriate depending on a child's age, maturity and experience with a disease or condition. The child must agree whether the research as he or she understands it is an activity which he or she wants to take part in. Researchers must be sensitive to a child's non-verbal cues reflecting his or her willingness or unwillingness to take part. The older the minor, the more an assent form will mirror a parental consent form.

Considerations for 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. If a child becomes 13 years old during the course of the study, then written assent must be obtained in addition to parent/LAR consent.
- For children between 12 and 18 years, written assent must be obtained. This assent form 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 behavioral studies in IV drug users where parental consent may not be possible.
- Re-assent must be taken in all the same situations as re-consent as mentioned above.
- Refusal of child to participate must always be respected. The child must also be explained that he/she may withdraw his/her assent any time during the study.

Waiver of assent

- Waiver of assent may be provided by the ethics committees in the following situations:
- If the research has the potential of directly benefitting the child and this benefit is available only in the research context. In such situation child's dissent is overruled.

- Waiver of assent may also be considered if the research involves children with mental retardation and other developmental disabilities, where the children may not have the developmental level and intellectual capability of giving assent.
- Waiver of assent may be considered in community-based research if in socio-cultural-educational context, the children are considered to be immature and not capable of giving assent.
- Assent may also be waived under the same conditions in which adult's informed consent maybe waived.

Desirable elements in Assent Forms

The type and amount of information presented should be adapted to the child's cognitive and emotional status and experiences. The information should be simple, and age-appropriate. The basic information which needs to be provided includes:

1) What the study is about and whether it might help?
2) What will happen and when?
3) What discomfort there might be and what will be done to minimize it?
4) Who will answer the child's questions during the study?
5) Whether an option to say "no" exists?

G. Social value

The basic requirement for health research to be ethically permissible is that it must have anticipated social value. The outcome of the research should be relevant to the health problems of society. All stakeholders, including sponsors, researchers and ECs must ensure that the planned research has social value.

H. Community Considerations

If applicable, community involvement and impact/benefit of the study to community and/or the institution are examined and if relevant, noting the following:

- the impact and relevance of the research on the local community and on the concerned communities from which the research participants are drawn;
- an explicit assurance that no undue influence on the community is exerted in the informed consent taking process. The proposed research should not lead to any stigma or discrimination. Harm, if any, should be minimized
- involvement of local researchers and institutions in the study protocol design,
- analysis and publication of the results;
- contribution to development of local capacity for research and treatment;
- benefit to local communities;
- availability of study results,
- benefit sharing.

I. Recruitment of Research Participants

- A fair selection of research participants is desirable for sharing of burdens of risks and benefits of research. All research protocols should explicitly state subject recruitment strategies for review.

- Participants should be fairly selected as per inclusion and exclusion criteria. However, selection of participants should be distributive such that a particular population or tribe or economic group is not coerced to participate or benefit.
- Efforts should be made to not over-sample and hence size selection should be scientific and statistically determined
- Recruitment should be voluntary and non-coercive.
- Explicit selection criteria or prioritization of participants with proper justification; the characteristics of the population from which the research participants will be drawn (including gender, age, literacy, culture, economic status, and ethnicity)should be provided in the protocol.
    - the means by which initial contact and recruitment is to be conducted;
    - the means by which full information is to be conveyed to potential research participants or their representatives;
    - information contained in the advertisement and mode of its communication.
    - final copy of printed advertisements.
    - final audio or video taped advertisements.
    - electronic display in patient waiting area
    - posters / pamphlets/ standees etc.
- Specific groups such as children with special needs etc. may be recruited after proper justification is provided
- Participants should be able to opt out at any time without their routine care being affected.
- No individual or group of persons must bear the burden of participation in research without accruing any direct or indirect benefits.

J. Advertisements and other recruitment strategies

The IECBMHR reviews advertising and other recruitment strategies to ensure that advertisements do not:

- State or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.
- Exclude exculpatory language.
- Emphasize the payment or the amount to be paid, by such means as larger or bold type.
- Promise "free treatment" when the intent is only to say participants will not be charged for taking part in the investigation.
- Advertisements are limited to the information prospective participants need to determine their eligibility and interest, such as:
    - The name and address of the researcher or research facility.
    - The purpose of the research or the condition under study.
- In summary form, the criteria that will be used to determine eligibility for the study.
- A brief list of benefits to participants, if any.
- The time or other commitment required of the participants.
- The location of the research and the person or office to contact for further information.

K. Compensation for participation

- Parents and children should not be asked to bear the expenses of research participation.
- Children involved in research may also receive free medical services
- The Committee will ensure that the protocol to be reviewed has explicit statement/s regarding compensation for research participants. Compensation given to participants for lost earnings, transportation, and other expenses incurred in taking part in the study, and compensation for the inconvenience and time spent by those who do not have direct benefit from the research.
- There is a need to determine that payments are not so large as to encourage prospective participants to participate in the research without due consideration of the risks or against their better judgment. No undue inducement must be offered.
- Protocols should provide IECBMHRs with details about the type, level, and timing of payments to participants at the time of initial review and the details should also be included in the informed consent form.
- A minimum amount of Rs 100.00 and a maximum of Rs 500.00 have been decided as limits of payment. These may be revised in special conditions by the IECBMHR.
- IECBMHR will approve the type, level, and timing of payments made by the researchers.
- Full details of payments to be given to parents/child and other benefits of participation (e.g. free medical care) should be clearly mentioned in the protocol and parent/patient information sheet.
- Assessment of potential for undue influence, especially if such payments are proposed for studies that focus on low income populations should be done.
- When a guardian is asked to give consent on behalf of an incompetent person, no remuneration should be offered except a refund of out of pocket expenses.

L. Protection of research participants' privacy and confidentiality

- ECs will examine the processes that are put in place to safe guard participants' privacy and confidentiality.
- Research records to be filed separately than routine clinical records such as in a hospital setting.

M. Plans for medical management and compensation for study related injury

- The proposed plan for tackling any medical injuries or emergencies should be reviewed.
- Source and means for compensation for study related injury should be ascertained
- The IECBMHR's policy on compensation and has been prepared as per guideline of The New Drugs and Clinical Trials Rules, 2019. As per provision of The New Drugs and Academic research Rules, 2019 Compensation and formula of determining the quantum of compensation as under:

  COMPENSATION as per rules:

  39. Compensation in case of injury or death in academic research or bioavailability or bioequivalence study of new drug or investigational new drug.—

  (1) Where any death of astudy subject occurs during a academic research or bioavailability or bioequivalence study, the legal heir of thestudy subject shall be

provided financial compensation by the sponsor or its representative, who has obtained permission to conduct the academic research or bioavailability or bioequivalence study, in accordance with the procedure specified in rule 42.

(2) Where permanent disability or any other injury occurs to astudy subject during a academic research or bioavailability or bioequivalence study, thestudy subject shall be provided financial compensation by the sponsor or its representative, who has obtained permission to conduct the academic research or bioavailability or bioequivalence study, in accordance with the procedure specified in rule 42.

(3) The financial compensation referred to in sub-rule (1) or sub-rule (2) shall be in addition to any expenses incurred on medical management of thestudy subject.

(4) In the event of an injury, not being permanent in nature, the quantum of compensation shall be commensurate with the loss of wages of the subject as provided in the Seventh Schedule.

(5) The sponsor or its representative shall give an undertaking along with the application for academic research permission to the Central Licencing Authority to provide compensation in the case of academic research related injury or death for which subjects are entitled to compensation.

(6) Where the sponsor or its representative, who has obtained permission to conduct academic research or bioavailability or bioequivalence study, fails to provide financial compensation, as referred to in sub-rule (1) or sub-rule (2), the Central Licencing Authority shall, after affording an opportunity of being heard, by an order in writing, suspend or cancel the academic research or bioavailability or bioequivalence study or restrict the sponsor including its representative, who has obtained permission to conduct academic research or bioavailability or bioequivalence study, to conduct any further academic research or bioavailability or bioequivalence study or take any other action for such period as considered appropriate in the light of the facts and circumstances of the case.

40. Medical Management in academic research or bioavailability and bioequivalence study of new drug or investigational new drug.—

(1) Where an injury occurs to any subject during academic research or bioavailability and bioequivalence study of a new drug or an investigational new drug, the sponsor, shall provide free medical management to such subject as long as required as per the opinion of investigator or till such time it is established that the injury is not related to the academic research or bioavailability or bioequivalence study, as the case may be, whichever is earlier.

(2) The responsibility for medical management as referred to in sub-rule (1), shall be discharged by the sponsor or the person who has obtained permission from the Central Licensing Authority.

(3) Where the sponsor or its representative, who has obtained permission to conduct academic research or bioavailability or bioequivalence study, fails to provide medical management, as referred to in sub-rule (1), the Central Licensing Authority shall after

affording an opportunity of being heard, by an order in writing, suspend or cancel the academic research or bioavailability or bioequivalence study or restrict the sponsor including its representative, who has obtained permission to conduct academic research or bioavailability or bioequivalence study, to conduct any further academic research or bioavailability or bioequivalence study or take any other action for such period as considered appropriate in the light of the facts and circumstances of the case.

41. Consideration of injury or death or permanent disability to be related to academic research or bioavailability and bioequivalence study.— Any injury or death or permanent disability of a study subject occurring during academic research or bioavailability or bioequivalence study due to any of the following reasons shall be considered as academic research or bioavailability or bioequivalence study related injury or death or permanent disability, namely:-

(a) adverse effect of the investigational product;

(b) violation of the approved protocol, scientific misconduct or negligence by the sponsor or his representative or the investigator leading to serious adverse event;

(c) failure of investigational product to provide intended therapeutic effect where, the required standard care or rescue medication, though available, was not provided to the subject as per academic research protocol;

(d) not providing the required standard care, though available to the subject as per academic research protocol in the placebo controlled study;

(e) adverse effects due to concomitant medication excluding standard care, necessitated as part of the approved protocol;

(f) adverse effect on a child in-utero because of the participation of the parent in the academic research;

(g) any academic research procedures involved in the study leading to serious adverse event.

42. Procedure for compensation in case of injury or death during academic research, bioavailability and bioequivalence study.—

(1) The investigator shall report all serious adverse events to the Central Licencing Authority, the sponsor or its representative, who has obtained permission from the Central Licensing Authority for conduct of academic research or bioavailability or bioequivalence study, as the case may be, and the Ethics Committee that accorded approval to the study protocol, within twenty-four hours of their occurrence; and if the investigator fails to report any serious adverse event within the stipulated period, he shall have to furnish the reasons for delay to the satisfaction of the Central Licencing Authority along with the report of the serious adverse event.

(2) A case of serious adverse event of death shall be examined in the following manner, namely:-

(i) the Central Licencing Authority shall constitute an independent expert committee to examine the cases and make its recommendations to the said authority for arriving

at the cause of death and quantum of compensation in case of academic research related death;

(ii) the sponsor or its representative and the investigator shall forward their reports on serious adverse event of death after due analysis to the Central Licencing Authority and the head of the institution where the academic research or bioavailability or bioequivalence study has been conducted within fourteen days of the knowledge of occurrence of serious adverse event of death;

(iii) the Ethics Committee for academic research shall forward its report on serious adverse event of death after due analysis along with its opinion on the financial compensation, if any, determined in accordance with the formula specified in the Seventh Schedule, to be paid by the said sponsor or its representative, who has obtained permission from the Central Licensing Authority for conduct of academic research or bioavailability or bioequivalence study, as the case may be, to the Central Licensing Authority within a period of thirty days of receiving the report of the serious adverse event of death from the investigator;

(iv) the Central Licensing Authority shall forward the report of the investigator, sponsor or its representative and the Ethics Committee to the Chairperson of the expert committee;

(v) the expert committee shall examine the report of serious adverse event of death and make its recommendations available to the Central Licensing Authority for the purpose of arriving at the cause of the serious adverse event of death within sixty days from the receipt of the report of the serious adverse event, and the expert committee while examining the event, may take into consideration, the reports of the investigator, sponsor or its representative and the Ethics Committee for academic research;

(vi) in case of academic research or the bioavailability or bioequivalence study related death, the expert committee shall also recommend the quantum of compensation, determined in accordance with the formula specified in the Seventh Schedule, to be paid by the sponsor or his representative who has obtained the permission to conduct the academic research or the bioavailability or bioequivalence study, as the case may be;

(vii) the Central Licensing Authority shall consider the recommendations of the expert committee and shall determine the cause of death with regards to the relatedness of the death to the academic research or the bioavailability or bioequivalence study, as the case may be;

(viii) in case of academic research or the bioavailability or bioequivalence study related death, the Central Licensing Authority shall, after considering the recommendations of the expert committee, by order, decide the quantum of compensation, determined as per the formula specified in the Seventh Schedule, to be paid by the sponsor or its representative and shall pass orders as deemed necessary within ninety days of the receipt of the report of the serious adverse event;

(ix) the sponsor or its representative shall pay the compensation in case the serious adverse event of death is related to academic research or the bioavailability or bioequivalence study, as specified in the order referred to in clause (viii) of the Central Licensing Authority within thirty days of the receipt of such order.

(3) **Cases of serious adverse events of permanent disability or any other injury other than deaths shall be examined in the following manner, namely: —**

(i) the sponsor or its representative, and the Investigator shall forward their reports on serious adverse event, after due analysis, to the Central Licensing Authority, chairperson of the Ethics Committee for academic research and head of the institution where the study or bioavailability or bioequivalence study has been conducted within fourteen days of the reporting of serious adverse event;

(ii) the Ethics Committee for academic research shall forward its report on serious adverse event of permanent disability or any other injury other than deaths, as the case may be, after due analysis along with its opinion on the financial compensation, if any, determined in accordance with the formula specified in the Seventh Schedule, to be paid by the sponsor or its representative who has obtained permission to conduct academic research or the bioavailability or bioequivalence study, as the case may be, within thirty days of receiving the report of the serious adverse event;

(iii) the Central Licensing Authority shall determine the cause of the injury and pass order as specified in clause (iv), or may constitute an independent expert committee, wherever it considers necessary, to examine such serious adverse events of injury, and such independent expert committee shall recommend to the Central Licensing Authority for the purpose to arrive at the cause of the serious adverse event and also the quantum of compensation, as determined in accordance with formula as specified in the Seventh Schedule in case of academic research or bioavailability or bioequivalence study related injury, within a period of sixty days of receipt of the report of the serious adverse event;

(iv) in case of academic research or the bioavailability or bioequivalence study related injury, the Central Licensing Authority shall, by order, decide the quantum of compensation, determined in accordance with the formula specified in the Seventh Schedule, to be paid by the sponsor or his representative who has obtained the permission to conduct the academic research or the bioavailability or bioequivalence study, as the case may be, within a period of ninety days of receipt of the report of the serious adverse event;

(v) the sponsor or its representative, who has obtained permission to conduct the academic research or bioavailability or bioequivalence study, as the case may be, shall pay the compensation in case of academic research or bioavailability or bioequivalence study related injury, as specified in the order of the Central Licensing Authority referred to in clause (iv) within thirty days of receipt of such order.

43. Medical management and compensation for injury or death relating to biomedical and health research overseen by an Ethics Committee for biomedical and health research as referred to in Chapter IV.—

Notwithstanding anything contained in these rules, medical management and compensation for injury or death relating to biomedical and health research, overseen by an Ethics Committee for academic research as referred to in Chapter IV, shall be in accordance with the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants specified by the Indian Council of Medical Research from time to time.

SEVENTH SCHEDULE

(See rules 39, 40, and 42)

FORMULAE TO DETERMINE THE QUANTUM OF COMPENSATION IN THE CASES OF ACADEMIC RESEARCH RELATED INJURY OR DEATH

1. Formula in case of academic research related death:

Compensation = (B x F x R) / 99.37

Where,

B = Base amount (i.e. 8 lacs)

F = Factor depending on the age of the study subject as per Annexure 1 (based on Workmen Compensation Act)

R = Risk Factor depending on the seriousness and severity of the disease, presence of co-morbidity and duration of disease of the study subject at the time of enrolment in the academic research between a scale of 0.5 to 4 as under:

(1) 0.5 terminally ill patient (expected survival not more than (NMT) 6 months)

(2) 1.0 Patient with high risk (expected survival between 6 to 24months)

(3) 2.0 Patient with moderate risk

(4) 3.0 Patient with mild risk

(5) 4.0 Healthy Volunteers or study subject of no risk.

However, in case of patients whose expected mortality is 90% or more within 30 days, a fixed amount of Rs. 2 lacs should be given.

2. Formula in case of academic research related injury (other than death):

For calculation of quantum of compensation related to injury (other than death), the compensation shall be linked to the criteria considered for calculation of compensation in cases of death of the study subject as referred to in section of this Schedule. The quantum of compensation in case of Academic research related SAE should not exceed the quantum of compensation which would have been due for payment in Case of death of the study subject since the loss of life is the maximum injury possible. As per the definition of SAE, the following sequelae other than death are possible in a academic research subject, in which the study subject shall be entitled for compensation in case the SAE is related to academic research.

(i) A permanent disability: In case of SAE causing permanent disability to the study subject, the quantum of compensation in case of 100% disability shall be 90% of the

compensation which would have been due for payment to the nominee (s) in case of death of the study subject.

The quantum for less than 100% disability will be proportional to the actual percentage disability the study subject has suffered.

Accordingly, following formula shall be applicable for determination of compensation:

Compensation = (C x D x 90) / (100 x 100)

W h e r e:

D = Percentage disability the study subject has suffered.

C = Quantum of Compensation which would have been due for payment to the study subject's nominees)

in case of death of the study subject.

(ii) Congenital anomaly or birth defect: The congenital anomaly or birth defect in a baby may occur due to participation of anyone or both the parent in academic research. Following situations may arise due to congenital anomaly or birth defect.

(a) Still birth;

(b) Early death due to anomaly;

(c) No death but deformity which can be fully corrected through appropriate intervention;

(d) Permanent disability (mental or physical).

The compensation in such cases would be a lump sum amount such that if that amount is kept by way of fixed deposit or alike, it shall bring a monthly interest amount which is approximately equivalent to half of minimum wage of the unskilled worker (in Delhi). The quantum of compensation in such cases of SAE shall be half of the base amount as per formula for determining the compensation for SAE resulting into death. In case of birth defect leading to sub-clause (c) and (d) of this clause to any child, the medical management as long as required shall be provided by the Sponsor or his representative which will be over and above the financial compensation.

(iii) Chronic life-threatening disease; and

(iv) Reversible SAE in case it is resolved. In case of academic research related SAE causing life-threatening disease and reversible SAE in case it is resolved, the quantum of compensation would be linked to the number of days of hospitalization of the study subject. The compensation per day of hospitalization shall be equal to the wage loss. The wage loss per day shall be calculated based upon the minimum wage of the unskilled worker (in Delhi). Since, in case of hospitalization of any patient not only the patient loses his/her wage, there will be direct or indirect losses of various kind including inconvenience, wage loss of attendant, etc. The compensation per day of hospitalization in such case shall be double the minimum wage.

Accordingly, following formula shall be applicable for determination of compensation:

Compensation = 2 X W X N.

Where,
W = Minimum wage per day of the unskilled worker (in Delhi)
N = Number of days of hospitalization

Annexure

1 Factor (F) for calculating the amount of compensation

Age Not more than...	Factor
16	228.54
17	227.49
18	226.38
19	225.22
20	224.00
21	222.71
22	221.37
23	219.95
24	218.47
25	216.91
26	215.28
27	213.57
28	211.79
29	209.92
30	207.98
31	205.95
32	203.85
33	201.66
34	199.40
35	197.06
36	194.64
37	192.14
38	189.56
39	186.90
40	184.17
41	181.37
42	178.49
43	175.54
44	172.52
45	169.44
46	166.29
47	163.07
48	159.80
49	156.47
50	153.09
51	149.67

52	146.20
53	142.68
54	139.13
55	135.56
56	131.95
57	128.33
58	124.70
59	121.05
60	117.41
61	113.77
62	110.14
63	106.52
64	102.93
65 or more	99.37

N. Academic research agreement (MOU) and Budget

MOU shall clearly define duties, right and privileges of ICH (Site), the Principal Investigator (PI) and sponsors for conducting sponsored initiated study and provides protection of all subjects in all necessary areas applicable to their specific project. Submission of MOU is mandatory for all sponsored initiated studies conducted or studies initiated at ICH for multicentre purpose.

Review of draft MOU

Sponsor/industry representative will provide draft MOU to Principal Investigator for finalization.

The Principal Investigator (PI) will inform the same to the head of the institution, and copy of the MOU along with the study protocol shall be sent to IECBMHR (along with initial submission of project) for review.

MOU shall include the following elements to ensure Good Clinical Practice and other responsibilities for the study. It is the responsibility of the PI to ensure to incorporate following all elements in the MOU for conducting a study-

- Title of the MOU
- Name and address of the Parties
- Recitals
- Protocol title with IP name
- Definition
- A listing of the study, clinical, and legal responsibilities of Investigator site
- Effective date of MOU
- Estimated study starts and finish dates
- Terms of payment including terms for delays and termination of the study
- Number of study subjects required to enter and complete the study and the criteria for a "completed" (fully paid) study subject
- Confidentiality agreement

- Information on personal data and biological material if any
- Dissemination of findings, and publication rights
- Data ownership rights
- Indemnification
- Research related injury responsibilities including the provision and payment and/or reimbursement of necessary medical care for research participants when appropriate
- Compensation guidelines
- Guidelines or requirements for promptly reporting of the findings that could affect the safety of participants or influence the conduct of the study
- Data and safety monitoring process and reporting requirements
- The notification of the research department by the Sponsor and/or CRO of study results after the study has ended when participant safety could be directly affected by those study results, in order to consider informing participants
- Jurisdiction
- Governing Law
- Dispute resolution
- Other legal issues as necessary per ICH Legal expert(s)

PI/IECBMHR/Legal expert must check for the availability of clause in MOU or other funding agreements that require the sponsor to promptly (no longer than within 30 days) report to the organization in case of any findings that could:

- Affect the safety of participants.
- Influence the conduct of the study or alter the IECBMHR's approval to continue the study.

The Legal department and IECBMHR will correspond with the PI regarding any revisions that are required in the MOU.

Legal expert will approach Institutional head, in case of queries.

Revision of MOU

- The Legal expert(s) will correspond with the PI in case of suggestion/revision including the revision suggested by Institutional head.
- IECBMHR will also correspond with the PI regarding any revisions that are required in the MOU.
- In case of sponsored study PI will further correspond with the sponsor/CRO/collaborators for all the relevant suggestion/revision and changes if any put forward by Legal expert and IECBMHR.
- The Institution head will be included in all correspondence between the Legal department, IECBMHR and Sponsor/CRO/collaborator.
- PI or Sponsor (in case of sponsored study) will study the revision suggested and incorporate the suggested changes as applicable.

Finalization of MOU

o Once the MOU is approved by the Legal expert and IECBMHR, PI will further correspond with the Sponsor/CRO/collaborators.

o A minimum of three originals should be prepared on stamp paper (INR100) or as many originals as the Sponsor/CRO/collaborator specifies.

o PI is responsible for assuring that all required signatures are obtained. All originals should be identical and have consistent signatures and dates.

o *Note: Institutional Head will sign the MOU only after IECBMHR approval.*

o After signature of the Institution head (along with the institution stamp) and Principal Investigator the originals will be sent to the Sponsor/CRO for signature.

o A copy will be retained in the interim; this copy will be discarded when the signed original is returned from the sponsor/CRO.

o One copy will be retained by the Institution head, one by Principal Investigator and the other will be with the Sponsor/CRO. The PI should keep the signed MOU in site master file.

o One copy of the MOU will be submitted to the IECBMHR for approval before the conduct of the study at site.

Addendum/Amendment to MOU

o During the course of the study, PI/Sponsor can amend the MOU if required.

o Any addendum/amendment to the MOU also needs to be reviewed by legal experts and a copy will be submitted to IECBMHR for review and opinion if any.

o One copy each of finalized (signed and dated) amended MOU will be retained by PI, one by the Institution head and one by the sponsor.

O. Post study access

- There must be a statement in the protocol stating that the population in which the research is carried out will likely benefit from the research results. Likewise, the standard of care and other medical interventions must be offered to subjects after their study participation.
- Post-trial access must be available to all study participants, i.e., the standard medical care, adequate medical advice and consultation including prescription of appropriate post-study medications and other medical intervention must be available and offered to subjects after their study participation.

P. Rights & Responsibilities of a Clinical Study Participants

The informed consent process focuses on the study participant's rights and protections. Documented in a charter on display for study participants are:

You have the right:

- To safe, considerate and respectful care, provided in a manner consistent with your beliefs;
- To expect that all communications and records pertaining to your participation in the research project will be treated as confidential to the extent permitted by law;

- To know the physician responsible for coordinating your care at the hospital
- To receive complete information about diagnosis, treatment, and prognosis from the physician, in terms that are easily understood. If it is medically inadvisable to give such information to you, it will be given to a legally authorized representative;
- To receive information necessary for you to give informed consent prior to any procedure or treatment, including a description of the procedure or treatment, any potential risks or benefits, the probable duration of any incapacitation, and any alternatives. Exceptions will be made in the case of an emergency;
- To receive routine services when hospitalized at the Institute in connection with your protocol. Complicating chronic conditions will be noted, reported to you, and treated as necessary without the assumption of long-term responsibility for their management;
- To know in advance what appointment times and physicians are available and where to go for continuity of care provided by the hospital;
- To receive appropriate assessment of ,and treatment for, pain;
- To refuse to participate in research, to refuse treatment to the extent permitted by law, and to be informed of the medical consequences of these actions, including possible dismissal from the study. If discharge would jeopardize your health, you have the right to remain under ICH's care until discharge or transfer is medically advisable;
- To be transferred to another facility when your participation in the study site is terminated;
- To expect that a medical summary from the study site will be sent to your referring physician;
- To designate additional physicians or organizations at any time to receive medical updates.

Your Patient Rights before Enrollment:

- Know all the information about potential benefits and risks of the study.
- Know the plan for the study, such as how long it will last, where it will be conducted, etc.
- Know what is expected of you during the study.
- Ask any questions or voice any concerns you may have about the study.

Your Patient Rights after Enrollment:

- Decline participation or withdraw from the study at any time without prejudice or loss of future treatment. (Participation is totally voluntary. However, you should intend on completing the study before enrolling.)
- Ask questions at any time concerning the study drug/intervention.
- Be kept informed of any significant new finding(s) that may affect your willingness to continue participation.

However, for a clinical study to be successful, study participants must also do their part, which is documented in a charter:
As are search study participant, the following are my responsibilities:

- **Informed Consent.** I have read the informed consent form, discussed its contents with the study team, and believe I understand the study well enough to participate in it.

- **My Information.** I will provide full and truthful information about my health and anything else the study team should know about.
- **Contact information.** I will keep the study team's contact information with me at all times. I will make sure the study team always knows how to find me. If they try to contact me, I will respond as soon as I can.
- **Questions and Problems.** If I ever have a question about the study, I will ask the study team about it and keep asking until I am satisfied with their answer. If I forget something I want to know, I will ask the study team to explain it to me again. If I have a problem with the study, I will tell the study team about that too. If my problem is with the study team itself, I will call the Institutional Ethics Committee at the telephone number in the consent form.
- **Visits, Medications and Records.** To the best of my ability, I will keep all visit appointments, take all medications, record all information, and follow any other instructions the study team gives me. If I cannot —or forget to — do any of these things — I will tell the study team as soon as possible.
- **Health Problems.** If, for any reason, I have any health problem at all during the study, I will tell the study team right away. Also, if I see a doctor for any reason, I will tell the study team about that, too.
- **Medications, Devices and Paperwork.** I will take good care of any medications, devices and paperwork entrusted to me by the study team.
- **Information Sharing.** I will not share information on social media that could interfere with the success of the study. For example, I will not coach other people on how to get into the study or help other study participants figure out whether they are getting the active medication or the placebo.
- **Dropping Out of the Study.** If I decide to drop out of the study, I will tell the study team right away. To the extent I am comfortable, I will tell them why I am dropping out and answer their questions.
- **End of Study.** After the study ends for me, I will return all medications, devices and paperwork to the study team right away.
- **Talk to the Study Team.** If I am unwilling or unable to meet the above responsibilities, I will discuss the situation with the study team.

vi. Special considerations in the review process:

Special situations –research in neonates, in HIV positive children, in adolescents; in emergency situations, internet/telephonic surveys, school based- and community based-research. The IECBMHR will take cognizance of the special needs of the participants in the above situations/settings & will deliberate on extra provision that may be required for participant protection & safeguard.

vii. For full Committee study protocols, the reviewers accomplishes the aforementioned forms and returns them to the Secretariat Staff after the meeting.

viii. The reviewers signify their decision by marking the appropriate section of the aforementioned of the aforementioned forms and affixing their signature in the space provided.

Decisions points are: **Approval, Minor Modifications, Major Modifications,** or **Disapproval**

1. *Minor modification* is one where a proposed change in research related activities does not significantly affect an assessment of the risks and benefits of the study and does not substantially change the specific aims or design of the study.

2. *Major modification* is one where a proposed change in research related activities significantly affects an assessment of the risks and benefits of the study or substantially changes the specific aims or design of the study.

ix. Expedited study protocols that are disapproved by the reviewers are referred for full Committee review. The full Committee review will be done on the next scheduled meeting and will take into consideration the assessment of the rest of the IECBMHR members who have been provided with the submission package.

x. The reviewers of full Committee study protocols discuss their findings in the meeting where Committee action is deliberated

xi. For decisions on resubmission and post approval submissions, the Committee may request information or clarificatory interview from PI, as the need arises

xii. In the event that a PI or the Sponsor decides not to continue the application for ethics review, the PI must write a letter requesting for withdrawal of study protocol from the ICH-IECBMHR.

All requests for withdrawal will be discussed during full Committee meetings regardless of initial review classification. Upon approval of request, study protocol will be archived as stipulated in **SOP 05-8: *Archived (Inactive/Completed/Terminated) Files***

xiii. In the event that a PI does not send any communication to the IECBMHR Secretariat regarding start of a researches/ studies which has been approved by the IECBMHR for more than one year, the study will be marked **Inactive** and the study protocol will be archived as stipulated in **SOP 05-8: *Archived (Inactive/Completed/Terminated) Files***.

xiv. In the event that a PI or the Sponsor decides not to continue the conduct of a academic study which has been approved by the IECBMHR, the PI must write a letter stating the reason for the decision and submission of accomplished **IECBMHR- ICH Form 4-E: *Early Study Termination Application Form***. All information regarding approval protocol not being conducted will be discussed during the full Committee meetings regardless of initial review classification. Committee action to the non-continuation of a academic research with an already approved protocol will be based on the reason provided by the PI and will be relayed to him/her at the earliest time possible. Upon approval of request, study protocol will be archived as stipulated in SOP 05-8: Archived (Inactive/ Completed/ Terminated) files.

xv. In the event that PI has to resubmit, the study will have to be submitted afresh and treated like a new protocol submission to be discussed in a full board meeting.

5. FULL COMMITTEE MEETING WORKFLOW

ACTIVITY	RESPONSIBILITY
Set regular meeting schedule ↓	IECBMHR Chair and Members/ Secretariat Staff
Distribute meeting agenda ↓	IECBMHR Secretariat Staff
Prepare meeting materials ↓	IECBMHR Secretariat Staff
Determine quorum ↓	IECBMHR Secretary
Call the meeting to order ↓	IECBMHR Chair
Confirm/Certify quorum ↓	IECBMHR Secretary
Declare conflict of interest ↓	IECBMHR Chair/IECBMHR Secretary/ IECBMHR Members
Read and approve the minutes ↓	IECBMHR Chair/IECBMHR Secretary/ IECBMHR Members
Review initial study protocol submissions and resubmissions ↓	IECBMHR Chair/IECBMHR Secretary/ IECBMHR Members
Conduct clarificatory interview ↓	IECBMHR Chair/IECBMHR Secretary/ IECBMHR Members
Review post-approval submissions (including SAEs) ↓	IECBMHR Chair/IECBMHR Secretary/ IECBMHR Members
Review report of results of expedited review ↓	IECBMHR Chair/IECBMHR Secretary/ IECBMHR Members
Adjourn meeting ↓	IECBMHR Chair
Collect, store and dispose meeting materials	IECBMHR Secretariat Staff

5. DETAILED INSTRUCTIONS FOR MEETING SCHEDULE

a. Regular Meeting Schedule

i. The ICH-IECBMHR will have its regular meeting once every three months. The meetings, however, few could be consolidated into only one meeting, depending on the number of items in the agenda that are to be discussed. As a general rule, 4 meetings per year i.e. once in 3 months are planned. However, frequency of meetings maybe altered at the discretion of Chairperson and/ or Member Secretary. Emergency meetings maybe conducted when there is urgency in reviewing (fast track reviews), or in the event of any SAE.

ii. The Secretariat Staff confirms the scheduled meeting date, time and venue at least **three (3)** days before the meeting.

iii. The Secretariat staff ensures that the venue, equipment and facilities are made available and in good working condition prior to the meeting day to allow ample time for equipment

replacement or purchase of necessary supplies. The meeting will be held in the Seminar room at ICH premises, unless otherwise specified

b. Preparation and Distribution of the Meeting Agenda

i. Schedule studies on the agenda on first come first serve basis. No limits placed on the number of items on the agenda. The number of items is based on available expertise (members and consultants), urgency, and order of submission to the IECBMHR and IECBMHR workload.

ii. In addition, the IECBMHR administrator will check the agenda prior to the meeting to identify IECBMHR members who may have a conflict of interest due to their participation as key personnel on a current or proposed research project. If a conflict of interest is identified, the study is assigned to another member who does not have a conflict of interest. An IECBMHR member who has a conflict of interest with regard to a research project that will be reviewed at a convened IECBMHR meeting must notify the IECBMHR office of the conflict prior to the meeting. Once the IECBMHR office receives notice of recues, the IECBMHR Member Secretary will seek an alternate IECBMHR member to join the meeting for the review of that project if necessary to meet quorum.

iii. The Secretariat Staff distributes (through email or messenger service) the ***Meeting Agenda*** together with the related study documents that may be available to meeting attendees (members, invited PIs, independent consultants, and others) at least seven (7) days before the meeting. If necessary & required, the same may be distributed electronically under password protection.

iv. Member should confirm their attendance within ***three (3)*** days of the meeting.

v. The Secretariat Staff sends meeting reminders to all persons who will be in attendance, through mobile phone, email, or regular telephone the day before the meeting. Non-members who will be attending only specific portions of the meeting should be informed accordingly, as specified in formal invitation issued to them to attend the meeting.

vi. The Secretariat informs the meeting date and time to the principal investigators through mobile phone, email, or regular telephone

c. Receipt of Study Documents

i. Receipt copies of the protocols/documents are distributed to the IECBMHR members by hand or by courier of hard copies and CD(softcopy)preferably **fourteen (14)** days in advance of the scheduled meeting [at least **seven (7)** days]

ii. Verify (verbally or by e-mail) with the members whether the protocol packages are received

iii. It is the responsibility of the IECBMHR member to verify items of the parcel on receipt and incase of any missing items, intimate the IECBMHR office immediately so that the relevant documents could be made available to the members before the meeting

iv. It is the responsibility of the IECBMHR member to identify any conflict of interest and notify the IECBMHR office of the conflict prior to the meeting.

d. Preparation of Members' Meeting Folders, Study Protocols, and Study Protocol-Related Submission Scheduled for Review

i. The Secretariat Staff e-mails of the approved Minutes (**IECBMHR-ICH Form 5-A: *Format of the Minutes of the Meeting***) of the previous meeting, for all members attending the meeting. For details regarding preparation of the Minutes, refer to **SOP 05-4: *Minutes of the Meeting***

ii. The Secretariat Staff distributes the folders containing meeting materials (such as agenda of previous meeting) at the start of the meeting. The folders are collected afterwards.

iii. During the actual meeting the IECBMHR Members must bring all meeting-related materials sent to them to serve as their reference during the review.

e. Determination of Quorum

i. Quorum is defined as the presence of at least 5 members with the following representation as per the ICMR guidelines 2017:

- Basic medical scientist
- Clinician
- Legal Expert
- Social scientist/ representatives of NGO/ Philosopher/ Ethicist/ Theologian or similar person
- Lay person from the community

ii. In case of anticipated lack of quorum, the ICH-IECBMHR Chair will reschedule or cancel the meeting

iii. On the appointed meeting time, the IECBMHR Secretary determines quorum viability and informs the IECBMHR Chair to indicate readiness to call the meeting to order.

f. Calling the Meeting to Order and Complete Required Procedures prior to Review Proper

i. The IECBMHR Chair, or a designated IECBMHR member in the Chair's absence, calls the meeting to order upon confirmation of quorum by the IECBMHR Secretary

ii. The ICH-IECBMHR also allows, at the discretion of the IECBMHR Chair, guests (such as auditors or surveyors) or observers (such as students or trainees) to observe IECBMHR meetings. Non-members (who are not PIs) attending any ICH-IECBMHR Meeting are required to sign a ***Confidentiality Agreement for Guests/Observers*** **(IECBMHR-ICH 3-H)**

iii. The Secretary documents the proceedings of the meeting, as soon as the meeting is called to order by the IECBMHR Chair, noting the time of the meeting start. The Secretary documents the development of the agenda, specifically all Committee opinions and actions with respective

reasons, for inclusion in the meeting minutes, and subsequent communication with the principal investigator. For details regarding preparation of the Minutes of the Meetings, refer to **SOP 05-4: *Minutes of the Meeting.***

iv. The IECBMHR Chair calls upon the Secretary to formally confirm quorum by citing the attendance requirements.

v. The IECBMHR Chair calls for declaration of Conflict of Interest (COI) with respect to any study protocol or submission scheduled for review. Members declaring COI are documented by the Secretary. The IECBMHR Chair instructs the members who declared COI to inhibit themselves from the deliberation of the respective study protocol for which the COI declaration was made.

A conflict of interest arises when a member(s) of the IECBMHR holds interests with respect to specific applications for review that may jeopardize his/her ability to provide free and independent evaluation of the research focused on the protection of the research participants. Conflict of interests may arise when an IECBMHR member has financial, material, institutional or social ties to the research.

If the unanticipated declaration of COI affects quorum, the particular item will not be discussed and deferred to the next meeting.

vi. The IECBMHR Chair presides over the review of the Minutes of the previous meeting. Any member can declare a motion for approval, which any member can second. The IECBMHR Chair then declares approval of the Minutes of the previous meeting.

vii. The IECBMHR Chair proceeds to facilitate discussion of matters arising from the minutes, the results of which are noted by the Secretariat Staff for inclusion in the Minutes of the current meeting.

g. Discussion of Initial Study Protocol Submission and Resubmission

i. Full Committee review of study protocol and study protocol-related submissions typically includes review of the following in sequence:

- Initial Study Protocol Submissions
- Resubmission or Study Protocols for Modification
- Request for Clarificatory Interview
- Withdrawal of Study Protocol Applications
- Study Protocol Amendment Applications
- Continuing Review Application
- Final Reports
- Serious Adverse Event Reports
- Site Visit Reports
- Study Protocol Non-Compliance (Deviation or Violation) Reports
- Early Study Termination Applications
- Queries from Various Stakeholders

ii. The IECBMHR Chair may allow some modification of the sequence of review in exigent circumstances. For example, if a clarificatory interview is included in the agenda, the Committee may opt to move this up in the review sequence.

iii. The IECBMHR Chair instructs the member who had previously declared conflict of interest (COI) to inhibit himself/herself from ensuing study protocol deliberation by leaving the room just before the respective study protocol is presented for deliberation. In some instances, such members may be called in by the Committee to answer questions to assist in arriving at a Committee action. Under no circumstances will IECBMHR members who have declared COI be allowed to participate in the decision.

iv. For initial review, the IECBMHR Chair calls the reviewers to discuss findings on respective study protocols based on study protocol assessment points specified in **BMHR Form 3-GA+B: *Protocol Assessment Form and Informed consent Assessment Form.*** The scientific, ethical & legal issues are also used.

v. Any IECBMHR Member may offer his/her opinion on the soundness of either the technical or ethical aspects of a clinical protocol under deliberation. All IECBMHR Members present in the meeting then deliberate on the study assessment points and informed consent elements as detailed in the aforementioned forms.

vi. For decision on either initial study protocol submission or resubmission, the IECBMHR Chair calls for any of the following actions after due consideration of the assessments made by the IECBMHR members and which are arrived at through consensus or through majority after a process of actual voting:

- **Approval**
- **Major Modification, which require full Committee deliberation**
- **Minor Modification, which can be expedited at the level of the Chair**
- **Disapproval**

vii. If the Chair feels that the present IECBMHR composition does not have the expertise to proceed with the review, the discussion of the study protocol may be deferred till the next meeting. Also, the IECBMHR may request comments or clarificatory interview from the PI at another meeting.

viii. The ICH-IECBMHR may allow investigators and other resource persons (such as an independent consultant commissioned by the IECBMHR) of highly specialized areas to attend the part of the IECBMHR meeting related to specific studies for purpose of clarifying issues related to the study protocol only, but not to present the study protocol to the Committee.

h. Conduct of Clarificatory Interview

i. If needed, the IECBMHR conducts clarificatory interviews with PIs and/or study team members whose submissions raise ethical or technical issues that are better addressed by the PI himself/herself.

ii. The Secretariat Staff sends **IECBMHR - ICH Form 5-D: *Letter for Clarificatory Interview*** to PIs called for interview. PIs may also request a clarificatory interview with the Committee by formally expressing their intention in writing.

iii. PIs or study team members to be interviewed by the IECBMHR must sign **IECBMHR-ICH Form 3-H: *Confidentiality Agreement for Guests/Observers*** prior to the interview. They are allowed inside the meeting room only during the actual interview, after which they will be requested to leave.

iv. The IECBMHR Chair calls for action depending on the type of submission (see **SOP 02-4b)** Decisions are based on the IECBMHR's assessment of the PI's response to their queries.

i. Discussion of Post-Approval Submissions

i. The IECBMHR Chair presents, if any, ***Study Protocol Amendment Submission Form* (IECBMHR-ICH Form 4-A)** that entail major amendments substantially affecting previous risk-benefit assessment on the study protocol. For details on classification of amendments and subsequent processing requirements, refer to **SOP 04-A: *Study Protocol Amendment***. The IECBMHR Chair calls for any of the following actions:

- Approval
- Major Modification to the study protocol, subject to full Committee review
- Minor Modification to the study protocol, subject to expedited review at the level of the Chair
- Disapproval

ii. The IECBMHR Chair presents, if any, submissions for Continuing Review of study protocols previously approved through full Committee and any ***Continuing Review Applications Forms* (IECBMHR-ICH Form 4-B)** ascertained to have altered previous risk-benefit assessment on the study protocol. For details on how continuing review applications are processed, refer to ***SOP - 4-4B: Continuing Review Application***. The IECBMHR Chair calls for any of the following actions:

- Uphold original approval with no further action
- Request information
- Recommend further action

iii. The IECBMHR Chair presents, if any, ***Final Report Forms* (IECBMHR-ICH 4-C)** of completed studies. For details on how Final Reports are processed, refer to **SOP 04-4C: *Final Reports***. The IECBMHR Chair calls on the Members to deliberate on the summary of findings and related ethical issues, including post-study management of study participants, and decide on Committee action such as:

- Approved
- Request information
- Recommend further action

- Uphold original approval with no further action
- Request information
- Recommend further action

j. Review of Results of Expedited Review

i. The IECBMHR Chair reports all the study protocols and study protocol-related submissions that were processed under expedited review.

ii. The submissions are reported in the same sequence as full Committee review with similar corresponding actions (see **SOP 03-4**).

k. Discussion of Other Matters: Before closing the meeting, the IECBMHR Chair calls for any non-study protocol matters that need attention or action, as the need arises.

l. Meeting Adjournment: With no other matters for discussion, the IECBMHR Chair formally adjourns the meeting, with the time noted by the Secretariat Staff who is documenting the meeting.

m. Collections and Storage or Disposal of Meeting Materials

i. The Secretariat Staff collects all meeting materials, including the documentation collected for the Minutes of the meeting; mindful that these materials are confidential and must be handled in accordance with **SOP V-9: *Maintenance of Confidentiality of Study Files*** and ICH-IECBMHR Documents.

ii. The Secretariat Staff files all meeting materials that must be stored in the relevant study files in a manner prescribed by instruction found in **SOP V-7: *Active Files and SOP V-8: Archived (Inactive/Completed/Terminated) Files***.

6. SPECIAL MEETINGS

a. Preparation for Conduct of Special Meeting

i. A special meeting may be called by the IECBMHR Chair as he determines the need for such or as it may be proposed by majority of the IECBMHR members.

ii. The decision to call a special meeting is based on the:

- Urgency of issues at hand such that, if delayed, it may have a negative impact on public benefit
- Occurrence of unexpected serious adverse events
- Life and death situations
- Other similar situations or occurrences

iii. The Secretariat informs the IECBMHR members, and invited persons, whose presence is determined as vital that the special meeting will be called.

iv. Quorum is defined as given earlier. If needed, a member/or invited guest with expertise on the item to be discussed

v. The meeting conducted in the same sequence as full Committee review with similar corresponding actions (see **SOP 03-4**)

vi. The collection and storage or disposal of special meeting materials follows the procedures described for the regular meeting

7. LIST OF FORMS

ICH-IECBMHR Form 3-A	Application form for Initial Review
ICH-IECBMHR Form 3-B	Application Form for Exemption from Review
ICH-IECBMHR Form 3-C	Application Form for Expedited Review
ICH-IECBMHR Form 3-D	Application Form for Human Genetics Testing Research
ICH-IECBMHR Form 3-E	Application Form for Socio-Behavioural and Public Health Research
ICH-IECBMHR Form 3-F	Guide for Thesis submission to IEC
ICH-IECBMHR Form 3-G	Protocol and Informed consent Assessment Form
ICH-IECBMHR Form 3-H	Confidentiality Agreement for Guests or observers

Application Form for Initial Review

Institutional Ethics Committee For Biomedical And Health Research, Institute of Child Health, Kolkata

IECBMHR Ref. No. *(For office use):*

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

SECTION A - BASIC INFORMATION

1. ADMINISTRATIVE DETAILS

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

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

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

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

(f) Type of review requested[1] :

Exemption from review ☐ Expedited review ☐ Full committee review ☐

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

.....

.....

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

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

(i) Details of Investigators:

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

(j) Number of studies where applicant is a:

i) Principal Investigator at time of submission .....

ii) Co-Investigator at time of submission: .....

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

[1] *Refer to National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017 on Page 36 Table 4.2. for types of review*

[2] *Include telephone/mobile, fax numbers and email id*

2. FUNDING DETAILS AND BUDGET

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

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

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

.....

SECTION B - RESEARCH RELATED INFORMATION

3. OVERVIEW OF RESEARCH

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

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(b) Type of study:

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

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. 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

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

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

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

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

Review within multi-centre research group ☐ No review ☐

Date of review: dd | mm | yy

Comments of scientific committee, if any (100 words)

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SECTION C: PARTICIPANT RELATED INFORMATION

5. RECRUITMENT AND RESEARCH PARTICIPANTS

(a) Type of participants in the study:

Healthy volunteers ☐ Patients ☐ Vulnerable persons/ Special groups ☐

Others ☐ *(Specify)* .....

Who will do the recruitment? .....

Participant recruitment methods used:

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

Others ☐ *(Specify)* .....

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

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

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

Any other *(Specify)*: ☐ .....

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

.....

.....

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

.....

.....

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

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

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

.....

.....

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

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

.....

.....

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

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

.....

.....

6. BENEFITS AND RISKS

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

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

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

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

.....

.....

(b) What are the potential benefits from the study?

	Yes	No	If yes,	Direct	Indirect
For the participant	☐	☐		☐	☐
For the society/community	☐	☐		☐	☐
For improvement in science	☐	☐		☐	☐

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

.....

.....

.....

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

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

If Yes, Specify .....

.....

.....

7. INFORMED CONSENT

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

.....

.....

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

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

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

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

(c) Type of consent planned for :

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

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

.....

Other ☐

(specify) .....

(d) Who will obtain the informed consent?

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

Any tools to be used .....

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

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

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

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

.....

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

.....

.....

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

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

.....

3. PAYMENT/COMPENSATION

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

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

.....

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

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

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

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

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

.....

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

Yes ☐ No ☐ N/A ☐

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

[8]Enclose undertaking from PI confirming the same

9. STORAGE AND CONFIDENTIALITY

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

Anonymous/Unidentified ☐ Anonymized: Reversibly coded ☐ Irreversibly coded ☐ Identifiable ☐ If identifiers must be retained, what additional precautions will be taken to ensure that access is limited /data is safeguarded? (e.g. data stored in a cabinet, password protected computer etc.) .....

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(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 ☐

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.....

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

SECTION E: DECLARATION AND CHECKLIST [10]

11. DECLARATION (Please tick as applicable)	
☐	I/We certify that the information provided in this application is complete and correct.
☐	I/We confirm that all investigators have approved the submitted version of proposal/related documents.
☐	I/We confirm that this study will be conducted in accordance with the latest ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants and other applicable regulations and guidelines.
☐	I/We confirm that this study will be conducted in accordance with the Drugs and Cosmetics Act 1940 and its Rules 1945 as amended from time to time, GCP guidelines and other applicable regulations and guidelines.
☐	I/We will comply with all policies and guidelines of the institute and affiliated/collaborating institutions where this study will be conducted.
☐	I/We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the EC approved protocol.
☐	I/We declare that the expenditure in case of injury related to the study will be taken care of.
☐	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 wherever 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

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

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

12. CHECKLIST

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

PERMISSION FROM GOVERNING AUTHORITIES

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

ANY OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY

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

**For multicentre research.*

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

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

(3B)

Application Form for Exemption from Review

Institutional Ethics Committee For Biomedical And Health Research, Institute of Child Health, Kolkata

IECBMHR 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)*

(3C)

Application Form for Expedited Review

Institutional Ethics Committee For Biomedical And Health Research
Institute of Child Health, Kolkata

IECBMHR 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*

(3D)

Application Form for Human Genetics Testing Research

Institutional Ethics Committee For Biomedical And Health Research, Institute of Child Health, Kolkata

IECBMHR 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

(3E)

Application Form for Socio-Behavioural and Public Health Research

Institutional Ethics Committee For Biomedical And Health Research, Institute of Child Health, Kolkata

IECBMHR 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 behavior 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 ☐

.....

.....

.....

FORMAT FOR SUBMISSION OF PROTOCOL INVOLVING RESEARCH IN HUMAN SUBJECTS FOR CLEARANCE BY INSTITUTIONAL ETHICS COMMITTEE (IEC) OF INSTITUTE OF CHILD HEALTH (ICH) FOR ACADEMIC STUDIES (&FOR STUDENT'S THESIS OR DISSERTATION)

Submit fifteen (11) copies of the Research Project along with Covering letter and 'soft copy' on CD with following information to the Member Secretary, Institutional Ethics Committee For Biomedical and Health Research at Room No. 122, Ground Floor, ICH. The Investigator must submit protocol through Chief Guide and Head of Department who ensures that the project has been vetted both from the scientific and ethical point of view.

No research project shall be / can be started unless ethics clearance/approval is obtained. Please bear in mind that no retrospective / post facto ethical clearance can be provided to research projects which were neither submitted nor vetted by the ethics committee.

Eligibility: Investigator must be a student/ faculty of ICH, Kolkata and have appropriate post graduate qualification approved by respective statutory council

All submissions should be made in the prescribed Format of the **Institutional Ethics Committee For Biomedical and Health Research** with signatures of all the investigators. The submission must be accompanied with a submission checklist (attached). *Participant Informed Consent Form* (PICF) and *Participant Information Sheet* (PIS), in English, Bengali and Hindi, should be prepared **in a simple layman's language in a narrative form, directed to Participant /LAR, covering all the points given as per ICMR 2017 guidelines (available on the ICMR website** www.icmr.nic.in for details). Also ensure that all the pages are numbered.

Project Submission Time: Submissions will be received on all days (except Sundays and Holidays) between 10.00 and 14.00 hrs. Proposals received before 20 days will be processed in the coming IECBMHR full board meetings and those received after scheduled date will be processed in the next meeting. All full board meetings of IECBMHR are held once every 2 months.

Reply Submission: In case proposal needs to be resubmitted, while submitting replies raised by the Institutional Ethics Committee, the candidates are advised to mention the IECBMHR reference number: IECBMHR/xxx/yyyy and also attach a copy of the comments of the IECBMHR. These changes should be incorporated as a soft copy in the CD.

Amendment Submission: While submitting amendments in protocols a covering letter should be provided clearly stating the changes, with changes marked in the revised protocol in red ink and soft copy of the same should be submitted in a CD.

Note to Guides:
It is desirable that topics pertaining to clinical/drug trials should be avoided as thesis topics to Ph.D.; MD and MBBS students. In case these are given, appropriate DCGI permission should be available.

Please fill up the form electronically and take a print out before submission:
Write NA where 'Not Applicable'. Incomplete forms will not be accepted

1. Full Title of Study:	
1a. IECBMHR Reference Number: (Obtain from IECBMHR office)	
2.1 Name & signatures of the candidate	2.1 Signatures
2.2 Department	2.2
2.3 Degree/course	2.3 MD /DNB / Ph.D. (encircle)
2.4 Batch of admission to course	2.4 Month/year
2.5 Month & year of submission of thesis	2.5 Month/year
2.6 Email ID of the Candidate	
Email ID of Chief Guide	
3. Name of Faculty & Department (Guide/Co-guide) (Minimum two co-guides signatures are required)	Signatures (Guide/Co-Guides)
3.1	3.1
3.2	3.2
3.3	3.3
3.4	3.4
3.5	3.5
(Expand if any more co-guides)	
4. Objectives of the study	4.1
	4.2
	4.3
	4.4
	4.5

5. Why this study is required? Please provide brief justification		
6. Methodology	6.1 Number and Age range of Patients Methods of Recuitment?	
	6.2. Inclusion criteria	
	a)	
	b)	
	c)	
	d)	
	6.3. Exclusion criteria	
	a)	
	b)	
	c)	
	d)	
	6.4. Control(s)	
	6.5. Study design *(mark √)* **Observational:** • Prospective • Retrospective • Cross-sectional **Interventional:** If yes, does the study involve any deviation from routine standard practice? If yes, Drug marketed in India? Applied to DCGI?	
	6.6. Dosages of drug	
	6.7. Duration of treatment	
	6.8. *(mark √)* Does the study involve- Any new device? Any New Technique (Surgery/PT/OT)? Diagnostic Kit/ Application? Fetal tissue/ abortus? Organs/ body fluids? Gene therapy? Ionizing radiations/ Radioisotopes? Blood/ urine specimens (specifically drawn for project)? Will stored (left over) tissue/ samples be used? Will samples be stored for future research purpose? Will samples be sent to any outside lab?	
	6.9 Permission to use copyrighted Questionnaire/profroma	
	6.10 Brief Methodology (including statistical procedures to be employed)	
7. Permission from Drug Controller General of India (DCGI)	1. Required	2. Not required
	3. Received	4. Applied when:
8. Permission from other agencies , if required	1. Required	2. Not required
	3. Received	4. Applied when:

9. a) Safety measures for proposed interventions	a)		
b) Results of relevant laboratory tests will be provided to participant	b)		
c) Would A-V recording be necessary?	c)		
d) Would participants be compensated for participation?	d) Monetary Kind		
10. Plans to withdraw standard therapy in research?	Yes	No	
	Remarks:		
11. Plan for provision of coverage for medical risk (if applicable)			
12. How you will maintain Confidentiality of subject?			
13. Costs Involved (Appx.) in Rs.			
13.1 Investigations	13.1		
13.2 Disposables	13.2		
13.3 Devices	13.3		
13.4 Drugs / Contrast Media	13.4		
	Remarks:		
Who will bear the costs of the Requirements? *(mark √)*	Patient	Institute (Research Fund)	Exempted
	Other Sponsor Agencies (Name)		
14. Participant Information Sheet *(mark √ if yes)*	Attached English version		
	Attached Hindi version		
	Attached Bengali version		
15a. Participant Informed Consent Form *(mark √ if yes)*	Attached English version		
	Attached Hindi version		
	Attached Bengali version		
15b. Participant Assent Form (Participant >7 years of age) *(mark √ if yes)*	Attached English version		
	Attached Hindi version		
	Attached Bengali version		
16. Whether any work on this project has started or not?	*(mark √ if yes, X if no)* *(Please enclose a separate certificate to this effect).*		

17.Attached documents	**Yes**	**No**	**Date by which it will be submitted, if pending**	**NA**
Covering letter, through proper channel, to Chairperson/ Member Secretary, IECBMHR- ICH				
Project submission application form duly filled				
Approval of Scientific Review Board of ICH (for thesis/dissertations proposals)				

Summary of protocol (in not more than 500 words)				
Protocol				
Informed consent document in English, Hindi and Bengali				
Assent document in English, Hindi and Bengali				
Audio Visual Consent				
Case Record Forms				
Questionnaire or other material to be used				
• Undertaking that the study shall be done in accordance with ICMR and GCP guidelines • Definite undertaking as to who will bear the expenditure of injury related to the project • Investigator should provide undertaking what they will do with the leftover sample/ tissue				
Permission from Head of Institute if ICH is funding any extra costs for the project				
Permission as mentioned in 6.9				
Certificate/undertaking as mentioned in 16				
In case of multicentric study, IECBMHR clearance of other centers must be provided				
In case an insurance cover is intended, Insurance certificate must be provided (as per Schedule Y/ICMR guidelines)				
In case of Clinical trials, proof of registration of Clinical trial with CTRI needs to be submitted.				
17.12 Soft Copy on CD:				
17.13 Others:				

STUDY PROTOCOL ASSESSMENT FORM

STUDY PROTOCOL INFORMATION

Study No.	
Study Protocol Title	
Principal Investigator	
Date of Submission	

INSTRUCTIONS:

To the **PRINCIPAL INVESTIGATOR**: *OBTAIN AN ELECTRONIC COPY OF THIS FORM AND ENCODE ALL INFORMATION REQUIRED IN THE SPACE PROVIDED. PRINT NAME, DATE AND SIGN THIS FORM BEFORE SUBMISSION.* Please indicate in the space provided below whether or not the specified assessment point is addressed by your study protocol. Indicate also if such assessment point is *not applicable* or is included in other documents submitted. To facilitate the evaluation of the assessment point, indicate the page and paragraph where this information can be found.

To the **IECBMHR REVIEWER**: Please evaluate how the assessment points outlined below have been appropriately addressed by the study protocol, as applicable, by confirming the submitted information and putting your comments in the space provided under "REVIEWER COMMENTS". Please finalize your review/evaluation by indicating your conclusions under "RECOMMENDED ACTION" and signing in the space provided for the reviewer.

ASSESSMENT POINTS	To be filled out by the PRINCIPAL INVESTIGATOR			To be filled out by the IECBMHR REVIEWER			
	Mark (√) contains the specified assessment point		Indicate page and paragraph where it is found				
	YES	N/A		YES	NO	N/A	COMMENT(S)
1. SCIENTIFIC DESIGN							
a. Objectives *Review of viability of expected output*							
b. Literature Review *Review of results of previous animal/ human studies showing known risks and benefits of intervention, including known adverse drug effects, in case of drug trials*							
c. Research Design *Review of appropriateness of design in view of objectives*							

Need for human participants *Need for placebo (if any)*							
d. Sampling Design *Review of appropriateness of sampling methods and techniques*							
e. Sample Size *Review of computation of sample size*							
f. Statistical Analysis Plan (SAP) *Review of appropriateness of statistical methods to be used and how participant data will be summarized*							
g. Data Analysis Plan *Review of appropriateness of statistical and non-statistical methods of data analysis*							
h. Inclusion Criteria *Review of precision of criteria both for scientific merit and safety concerns; and of equitable selection*							
i. Exclusion Criteria *Review of criteria both for scientific merit and safety concerns*							
j. Withdrawal Criteria *Review of criteria both for scientific merit and safety concerns*							
2. CONDUCT OF STUDY							
a. Specimen Handling *Review of specimen storage, access, disposal, and terms of use*							
b. PI Qualifications *Review of Curriculum Vitae and relevant certifications to ascertain capability to manage study related risks* *Disclosure of any COI* *Investigator Undertaking given* *Investigator conducting more than three active trials at site*							
c. Suitability of Site *Presence of adequate qualified staff and infrastructures*							
d. Laboratory facilities *Presence of adequate resources or facilities outsourced and whether samples sent abroad for testing*							
e. Duration *Review of length/extent of human participant involvement in the study*							
f. Data monitoring safety board *Provision of monitoring of data to ensure safety of participants*							

3. ETHICAL CONSIDERATIONS							
a. Conflict of Interest *Review of management of conflict arising from financial, familial, or proprietary considerations of the PI, sponsor, or the study site*							
b. Privacy and Confidentiality *Review of measures or guarantees to protect privacy and confidentiality of participant information as indicated by data collection methods including data protection plans*							
c. Informed Consent Process *Review of application of the principle of respect for persons, who may solicit consent, how and when it will be done; who may give consent especially in case of special populations like minors and those who are not legally competent to give consent, or indigenous people which require additional clearances* *Procedures, content, language of informed consent form* *Whether ICF is as per template* *Contact persons mentioned*							
d. Vulnerability *Review of involvement of vulnerable study populations and impact on informed consent. Vulnerable groups include children, the elderly, ethnic and racial minority groups, the homeless, prisoners, cancer patients, terminally ill patients, people who are politically powerless, or junior members of a hierarchical group*							
e. Recruitment *Review of manner of recruitment including appropriateness of identified recruiting parties*							
f. Assent *Review of feasibility of obtaining assent vis à vis incompetence to consent; Review of applicability of the assent age brackets in children:* *0 - under 7: No assent* *7 - under 12: Verbal assent* *12 - under 15: Simplified assent form* *15 - under 18: Co-sign informed consent form with parents*							

g. **Risks** *Review of level of risk and measures to mitigate these risks (including physical, psychological, social, economic), including plans for adverse event management; Review of justification for allowable use of placebo as detailed in Declaration of Helsinki (as applicable)*							
h. **Benefits** *Review of potential direct benefit to participants; the potential to yield generalizable knowledge about the participants' condition/ problem; non-material compensation to participant (health education or other creative benefits), where no clear, direct benefit from the project will be received by the participant*							
i. **Incentives or compensation** *Review of amount and method of compensations, financial incentives, or reimbursement of study-related expenses* *Inducement for participation likely or unlikely*							
j. **Post trial access** *Provision for post trial benefits* *Study results/ findings shared*							
k. **Study related injuries/death and compensation** *Provision of free medical treatment in cases of study related injuries or death and appropriate compensation*							
l. **Community Considerations** *Review of impact of the research on the community where the research occurs and/or to whom findings can be linked; including issues like stigma or draining of local capacity; sensitivity to cultural traditions, and involvement of the community in decisions about the conduct of the study*							
m. **Collaborative Study Terms of Reference** *Review of terms of collaborative study especially in case of multi-country/multi-institutional studies, including intellectual property rights, publication rights, information and responsibility sharing, transparency, and capacity building*							

NAME OF PRINCIPAL INVESTIGATOR:	SIGNATURE:	Date: (dd/mmm/yyyy)

**Note:* Please fill *out this* form electronically *before printing.*

OTHER COMMENTS:
RECOMMENDED ACTION ☐ A) **APPROVAL** ☐ B) **MINOR MODIFICATIONS, subject to Expedited Review at the level of the Chair** ☐ C) **MAJOR MODIFICATIONS, subject to Full Board Review** ☐ D) **DISAPPROVAL**
JUSTIFICATION FOR RECOMMENDATION OF B, C, or D:

NAME OF REVIEWER:	SIGNATURE:	Date:(dd/mmm/yyyy)

To be filled out by the REVIEWER

Number of Issues Requested for Revisions [Note: Put a tick against elements that may have an issue during review]		
1	Research Question	
2	Objectives	
3	Risk & Benefit	
4	Study Design	
5	Research Methodology	
6	Sample Size	
7	Inclusion/ Exclusion Criteria	
8	Recruitment Process	
9	Specimen Data Collection	
10	Statistical & data analysis	
11	Privacy and Confidentiality	
12	Informed Consent (Document +Process]	
13	Participant Information Sheet	
14	Informed Consent Form	
15	Assent Form	
16	AV Consent Form	
17	Study Documents	
18	Related study documents (IB, Advertisement etc)	
19	Case Record Form	
20	Research facilities	
21	Trial Agreement	
22	Budgeting	
23	Insurance	
24	Compensation	
25	Any other	

INFORMED CONSENT ASSESSMENT FORM

STUDY PROTOCOL INFORMATION

Study No.	
Study Protocol Title	
Principal Investigator	
Date of Submission	

INSTRUCTIONS:

To the **PRINCIPAL INVESTIGATOR**: *OBTAIN AN ELECTRONIC COPY OF THIS FORM AND ENCODE ALL INFORMATION REQUIRED IN THE SPACE PROVIDED. PRINT NAME, DATE AND SIGN THIS FORM BEFORE SUBMISSION.*
Please indicate in the space provided below whether or not the specified element is addressed by the informed consent form (ICF). To facilitate the evaluation of the assessment point, indicate page and paragraph where this information can be found.

To the IEC **REVIEWER**: Please evaluate how the elements outlined by the principal investigator have been addressed by the informed consent form (ICF), confirm the submitted information and put your comments in the space provided under "IECBMHR REVIEWER COMMENTS". Please finalize your review/evaluation by indicating your conclusions under "RECOMMENDED ACTION" and signing in the space provided for the reviewer.

ESSENTIAL ELEMENTS	To be filled out by the PRINCIPAL INVESTIGATOR			To be filled out by the IECBMHR REVIEWER			
	Mark (√) contains the specified assessment point		Indicate page and paragraph where it is found				
	YES	N/A		YES	NO	N/A	COMMENT(S)
Does the informed consent form have a statement on the following?							
1. the study being a research							
2. the purpose of the study							
3. study-related treatments and the probability for random assignment							
4. study procedures including all invasive procedures are defined							
5. the responsibilities of the participants are outlined							
6. expected duration of participation in the study							
7. the approximate number of participants in the study							

8. the study aspects that are experimental							
9. foreseeable risks to participant/ embryo/fetus/ nursing infant; including pain, discomfort, or inconvenience associated with participation including risks to spouse or partner;							
10. risks from allowable use of placebo (as applicable)							
11. reasonably expected benefits; or absence of direct benefit to participants, as applicable							
12. expected benefits to the community or to society, or contributions to scientific knowledge							
13. description of post-study access to the study product or intervention that have been proven safe and effective							
14. alternative procedures or treatment available to participant							
15. compensation or insurance or treatment entitlements of the participant in case of study-related injury							
16. anticipated payment, if any, to the participant in the course of the study; whether money or other forms of material goods, and if so, the kind and amount							
17. compensation (or no plans of compensation) for the participant or the participant's family or dependents in case of disability or death resulting from study-related injuries							
18. anticipated expenses, if any, to the participant in the course of the study							
19. that participation is voluntary, and that participant may withdraw anytime without penalty or loss of benefit to which the participant is entitled							
20. that the study monitor(s), auditor(s), the IEC-ICH, and regulatory authorities will be granted direct access to participant's medical records for purposes ONLY of verification of clinical trial procedures and data							
21. that the records identifying the participant will be kept							

confidential and will not be made publicly available, to the extent permitted by law; and that the identity of the participant will remain confidential in the event the study results are published; including limitations to the investigator's ability to guarantee confidentiality							
22. description of policy regarding the use of genetic tests and familial genetic information, and precautions in place to prevent disclosure of results to immediate family relative or to others without consent of the participant							
23. possible direct or secondary use of participant's medical records and biological specimens taken in the course of clinical care or in the course of this study							
24. plans to destroy collected biological specimens at the end of the study; if not, details about storage (duration, type of storage facility, location, access information) and possible future use; affirming participant's right to refuse future use, refuse storage, or have the materials destroyed							
25. plans to develop commercial products from biological specimens and whether the participant will receive monetary or other benefit from such development							
26. that the participant or participant's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to willingness of the participant to continue participation							
27. describing access of participant to the result of the study							
28. Statement describing extent of participant's right to access his/her records (or lack thereof *vis à vis* pending request for approval of non or partial disclosure)							
29. foreseeable circumstances and reasons under which participation in the study may be terminated							
30. sponsor, institutional affiliation of the investigators, and nature and sources of funds							

31. whether the investigator is serving only as an investigator or as both investigator and the participant's healthcare provider							
32. person(s) to contact in the study team for further information regarding the study and whom to contact in the event of study-related injury							
33. that the IEC-ICH has approved the study, and may be reached through the following contact for information regarding rights of study participants, including grievances and complaints: *Contact Person:* Name of Chair, IEC *Address:* IEC ICH, 11, Dr.Biresh Guha Street. Kolkata- 700017 *Tel. No.:* <<mobile no of chair>>							

NAME OF PRINCIPAL INVESTIGATOR:	SIGNATURE:	Date: (dd/mmm/yyyy)

**Note:* Please fill *out this* form electronically *before printing.*

To be filled out by the REVIEWER:

OTHER COMMENTS:(Please include comments on risk benefit assessment)
RECOMMENDED ACTION ☐ **A) APPROVAL** ☐ **B) MINOR MODIFICATIONS, subject to Expedited Review at the level of the Chair** ☐ **C) MAJOR MODIFICATIONS, subject to Full Board Review** ☐ **D) DISAPPROVAL**
JUSTIFICATION FOR RECOMMENDATION OF B, C, or D: _____ _____ _____ _____ _____ _____ _____ _____ _____

NAME OF REVIEWER	SIGNATURE:	Date(dd/mmm/yyyy)

Confidentiality Agreement for Guests/Observers

I, _____, understand that I am allowed to attend the IECBMHR-ICH meeting and to have supervised access to the IECBMHR-ICH files as a/an (Guest/Observer) _____. In the course of the meeting of the IECBMHR-ICH and opening of its files, some confidential information may be disclosed or discussed. Upon signing this form, I agree to take reasonable measures to keep all information confidential.

Date of IECBMHR-ICH Meeting : _____

Purpose of attendance/access

:_____

_____

_____

_____

IECBMHR SECRETARY	Name & Signature _____ Date
IECBMHR CHAIR	Name & Signature _____ Date

Post Approval Review
SOP Code: SOP 04/V2

Reviewed By:

Name and Position in IECBMHR	Signature
Dr. Phalguni Dutta Chairperson	
Dr. Surupa Basu Member Secretary	
Dr. Arunaloke Bhattacharyya Clinician	
Prof. Jaydeep Choudhury Clinician	
Dr. Supriyo Choudhury Basic Medical Scientist; Clinical Pharmacologist	
Mr. Tamal Chatterjee Legal expert	
Ms. Anasuya Basu Layperson	
Ms. Kaberi Mukherjee Theologian	

Approved By

Name and Position in IECBMHR	Signature
Dr. Phalguni Dutta Chairperson	

TABLE OF CONTENTS

Supersedes	01
Version	02
Authored By	SOP Team
Version Date	30 September 2022
Approved By	Dr. Phalguni Dutta
Effective Date	05 December 2022

1. OBJECTIVES

This SOP describes how the ICH-IECBMHR processes post approval submissions by the Principal Investigators. Depending on the nature of the submissions, they may be processed by either "expedited" or "full board" review. This chapter describes submission procedures, required forms, documentation of committee, communication of committee to the PI, and filing of results.

2. SCOPE

This SOP applies to all study protocol-related submissions after initial approval has been issued for the study protocol-related documents. These submissions include request for amendments, continuing review applications, final reports, adverse event reports, deviation/non-compliance/violation reports, study participant queries, and site visit / monitoring reports.

3. RESPONSIBILITIES

It is the responsibility of the Principal Investigator to comply with post-approval requirements such as submission of amendment applications if there are changes in the study protocol or informed consent form, continuing review reports within the prescribed period, serious adverse events reports, study protocol non-compliance (deviation/violation) or early study termination reports, and final reporting.

The Secretariat Staff is responsible for receiving and processing all submissions, including questions, queries and/or complaints from research participants. IECBMHR members are responsible for reviewing these post-approval submissions related to study protocols for which they are primary reviewers.

In the event that a Site Visit (Monitoring/Audit) becomes necessary, it is the responsibility of the Chair to form a Site Visit Team, the responsibility of the assigned members to conduct the Site Visit and issue a report for presentation in the IECBMHR meeting, and responsibility of the Secretariat Staff to organize the Site Visit.

4. STUDY PROTOCOL AMENDMENTS, CONTINUING REVIEW APPLICATIONS, FINAL REPORTS, NONCOMPLIANCE REPORTS, EARLY STUDY TERMINATION APPLICATION, AND PARTICIPANT QUERIES OR COMPLAINTS WORKFLOW

ACTIVITY	RESPONSIBILITY
Receive and manage documents submission pertaining to study protocol amendments/continuing review applications/final reports/noncompliance reports/early study termination applications/participant queries or complaints ↓	Secretariat Staff
Submit documents to the IECBMHR Chair to determine classification of review as expedited or full board ↓	Secretariat Staff
IECBMHR Chair, Members reviews submissions classified as expedited review (Expedited Review at the level of the Chair)	IECBMHR Chair AND Members Secretary /Reviewers

↓ Review full board study protocols in *IECBMHR* meeting	Members
↓ Communicate results to Principal Investigator	Secretariat Staff
↓ Manage study protocol files	Secretariat Staff

DETAILED INSTRUCTIONS:

a. Study Protocol Amendment

i. Receipt and management of Study Protocol Amendment package upon Submission

1. A study protocol amendment is a written description of a change to a protocol, informed consent document or any other study related material. Favorable opinion or approval should be obtained from the ICH-IECBMHR before an amendment can be implemented in the conduct of a study.

2. A study protocol amendment is facilitated through the submission of **IECBMHR-ICH Form 4-A: *Study Protocol Amendment Submission Form*** with the amended study protocol and/or protocol-related documents by the principal investigator to the ICH-IECBMHR, which issued the initial ethical clearance or approval to the study protocol. This comprises the Study Protocol Amendment Package.

3. Upon receipt of the Study protocol amendment package, the Secretariat Staff logs the date of submission on the ***Submission Database* (IECBMHR-*ICH* Form 5-N)**.

4. The Secretariat Staff checks the submission for completeness and gives a receiving stamp.

5. The Secretariat Staff ensures that sufficient copies for the IECBMHR Members have been submitted by the PI for full board submissions. Dossiers may be sent electronically (if required) ensuring confidentiality and controlled access.

ii. Classification of Review by the IECBMHR Chair

1. The Secretariat Staff sends the Study Protocol Submission Package to the *IECBMHR* Chair immediately for classification of review as expedited or full board.

6. The continuing review of a study protocol is initiated by the submission by the P.I. of the **IECBMHR-*ICH* Form 4-B: *Continuing Review Application Form***, together with the synopsis of the study protocol and current informed consent documents. This comprises the continuing review application package.

7. The Secretariat Staff checks the application package for completeness and gives a receiving stamp.

8. The Secretariat Staff logs the date of submission on the ***Submissions Database*** **(IECBMHR-*ICH* Form 5-N)**.

9. The Secretariat Staff ensures that sufficient copies for the *IECBMHR* Members have been submitted by the PI for full board submissions.

10. Thesis / Dissertation projects are exempted from Annual Review by *IECBMHR*

ii. Classification of Review by the IECBMHR Chair

1. The *IECBMHR* Chair classifies the submission as either full board or expedited review.

2. Unless otherwise dictated by circumstances in and specifics of the submitted information, the classification of continuing review as expedited or full board is based on the initial review classification (i.e. continuing review of full board study protocols is done through full board review).

iii. Review by IECBMHR Chair and members

1. The continuing review application package is sent together with a copy of the study protocol to the *IECBMHR* Chair for expedited review study protocols and to *IECBMHR* members either by mail or electronically.

2. For submissions under expedited review, action is finalized at the level of the *IECBMHR* Chair within fifteen (15) calendar days.

3. Continuing review application packages subject to full board review received within the cut-off period of twenty (20) days before the *IECBMHR* meeting are sent to Reviewers as soon as they are received by the *IECBMHR* or at least ten (10) calendar days before the meeting.

4. The Secretariat Staff places the continuing review application on the agenda for the next *IECBMHR* meeting.

5. The reviewers accomplish the review & return on the day of the *IECBMHR* meeting the review application package.

iv. Full Board Review of Continuing Review Application

1. The Secretariat Staff distributes the following continuing review application package to *IECBMHR* Members along with the meeting agenda:
   - **IECBMHR-*ICH* Form 4-B: *Continuing Review Application Form***
   - Study protocol synopsis
   - Current informed consent documents

2. The documents are presented to *IECBMHR* Members when continuing review applications are deliberated on. For detailed information on the conduct of full board review of continuing review application, see SOP 03.

v. Communication of Results

1. The PI is notified of the decision noting board action on the continuing review application through a letter.

2. The PI may be requested to provide additional information or submit additional documents. The Committee may also recommend further action on the continuing review application.

vi. Files management

1. The *IECBMHR* Chair and *IECBMHR* Secretary sign **IECBMHR-*ICH* Form 4-B: *Continuing Review Application Form***.

2. The Secretariat Staff stores the signed continuing review application documents in the study protocol file folder.

c. Final Report

i. Management of the Final Report Package Upon Submission

1. Upon completion of the study, the investigator should provide the ICH-*IECBMHR* with a summary of the outcome of the study, especially of the human participants who were involved, in a form of an end of study report.

2. The end of study reporting is facilitated through the submission of **IECBMHR-*ICH* Form 4-C: *Final Report Form***, together with the documents deemed relevant by the investigator to clarify information indicated in the final report. This comprises the final report package.

3. The Secretariat Staff checks the submission for completeness and gives a receiving of stamp.

4. The Secretariat Staff logs the date of submission on the ***Submissions Database*** **(IECBMHR –ICH Form 5-N).**

ii. Classification of Review by the IECBMHR Chair

1. The *IECBMHR* Chair classifies the submission as either full board or expedited review.

2. Generally, classification of review of final report as expedited or full board is based on the initial review classification (i.e. final report of full board study protocols is done through full board review); unless otherwise indicated by the specifics or details of the submitted information.

iii. Expedited Review by IECBMHR Chair & members

1. The Secretariat Staff sends the final report package together with a copy of the study protocol to the Chair & members.

2. For submission under expedited review, action is finalized at the level of the Chair within seven (7) calendar days.

3. Final Report packages subject to full board review received within the cut-off period of two (2) weeks or fourteen (14) calendar days before the *IECBMHR* meeting are sent to all members ten (10) to twelve (12) calendar days before the meeting.

4. The Secretariat Staff places the final report submission on the agenda for the next *IECBMHR* meeting.

5. The members accomplish the review and return the signed on the day of the *IECBMHR* meeting the final report package.

iv. Full Board Review of Final Report

1. The Secretariat Staff distributes the following final report package to *IECBMHR* Members along with the meeting agenda:
   - **IECBMHR-*ICH* Form 4-D: *Final Report Form***
   - Relevant documents or attachments

2. The documents are presented to *IECBMHR* Members when final reports are deliberated on. For detailed information on the conduct of full board review reports, see SOP 03.

v. Communication of Results

1. The PI is notified of the *IECBMHR* decision, noting *IECBMHR* action on the final report through an action letter.

2. The PI may be requested to provide additional information or submit additional documents, in which case the final report may be accepted, but action regarding archiving may be deferred pending submission of results of the study.

3. Once the final report is approved,
   - The study protocol is now classified as inactive.
   - Ethical clearance is deemed expired effective on the day of the *IECBMHR* meeting.
   - Study Protocol records will be made available for five (5) years in the archives after the expiration date.

vi. *Files Management*

1. The *IECBMHR* Secretary and *IECBMHR* Chair sign **IECBMHR-*ICH* Form 4-C:*Final Report Form***

2. The Secretariat Staff stores the signed final report documents in the study protocol file folder, upon approval of the final report, when no further action is expected from the PI.

3. The Secretariat Staff enters relevant study protocol data into the Study Protocol Database to signify the end of study.

4. The Secretariat Staff transfers the study protocol folder to the inactive files. See **SOP V-8: Archived (Inactive/Completed/Terminated) Files** for management of inactive files.

d. **Study Protocol Deviation and Noncompliance Report**

i. *Management of the Study Protocol Noncompliance Reports Upon Submission*

1. The investigator should document, explain, and report to the ICH-*IECBMHR* any noncompliance from the approved protocol, whether minor or major, **on a quarterly basis.**

2. The investigator may implement a deviation from the protocol to eliminate an immediate hazard(s) to study subjects without prior ICH-*IECBMHR* approval, but must submit as soon as possible, a report of deviation or change, the reasons for it, and, if appropriate, an appropriate study protocol amendment(s).

3. Any protocol deviation which results in a serious adverse event should be reported to the *IECBMHR* within 24 hours (following the timelines of reporting on SAE).

4. Reporting of protocol noncompliance is facilitated by the submission of **IECBMHR-*ICH* 4-D: *Study Protocol Deviation or Non-Compliance Report***, together with a document deemed relevant by the investigator to clarify information indicated in the report. This comprised the study protocol noncompliance report package.

5. The Secretariat Staff checks the submission for completeness and gives a receiving copy of **IECBMHR-*ICH* 4-D: *Study Protocol Deviation or Non-Compliance Report*** to the P.I. or his/her representative.

6. The Secretariat Staff logs the date of submission on the ***Submissions Database*** **(IECBMHR-*ICH* 5-N)**.

ii. *Classification of Review by the IECBMHR Chair*

1. The IECBMHR Chair classifies the submission as either full board or expedited review.

2. Minor or administrative deviations that do not affect the scientific soundness of the study protocol nor compromise the rights, safety, or welfare of human participants in the study are classified under expedited review.

3. Major deviations or protocol violations that consist of persistent protocol noncompliance with potentially serious consequences that could put patients' safety at risk or could critically affect data analysis are classified under full board review.

iii. Review by IECBMHR Chair and members

1. For submissions under expedited review, action is finalized at the level of the *IECBMHR* Chair within seven (7) calendar days.

2. Study Protocol noncompliance report packages subject to full board review received within the cut-off period of two (2) weeks or fourteen (14) calendar days before the *IECBMHR* meeting are sent to IECBMHR members ten (10) calendar days before the *IECBMHR* meeting.

3. The Secretariat Staff places the study protocol noncompliance report on the agenda for the next *IECBMHR* meeting.

4. The members accomplish the review and return the study protocol noncompliance report package to the Secretariat on the day of IECBMHR meeting.

iv. Full Board Review of Study Protocol Noncompliance Report

1. The Secretariat Staff distributes the following Study Protocol Noncompliance Report package to *IECBMHR* Members along with the meeting agenda:
   - **IECBMHR-*ICH* 4-D: *Study Protocol Deviation or Non-Compliance Report***
   - Documents related to the deviation

2. The documents are presented to *IECBMHR* members when study protocol noncompliance reports are deliberated on. The committee deliberates on both the type and degree of noncompliance and takes the appropriate action.

3. The *IECBMHR* Panel can suspend ethical clearance or subject recruitment until noncompliance issues are addressed
4. The *IECBMHR* Panel may opt to withdraw ethical approval under following circumstances:
   - Fraud
   - Unresolved serious safety issues
5. For detailed information on full board review of study protocol noncompliance, see SOP03.

v. Communication of Results

1. The PI is notified of the *IECBMHR* decision, noting appropriate action on the study protocol noncompliance report through an action letter.

2. The PI may be requested to provide additional information, submit additional documents, or implement corrective action.

vi. Files Management

1. The *IECBMHR* Secretary and *IECBMHR* Chair sign the **IEC*BMHR-ICH* 4-D: *Study Protocol Deviation or Non-Compliance Report***.

2. The Secretariat Staff stores the signed study protocol noncompliance report documents in the study protocol file folder.

e. Early Study Termination Application

i. Management of Early Study Termination Application Upon Submission

1. An application for early study termination is submitted when a study approved by the ICH-*IECBMHR* is being recommended for termination before its scheduled completion. This is done when the safety of the study participant is doubtful or at risk and also upon the request of the PI or the sponsor owing to the existence of unresolvable but valid complaints or circumstances.

2. Early study termination is facilitated through the submission of **IECBMHR-*ICH* 4-E: *Early Study Termination Application Form***, together with documents deemed relevant by the investigator to support or clarify information indicated in the application. This comprises the early study termination application package.

3. The Secretariat Staff checks the submission for completeness and gives a receiving copy stamp.

4. The Secretariat Staff logs the date of submission on the ***Submissions Database*** **(IECBMHR-*ICH* 5-N)**.

*ii. Classification of Review by the IEC*BMHR *Chair*

1. The *IECBMHR* Chair classifies the submission as either full board or expedited review.

2. Generally, classification of review early termination applications as expedited or full board is based on the initial review classification (i.e. final report of full board study protocols is done through full board review); unless otherwise indicated by the specifics of the submitted information.

iii. Review by IECBMHR Chair and IECBMHR members

1. For submissions under expedited review, action is finalized at the level of *IECBMHR* Chair within seven (7) calendar days.

2. Early study termination application packages subject to full board review received within the cut off period of 2 weeks or fourteen (14) days before the *IECBMHR* meeting are sent to Primary Reviewers at least ten (10) calendar days before the meeting.

3. The Secretariat Staff places the early study termination application on the next *IECBMHR* meeting.

4. The Primary Reviewers accomplish the review and return the early study termination application package to the Secretariat on the day of the IECBMHR meeting.

iv. Full Board Review of Early Termination Application

1. The Secretariat Staff distributes the following early study termination application package to *IECBMHR* Members along with the meeting agenda:
   - **IECBMHR-*ICH* 4-E: *Early Study Termination Application Form***
   - Documents related to the early study termination

2. The *IECBMHR* deliberates on the implications of the application on the rights, safety, and welfare of the study participants, including adapting specific provisions for continued protection and dissemination of specific information to the study participants.

3. The *IECBMHR* may request information from the PI or invite the PI for clarificatory interview.

4. For detailed information on full board review of early study termination application see SOP 03.

v. Communication of Results

1. The PI is notified of the *IECBMHR* decision, noting committee action on the early study termination application through an action letter.

2. The PI may be requested to provide additional information or submit additional documents.

3. If the application is approved, the PI is requested to accomplish the **IECBMHR-*ICH* Form 4-C: *Final Report Form***.

vi. Files Management

1. The *IECBMHR* Secretary and *IECBMHR* Chair sign the **IECBMHR-*ICH* 4-E: *Early Study Termination Application Form***.

2. The Secretariat Staff stores the early termination application documents in the study protocol file folder.

f. Study Participant Queries or Complaints

i. Management of Submitted queries or complaints

1. Participant queries and complaints are major considerations because they provide mechanisms that contribute to study participant empowerment.

2. The *IECBMHR* personnel can receive a query or complaints form a participant. Participant queries or complaints are managed through the documentation of queries and complaints using the **IECBMHR-*ICH* Form 4-I: *Study Participant Queries or Complaints***, which has to be accomplished by an *IECBMHR* personnel.

3. The above form has to be accompanied by a written disposition from the complainant.

4. Each query or complaint received will be individually entered into **IECBMHR-*ICH* Form 4-I: *Study Participant Queries or Complaints***, by respective *IECBMHR* personnel, and then forwarded to the Secretariat for processing.

5. The Secretariat Staff logs the query or complaint into the ***Submissions Database*** **(IECBMHR-*ICH* 5-N)**.

ii. Classification of Review by IECBMHR Chair

1. The *IECBMHR* Chair classifies queries as either full board or expedited review depending on the nature of query and response needed.

2. Complaints are always classified under full board review.

iii. Review by IECBMHR Chair and IECBMHR members.

1. For submission under expedited review, action is finalized at the level of the *IECBMHR* Chair within seven (7) calendar days.

2. Queries and complaints subject to full board review received within the cut-off period of 2 weeks or fourteen (14) days before the *IECBMHR* meeting

3. The Secretariat Staff places the query or complaint in the agenda of the next *IECBMHR* meeting

4. The *IECBMHR* Chair and members review the information entered in **IECBMHR-*ICH* Form 4-I: *Study Participant Queries or Complaints***.

5. If necessary, the PI will be contacted to provide information that will address the query or complain.

iv. Full Board Review of Study Participant Query or Complaint

1. The Secretariat Staff distributes the completed **IECBMHR-*ICH* Form 4-I: *Study Participant Queries or Complaints*** to *IECBMHR* members along with the meeting agenda.

ii. The Secretariat Staff places the serious adverse event report on the agenda for the next *IECBMHR* meeting.

iii. The Members Clinician accomplish the review and return the signed **IECBMHR-*ICH* Form4-G: *Serious Adverse Event/s Report*** to the Secretariat on the day of the *IECBMHR* meeting together with the serious adverse event/s report package and Clinical report along with his/her opinion on relatedness of SAE to IP.

c. Full Board Meeting

i. The Secretariat Staff distributes the following serious adverse event/s report package to *IECBMHR* Members along with the meeting agenda:

- **IECBMHR-*ICH* Form 4-G: *Serious Adverse Event/s Report***
- Relevant documents or attachment

ii. The documents are presented to *IECBMHR* Members when serious adverse event/s report are discussed and deliberated on. For detailed information on the conduct of full board review of serious adverse event/s reports, see SOP III.

d. The *IECBMHR* may recommend any of the following actions:

i. Study to continue, with no other action required

ii. Modification of the protocol to mitigate the newly identified risks; informed consent to be modified to include a description of newly recognized risks;

iii. Recommend implementation of additional procedures for protecting/safeguarding participants

iv. If there are serious issues related to the report of the adverse events in studies involving already marketed drugs, such reports will be transmitted for expert opinion for information and appropriate action.

v. Temporary suspension of enrolment of new participants

vi. Recommend suspension of the entire study

1. In cases where the *IECBMHR* recommendation is for the study to be suspended, the matter should be brought to the attention of the Director, ICH.

2. The P.I./or sponsor will be given ample time resolve the problem of SAE's before any further action (after the suspension) on the study can be made.

e. Communication of Results

i. The PI is notified of the *IECBMHR* decision, noting *IECBMHR* action on the Serious Adverse Event/s Report through a letter.

ii. The PI may be requested to provide additional information, submit additional documents, or implement corrective action.

iii. The IECBMHR communicates its decision on the SAE to the Director, ICH within 30 days of SAE occurrence.

f. Files Management

i. The *IECBMHR* Secretary and *IECBMHR* Chair sign the **IECBMHR-*ICH* Form 4-F: *Serious Adverse Event/s Report***.

ii. The Secretariat Staff stores the signed serious adverse event/s report in the study protocol file folder.

Flow Chart of handling, review and analysis of SAE of Ongoing Academic study/trial

SAE in a trial subject in an ongoing study /trial

↓

Principal Investigator within 24 hours of occurrence of SAE to submit Initial written report to Chairperson of IECBMHR, Head of Institution with a copy to the Member Secretary of IECBMHR

↓

Principal Investigator within 14 calendar days of occurrence of SAE to submit detailed follow up and outcome reports to IECBMHR, & Head of Institution

↓

IECBMHR Chairperson to convene meeting at the earliest
1) Review in details the SAE and its treatment
2) Redress any grievance of the participant or his/her legal representative
Decision regarding the following:
1) SAE relatedness (2) Whether it is a study related injury (3) Whether appropriate free medical management was given
(4) Whether financial compensation is payable

↓

IECBMHR Chairperson Within 30 calendar days will send the Analysis report of the SAE to: Head of Institution

↓

Archival of all SAE reports and correspondence in SAE file

6. SITE VISIT WORKFLOW (STUDY MONITORING)

ACTIVITY	RESPONSIBILITY
Select study to be audited ↓	*IECBMHR* Chair and Members
Notify PI of date of audit ↓	*IECBMHR* Chair and *IECBMHR* Secretary
Create Site Visit Team ↓	*IECBMHR* Chair and *IECBMHR* Secretary
Conduct Site Visit ↓	Site Visit Team
Present findings during *IECBMHR* meeting ↓	*IECBMHR* Chair
Communicate Results of Site Visit and subsequent *IECBMHR* action to PI ↓	Secretariat Staff
Manage Site Visit documents	Secretariat Staff

DETAILED INSTRUCTIONS:

a. Selection of Study Sites

i. Study is audited on demand(For cause)

ii. Study sites may be selected for Site Visits based on the following criteria

- A study considered a high-risk one.
- Frequent non-submission or failure to submit continuing review requirements
- Reports of major protocol noncompliance or deviations
- Significant number of serious adverse events
- Reports of complaints from study participants
- Reports of non compliance following external audit e.g. inspection

iii. A decision for Site Visit is deliberated on during a full board meeting of the *IECBMHR*

b. Notification of PI of Date of Site Visit

i. The *IECBMHR* Chair, through the Secretariat, informs the PI before the scheduled visit through a letter (Form 4 G).

ii. The letter provides Site Visit schedule details and instructions on what the PI needs to prepare such as documents and files that will be used for the Site Visit, as well as orderly preparation of the site.

c. Creation of a Site Visit Team

i. A Site Visit Team is organized for each site visit.
ii. The members of this team are assigned by the *IECBMHR* Chair.
iii. The Site Visit Team should be composed of at least two (2) members
iv. Each member of the Site Visit Team are informed of their assignment
v. The Secretariat Staff prepares a Study Visit Package for the Site Visit Team, inclusive of the **IECBMHR-*ICH* Form 4-H: *Site Visit Report Form.***
vi. The Site Visit Team prepares for the activity by reviewing the contents of the study file and the requirements of **IECBMHR-*ICH* Form 4-H: *Site Visit Report Form***.

d. Conduct of Site Visit

i. Upon arrival in the study site team uses to do the following:

- ☐ Review the study protocol
- ☐ Review the informed consent documents and verify if the site is using the most recently approved version.
- ☐ Ask the PI or staff to explain the informed consent process. Check for adequacy and continuity of consent.
- ☐ Review audio visual recordings to ensure that subjects are provided adequate time and information to understand risks and benefits of the study and are thus able to make a informed choice regarding participation.
- ☐ Review the post-approval documents and verify if the site is using the most recently approved version, or that these have been approved
- ☐ Verify security, privacy, and confidentiality of the documents at the study site
- ☐ Observe facilities in the study site
- ☐ Make an overall determination of the protection of the rights, safety, and welfare of human participants in the study
- ☐ Regulatory Documentation (if any)
- ☐ Site Operations
- ☐ Protocol Compliance
- ☐ Informed Consent Documentation
- ☐ Subject Records
- ☐ Safety Monitoring
- ☐ Drug/Device/Test Article Accountability

ii. At the end of the visit, the Site Visit Team will.

- ☐ Discuss the findings with the research team
- ☐ Issue a letter to PI of noncompliance observed
- ☐ Solicit feedback (written compliance report from PI)

e. Presentation of Findings at *IECBMHR* meeting

i. One of the members of Site Visit Team completes **IECBMHR-*ICH* Form 4-H: *Site Visit Report Form*** which should reflect the consensus opinion of the Site Visit Team members, and submits it to the Secretariat not later than Ten (10) calendar days after the Site Visit.

ii. The Secretariat Staff logs the date of submission on the ***Submissions Log* (IECBMHR-*ICH* Form 5-N)**.

iii. The Secretariat Staff places the Site Visit Report in the agenda of the next *IECBMHR* meeting.

iv. During the meeting, the Secretariat Staff distributes the completed **IECBMHR-*ICH* Form4- H: *Site Visit Report Form*** to *IECBMHR* members along with the meeting agenda.

The *IECBMHR* deliberates on the implications of results of the Site Visit on the rights, safety, and welfare of the study participants; and makes an overall determination of protocol compliance in the study site.

v. For detailed information on full board review of Site Visit Reports, see SOP 03.

f. Communication of Results

i. The PI is notified of the *IECBMHR* action or recommendations through a letter

ii. The PI may be requested to provide additional information, submit additional documents, or implement corrective action.

g. Site Visit Files Management

i. The *IECBMHR* Secretary and *IECBMHR* Chair sign the **IECBMHR-*ICH* Form4-H: *Site Visit Report Form***.

ii. The Secretariat Staff stores the Site Visit documents in the study protocol file folder.

7. LIST OF FORMS

IECBMHR-ICH Form 4-A	Application/ Notification Form For Amendments
IECBMHR-ICH Form 4-B	Continuing Review/ Annual Report Format
IECBMHR-ICH Form 4-C	Study completion/Final report format
IECBMHR-ICH Form 4-D	Protocol Violation/Deviation Reporting Form(Reporting by Case)
IECBMHR-ICH Form 4-E	Premature Termination/Suspension/Discontinuation Report Format
IECBMHR-ICH Form 4-F	Serious Adverse Event Reporting Format(Biomedical Health Research)
IECBMHR-ICH Form 4-G	Notice of Site Visit
IECBMHR-ICH Form 4-H	Site Visit Form
IECBMHR-ICH Form 4-I	Study Participant Queries or Complaints

(4A)

Application/Notification form for Amendments

Institutional Ethics Committee For Biomedical And Health Research
Institute of Child Health, Kolkata
IECBMHR 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.*

(4B)

Continuing Review / Annual report format

Institutional Ethics Committee For Biomedical And Health Research
Institute of Child Health, Kolkata

IECBMHR 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

(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:

.....

.....

.....

. 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

(4C)

Study completion/Final report format

Institutional Ethics Committee For Biomedical And Health Research
Institute of Child Health, Kolkata
IECBMHR 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.*

(4D)

Protocol Violation/Deviation Reporting Form (Reporting by case)

Institutional Ethics Committee For Biomedical And Health Research
Institute of Child Health, Kolkata
IECBMHR 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

(4E)

Premature Termination/Suspension/Discontinuation Report Format
Institutional Ethics Committee For Biomedical And Health Research
Institute of Child Health, Kolkata

IECBMHR 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

(4F)

Serious Adverse Event Reporting Format (Biomedical Health Research)

Institutional Ethics Committee For Biomedical And Health Research
Institute of Child Health, Kolkata
IECBMHR 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 infor-mation 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

Institutional Ethics Committee For Biomedical And Health Research
Institute of Child Health, Kolkata
11, Dr. Biresh Guha Street, Kolkata - 700017

STUDY AUDIT CHECKLIST

Principal Investigator:		GCP training: Y/N
Co-Investigator(s) (Name & affiliation or "None"):		
Title of Study:		Protocol No: Version:
Date of IECBMHR Approval		Date of Continued approval, if any:

STUDY STATUS:
#SUBJECTS ENROLLED:
LOCATION OF STUDY:
DATE OF AUDIT:
AUDITOR:

Audit worksheets completed for this audit:

- ☐ 1. Regulatory Documentation
- ☐ 2. Site Operations
- ☐ 3. Protocol Compliance
- ☐ 4. Informed Consent Documentation
- ☐ 5. Subject Records
- ☐ 6. Safety Monitoring

Auditor:		Date:		IECBMHR#	

REGULATORY DOCUMENTATION

1. HOI approval available: Comments:	☐ Yes ☐ No ☐ N/A
2. CTRI application no.: Comments:	☐ Yes ☐ No ☐ N/A

Study Participant Queries or Complaints

INSTRUCTIONS: *This form can be accomplished by any IECBMHR-ICH personnel who receive queries, complaints, or grievances from study participants of any study protocol under the responsibility of the IECBMHR-ICH. This form is preferably accompanied by a letter from the patient-complainant. Information reported in this form is processed as a protocol-related submission. This form should be printed in A4 size paper and duly signed by the personnel accomplishing the report.*

Study No.: IECBMHR/		
Study Protocol Title:		
Approval Date: <dd/mm/yyyy>		
Principal Investigator:		
E-mail:	**Telephone:**	**Mobile:**
Study Site:		
Study Site Address:		
Sponsor:		
Sponsor Contact Person:		
E-mail:	**Telephone:**	**Mobile:**
Date Received: <dd/mm/yyyy>		
1. **Received by (IECBMHR-ICH Personnel):** <Title, Name, Surname>		
2. **Request Delivered Through:** 2.1. □ Telephone 2.2. □ Fax No 2.3. □ Mailed letter dated: 2.4. □ E-mail dated: 2.5. □ Walk-in (indicate date/time) 2.6. □ Other, specify:		
3. **Study Participant** 3.1. <Title, Name, Surname> 3.2. Address: <Street Number, Street, City, Postal Code> 3.3. Telephone: <area code, number> 3.4. Mobile: <Provider code, number> 3.5. Email:		
4. **Participant Start Date:** <dd/mm/yyyy>		
5. **Participant Concerns:** 5.1. □ Query (specify) 5.2. □ Complaint (specify) 5.3. □ Others (specify)		
6. **Referred to** 6.1. □ Full Board Review by IECBMHR 6.2. □ Expedited Review at the level of IECBMHR Chair		
7. **Signature of IECBMHR-ICH Personnel:**		

Recommended Action: *(for IECBMHR-ICH use only)* □ Uphold original approval with no further action □ Request information: *(indicate information)* □ Recommend further action: *(indicate action)*	
IECBMHR SECRETARY Date: <*dd/mm/yyyy*>	Signature _____ Name <*title, name, surname*>
IECBMHR CHAIR Date: <*dd/mm/yyyy*>	Signature _____ Name <*title, name, surname*>

Institutional Ethics Committee For Biomedical And Health Research
Institute of Child Health, Kolkata

IECBMHR Ref. No. *(For office use)*

ICH/IEC//20……

Dated:……
Principal Investigator

Study No: IECBMHR//20…….

Ref: ……

Dear Dr……,

Your study (as above) has been identified for a site visit on **……. from ……..am onwards**. There will be at least two members of the Institutional Ethics Committee who will do the site visit. To this end, we are requesting you to make available to the Site Visit Team all documents and forms being used for the study. All letters and communications to and from the IEC source documents and patient charts must be made available for the perusal and examination of the Site Visit Team.

The Site Visit Team will do the following:

(1) Review the Informed Consent process.
(2) Review the post-approval documents and verify if the most recently approved version is being used.
(3) Verify the documents are securely stored and that confidentiality of said documents at the study site is maintained.
(4) Observe the facilities in the study site.
(5) Make an over-all determination of compliance of the site to New Drugs and Clinical Trial Rules 2019 and local regulatory guidelines.

At the end of the visit, the Team will be giving the Principal Investigator its initial evaluation of the process. A more thorough communication will be sent to you, within two weeks from the time of the Site Visit.

Please feel free to contact the IECBMHR Secretariat if you have any concerns.

Thank you
Very truly yours,

Dr. Surupa Basu
Member Secretary, IECBMHR-ICH

Documentation and Archiving

SOP Code: SOP 05/V2

Reviewed By:

Name and Position in IECBMHR	Signature
Dr. Phalguni Dutta Chairperson	
Dr. Surupa Basu Member Secretary	
Dr. Arunaloke Bhattacharyya Clinician	
Prof. Jaydeep Choudhury Clinician	
Dr.Supriyo Cgoudhury Basic Medical Scientist; Clinical Pharmacologist	
Mr. Tamal Chatterjee Legal expert	
Ms. Anasuya Basu Layperson	
Ms. Kaberi Mukherjee Theologian	

Approved By

Name and Position in IECBMHR	Signature
Dr. Phalguni Dutta Chairperson	

TABLE OF CONTENTS:

Supersedes	NA
Version	02
Authored By	SOP team
Version Date	30 September 2022
Approved By	Dr. Phalguni Dutta
Effective Date	05 December 2022

1. OBJECTIVES

This SOP describes how the IECBMHR- ICH manages documentation and communication of the review process, such as:

(1) How the minutes of the meetings are to be prepared, used, distributed, and filed;

(2) How to ensure proper completion, distribution, and filing of written study protocol- or review-process-related communication

(3) How administrative records and IECBMHR- ICH administrative documents (exclusive of study protocol files) are processed, stored, or disposed of;

(4) How active and inactive or archived study protocol files (including amendments) are maintained; and

(5) How original documents and copies of documents are handled in order to protect confidentiality of documents.

2. SCOPE

This SOP applies to the minutes of the meeting, all communication records related to study protocols with IECBMHR- ICH approval or undergoing IECBMHR- ICH review; to administrative documents, active study protocol files, and inactive study protocol files that are retained or archived for at least five (5) years after completion of the research so that the records are accessible for auditors and inspectors. This SOP applies to all kinds of handling, distribution, and storage of submitted study protocols, IECBMHR documents, and correspondences.

3. RESPONSIBILITIES

The Secretariat Staff, under the supervision of the IECBMHR Secretary, has the primary responsibility for study protocol and administrative documentation and archiving. The IECBMHR Chair is responsible for final approval of documents prior to archiving.

4. MINUTES OF THE MEETING WORKFLOW

ACTIVITY	RESPONSIBILITY
Prepare the template of the Minutes of the Meeting ↓	Secretariat Staff
Prepare draft of Minutes ↓	Secretariat Staff, IECBMHR Secretary
Approve the Minutes ↓	IECBMHR Chair and IECBMHR Secretary
Store the approved Minutes	Secretariat Staff

DETAILED INSTRUCTIONS:

a. Preparation of the Template of the Minutes of the Meeting

i. The IECBMHR Secretary and Secretariat Staff use the **IECBMHR-*ICH* Form 5-A.*Format of the Minutes of the Meeting*** to organize a template of the minutes ahead of the meeting date.

ii. All the relevant identifying information should be filled out such as standard text in the regular sections and relevant study protocol information.

iii. The minutes of the meeting is generated as the meeting progresses. The Secretariat Staff in charge of documentation notes all opinions and actions in all specific sections of the agenda, as the agenda is developed and discussed, with respective reasons in the case of study protocol-related actions.

b. Preparation of the Draft of the Minutes

i. Opinions and actions included in the minutes are collective in nature and need not to be attributed to specific members.

ii. The Secretariat Staff in charge of documentation submits complete draft of the minutes to the IECBMHR Secretary within seven (7) days after the meeting for form and content corrections and finalization. The finalized draft is sent to the IECBMHR Chair immediately for approval.

iii. The following information must be indicated in the minutes:

- Date and venue of meeting
- Members attendance (members present and absent)
- Guests and observers attendance
- Time when the meeting was called to order
- Presiding officer
- Items discussed per Meeting Agenda
- Name and signature of the IECBMHR Secretary to indicate that the contents have been verified and corrected
- Signature of the IECBMHR Chair to indicate approval
- Date of approval by the IECBMHR chair

c. Approval of the Minutes

i. The IECBMHR Chair approves the Minutes by affixing his/her signature and the date the minutes was signed.

ii. Upon approval of the minutes, the contents of the Conclusions and Recommendations section (per study protocol discussed) are transferred into:

1. Approval letter of a study protocol using **IECBMHR-ICH 5-B:** ***Approval Letter to Study Protocol within 20 days of IECBMHR meetings.***

2. Action letter or notification letter in response to specific kind of application submitted to the *IECBMHR*

a. **IECBMHR-ICH Form 5-C:** *Action Letter to Study Protocol Submissions/Resubmissions/Amendments*
b. **IECBMHR-ICH Form 5-D:** *Letter for Clarificatory Interview*
c. **IECBMHR-ICH Form 5-E:** *Approval Letter for Study Protocol Amendment Request*
d. **IECBMHR-ICH Form 5-F:** *Notification Letter (Request Information) to Progess Report/Continuing Review Application/Final Report/Deviation*
e. **IECBMHR-ICH Form 5-G:** *Archiving Notification*
f. **IECBMHR-ICH Form 5-H:** *Notification Letter for Site Visit*
g. **IECBMHR-ICH Form 5-M:** Notification Letter (Uphold Approval) for Continuing Review Application, Deviation/Non Compliance/Violation Report/SAE or SUSAR Report/Site Visit Report

d. **Storage of the Minutes**

i. The Secretariat Staff files the original copy of the Minutes in the Minutes Folder. Minutes are scanned & stored electronically.

ii. The Secretariat Staff makes copies of the minutes approved by the IECBMHR Chair (only when necessary).

iii. The Minutes approved by the IECBMHR Chair is distributed to the members within 3 weeks after the meeting by e-mail.

iv. The approved minutes will be presented in the next full board meeting for approval.

5. STUDY PROTOCOL COMMUNICATION RECORDS WORKFLOW

ACTIVITY	RESPONSIBILITY
Sort all communication received and issued by the IECBMHR - ICH ↓	Secretariat Staff
Record the details of the communication ↓	Secretariat Staff
Store communication files	Secretariat Staff

DETAILED INSTRUCTIONS:

a. Sorting of all communication related to Study Protocol received and issued by the IECBMHR- ICH

i. The objective of communication is to deliver the views and opinions of the ethics committee regarding protocol submission, informing meeting details, exemption from review, initial protocol review, amendments review, waiver of consent, final outcome of study, protocol deviations and violations, serious adverse events, notifying regarding the outcome of any internal audit findings and for cause audits.

- Submission from with checklist for required documents and content of protocol.
- Receipt of application with documents signed & dated
- Seek clarification if any
- Based on protocol, invite PI to present
- Ask for more information in writing if required
- Communication regarding status in writing within a reasonable time
  (a) Study related decisions / opinions.
  (b) The reasons for its decisions /opinions.
  (c) Procedures for appeal of its decisions/ opinions.
- Communication if proposal requires waiver of review/ consent.

ii. These communications are on the IECBMHR letterhead signed by the Chairperson/Member Secretary as defined in the respective SOPs. Meeting details and invitation to present the research proposal are communicated via the official e-mail of the IECBMHR.

iii. On a study-by-study basis, IECBMHR Secretariat may communicate with site staff (research coordinators) for intimation regarding study start updates, notifications and other pertinent details.

iv. IECBMHR engages in active consulting, as and when needed, with future investigators [individuals and resources] and may communicate via e-mail to receive/provide specific information and/or resolve queries.

v. IECBMHR mandates PI to modify its ongoing trial procedures and protocol as per latest guidelines

vi. Communications can come as letters, official memoranda or e –mails

vii. The Secretariat Staff all communication received and prepares them for recording

b. Recording of the Details of the Communication

i. Study protocol-related communications received by **IECBMHR- ICH** are recorded in the ***Submissions Log*** **(IECBMHR-ICH 5-N)**. This form is updated as each submission is received. The record should contain, but not limited to, the following:

- Date Received
- Study Code
- Title
- Principal Investigator
- Submitting Person
- Receiving Person
- Date of Document
- Type of Submission
- Content of Submission
- Action Taken by IECBMHR
- Further Action Required

c. Storage of Communication Records

i. Upon completion of the ***Submission Log*** **(IECBMHR-ICH Form 5-N)** the Secretariat Staff files a copy of the communication in the study file

ii. The Secretariat Staff then writes in the protocol folder contents index as each communication is filed.

6. ADMINISTRATIVE RECORDS WORKFLOW

ACTIVITY	RESPONSIBILITY
Compile administrative documents and/or records ↓	Secretariat Staff/ Members/*IECBMHR* Chair
Sort and store documents ↓	Secretariat Staff
Dispose unnecessary copies	Secretariat Staff

DETAILED INSTRUCTIONS:

a. Sorting of all communication related to IECBMHR Administration received and issued by the IECBMHR - ICH

i. Communication with Head of Institute and other departments of Institute

- The HOI is communicated with matters of IECBMHR administration including but not limited to appointment of new members, resignation of member(s), and in special cases, disqualification of any member(s).

- The HOI is informed on decisions regarding legal matters pertaining to the institute including but not limited to academic studies agreements.
- The HOI is communicated on financial matters such as budget allocation, IECBMHR Expenditures, and Financial Audit reports.
- The HOI is communicated in cases of SAEs including causality assessment and compensation if applicable.
- These communications are on the IECBMHR letterhead or via the official e-mail of the IECBMHR.
- The administrative and accounts departments are communicated with regarding matters of purchase and/or repair of assets and consumables. These are done through institutional modes of communication usually official letterheads, vouchers, and official e-mails.

ii. Internal Communication within members

- The Chairperson/ member secretary communicates with the IECBMHR members primarily via e-mail.
- The members are informed on meeting schedules, new regulatory updates and opportunities for training in bioethics.
- Communication of agenda and protocol dossiers are done before a meeting is scheduled.
- Members are contacted on a one to one basis for consultation or seeking opinion regarding a specific issue.

iii. Communication with research participants

- The IECBMHR is entrusted with the responsibility to provide redressal of grievance from any research participant or to resolve any queries that the participant may have.
- The usual mode of contact is the telephone as phone numbers of chairperson and/or member secretary are provided on the ICFs.
- These calls and the action taken are later recorded in the Study Participants Queries or Complaints Record In the event of written complaint received from patient an expedited or full committee meeting to be held based on IECBMHR SOP **(IECBMHR -ICH Form 4-I. *Study Participants Queries or Complaints)***

- Decision taken will be communicated in writing and redressal action taken in consultation with HOI
- When a participant doubts about a protocol or its practice, all the questions will be answered honestly and fully, in a language that she/he can understand

b. Compilation of Administrative Records

i. The Secretariat Staff maintains administrative documents not related to specific study protocols, but used in daily operation of the IECBMHR -ICH such as:

- Constitution and composition of the EC
- Financial records of EC
- Registration/accreditation documents, as required
- Regulatory notifications
- Meeting-related documents
- Agenda and minutes
- Reference materials and guidelines
- Standard Operating Procedures
- Communication issued to and received from persons other than principal investigators, on matters that are not related to any study protocols
- IECBMHR - ICH members and staff files (CVs, Appointment letters, Signed
- ***Confidentiality Agreement and Conflict of Interest Disclosure*** **(IECBMHR -*ICH* Form 2-D),** ***Training Records*** **(IECBMHR -*ICH* Form 2-E)**, Certificates of Training
- Forms

ii. These documents are maintained separately from study protocol-related documents.

c. Sorting and Storage of Documents

i. The Secretariat Staff labels and files administrative documents sequentially.

ii. Guidelines are filed numerically by subject alphabetically.

iii. SOP Manuals are filed chronologically.

iv. Important communications are filed in the specific communications folder and recorded chronologically in the ***Submissions Log*** **(IECBMHR -*ICH* Form 5-N)**.

v. Members' and staff files are filed alphabetically by last name.

vi. Only the most recently updated ***Curriculum Vitae*** **(IECBMHR-*ICH* Form 2-C)** are filed in the individual member's or staff's file.

vii. Signed ***Confidentiality Agreement and Conflict of Interest Disclosure*** **(IECBMHR-*ICH* Form 2-D)** and training certificates are filed chronologically under every member's or staff's file.

viii. ***Training Records*** **(IECBMHR-*ICH* Form 2-E)** must be updated as each training certificate is submitted by the member or staff for filing.

ix. Active ICH-*IECBMHR* blank forms are kept in individually labeled pockets in a folder. The folder contains an index of forms written as:

- Form number
- Subject of form

These are also stored electronically for future reference & for print on-demand.

d. Disposal of Unnecessary copies

i. Guidelines and references that have been superseded or outdated for three (3) years are removed from the files and disposed of properly.

ii. Removed document files are shredded and permanently deleted from physical files.

7. ACTIVE FILES WORKFLOW

ACTIVITY	RESPONSIBILITY
Create a coding system for active files ↓	ICH-*IECBMHR*
Organize the contents of the active study files ↓	Secretariat Staff
Maintain the active study files	Secretariat Staff

DETAILED INSTRUCTIONS:

a. Creation of Coding System for Active Study Files

i. Active files are study protocols that have been received by the ICH-*IECBMHR* Secretariat and are either undergoing review (full board or expedited) or has been approved by the respective ICH-IEC*BMHR* Active study files are given a study number upon receipt by the *IECBMHR*. The number is coded as follows IEC*BMHR*/NNN/YYYY where YYYY represents the year of the study protocol was submitted for review and NNN represents the chronological or sequential study

protocol number (as it is received by the *IECBMHR* Secretariat). NNN continues chronologically even at the beginning of each year.

ii. The assigned control number code should appear permanently on the study protocol folder.

b. Organization of Contents of Active Study Files

i. Study files are encoded into the Study Protocol Database, which contains the following information:
- Study No.
- Study Title & No.
- Principal Investigator
- Date Received
- Date of IECBMHR-ICH Review
- Date of Resubmission
- Date of Approval
- Date of Continuing Review Application
- Date of Submission of Amendment(s)
- Date of Study Closure/Termination
- Status

ii. The Secretariat Staff puts study protocol files in file folders upon processing of the submission of the study protocol, ensuring that one folder contains documents for one study protocol and labeled with the title and code of the study protocol.

iii. Folders are then kept in secured cabinets labeled as *"Active Files".*

iv. Cabinets labeled as *"Active Files"* should contain study file folders classified as *"Active".*

v. A study file folder contains the following documents, as applicable:
- All versions of study protocol
- Related documents that came with the study protocol
- Principal investigator and co-investigators' CVs and other similar documents
- Reviewers' assessment forms & risk benefit analysis
- Board action in the form of excerpts from minutes
- Amendment reports
- Continuing review applications
- Final report
- Serious Adverse Event Reports or Safety Notifications
- Non-compliance (Deviation or Violation) reports
- Site Visit Reports, if available

- Approval letters
- Action letter/Notification of ICH-*IECBMHR* Decision
- Miscellaneous communication

c. Maintenance of Active Study Protocol Files

i. The Secretariat Staff files all the aforementioned documents in the study folder as they come.

ii. The Secretariat Staff stamps the receiving date on all documents before putting them in the folders.

iii. All Active File Folders are maintained in the *"Active Files"* cabinet until the ***Final Report Form*** **(IECBMHR-ICH Form 4-C)** is approved by the IECBMHR-ICH.

iv. The Secretariat Staff maintains Active Files cabinets under the supervision of the IECBMHR Secretary.

8. ARCHIVED (INACTIVE/COMPLETED/TERMINATED) FILES WORKFLOW

ACTIVITY	RESPONSIBILITY
Manage completed/inactive/terminated study files ↓	Secretariat Staff
Sort administrative documents to be archived ↓	Secretariat Staff
Establish archived documents retrieval process	Secretariat Staff

DETAILED INSTRUCTIONS:

a. Management of Archived (inactive/completed/terminated) Study Files

i. Archived (inactive/completed/terminated) study files are either:
- Study protocols with approved (by the IECBMHR-ICH) final reports, or
- Study protocols declared inactive by the committee if no communication is received from the study team for a period of twelve months
- Study protocols submitted to the *IECBMHR* but withdrawn by the PI or sponsor before approval is obtained
- Study protocols submitted to and approved by the *IECBMHR* but withdrawn by PI or sponsor before actual study start

ii. Upon receipt of **IECBMHR-*ICH* Form 4-C: *Final Report Form***, the *IECBMHR* reviews it in accordance with **SOP 03-7: *Final Reports***.

	Visit Report
IECBMHR-ICH Form 5-N	Submission Log

Type of Meeting/
Meeting No nn/yyyy
Date of IECBMHR Meeting:
<dd/mm/yyyy>, Venue, Time

Minutes of the IECBMHR Meeting of <dd/mm/yyyy>

ATTENDANCE

Present	***Absent:***
Member 1	
Member 2	
Member 3	
Member 4	
Member 5	
Member 6	
Member 7	
Member 8	
Member 9	

Others:
Independent Consultant

1. **CALL TO ORDER**
   <Title, First Name, Surname> IECBMHR Chair, called this regular meeting to order at <time> AM.

2. **DETERMINATION OF QUORUM**
   A quorum was declared with the presence of <number> members, inclusive of the presence of <number> non-institutional and <number> lay members, and as confirmed by the IECBMHR Secretary, <Title, First Name, Surname>.

3. **DISCLOSURE OF CONFLICT OF INTEREST (COI)**
   <Title, First Name, Surname>, IECBMHR Chair, called for the disclosure of the Conflict of Interest (COI) in the protocols scheduled for deliberation on the meeting.

   The following IECBMHR member/s inhibited from participation in the IECBMHR deliberation during the full board meeting for the following reason:

   <Title, Name, Surname> as Principal Investigator for the study entitled, "TITLE" (Study Protocol number)

4. **READING AND APPROVAL OF THE MINUTES OF THE LAST MEETING**
   <Title, Surname of IECBMHR Chair> summarized and presided over the discussion of the minutes of the meeting held last <dd/mm/yyyy> (date of last meeting). The minutes were corrected during the discussion and approved as revised.

5. **BUSINESS ARISING FROM THE MINUTES OF LAST MEETING**
   6.1. Corrections in the Minutes
   6.2. Matters requiring IECBMHR-ICH action

6. **PROTOCOL REVIEW**

   6.1. FULL REVIEW
   6.1.1. Study Protocols for Initial Review

Control No.	
Study Protocol Submission Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Sponsor	
Quorum Status	
Conflict of Interest	
Assessment of Study Protocol	
Assessment of Informed Consent	
Conclusion & Recommendations	
Action Taken	Decision (Approval, Major Modification, which require full board deliberation, Minor Modification, which can be expedited at the levels of the IECBMHR Chair, Disapproval)

6.1.2. Resubmission or Study Protocols for Modification

Control No.	
Study Protocol Submission Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Sponsor	
Quorum Status	
Conflict of Interest	
Assessment of PI response to initial review	
Conclusion & Recommendations	
Action Taken	Decision (Approval, Major Modification, which require full board deliberation, Minor Modification, which can be expedited at the levels of the IECBMHR Chair, Disapproval)

6.1.3. Study Protocols for Clarificatory Interview

Control No.	
Study Protocol Submission Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Sponsor	
Quorum Status	
Conflict of Interest	
Assessment of PI response to IECBMHR queries	
Conclusion & Recommendations	
Action Taken	Decision (Request action or information)

6.1.4. Application for Study Protocol Withdrawal

Study No.	
Study Protocol Submission Date	<dd/mm/yyyy>
Withdrawal Application Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Sponsor	
Quorum Status	
Conflict of Interest	
Assessment of reasons for Study Protocol Withdrawal	
Conclusion & Recommendations	
Action Taken	Decision (Request action or information)

6.1.5. Study Protocol Amendments Applications

Study No.	
Study Protocol Approval Date	<dd/mm/yyyy>
Amendment Submission Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Sponsor	
Quorum Status	
Conflict of Interest	
Assessment of amendment requested	
Conclusion & Recommendations	
Action Taken	Decision (Approval, Major Modification, which require full board deliberation, Minor Modification, which can be expedited at the levels of the IECBMHR Chair, Disapproval)

6.1.6. Continuing Review Applications

Study No.	
Study Protocol Approval Date	<dd/mm/yyyy>
Application Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Sponsor	
Quorum Status	
Conflict of Interest	
Assessment of progress reported	
Conclusion & Recommendations	
Action Taken	Decision (Uphold original approval with no further action, Request information, Recommend further

	action)

6.1.7. Final Reports

Study No.	
Study Protocol Approval Date	<dd/mm/yyyy>
Report Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Sponsor	
Quorum Status	
Conflict of Interest	
Assessment of final report	
Conclusion & Recommendations	
Action Taken	Decision (Approve, Request information, Recommend further action)

6.1.8. SAE and Similar Reports (e.g. SUSAR)

Study No.		
Study Protocol Approval Date	<dd/mm/yyyy>	
Report Date	<dd/mm/yyyy>	
Study Protocol Title		
Principal Investigator		
Type of Review		
Sponsor		
Quorum Status		
Conflict of Interest		
Assessment of SAEs reported		
SAE1	Submission Date	<dd/mm/yyyy>
	Date of SAE	<dd/mm/yyyy>
	Date of randomization	<dd/mm/yyyy>
	Age	
	Sex	
	Country	
	Nature of AE	
	Co-morbidities	
	Status	
Conclusion & Recommendations		
Action Taken	Decision (Uphold original approval with no further action, Request information, Recommend further action)	
SAE 2	Submission Date	<dd/mm/yyyy>
	Date of SAE	<dd/mm/yyyy>
	Date of randomization	<dd/mm/yyyy>
	Age	
	Sex	
	Country	
	Nature of AE	
	Co-morbidities	
	Status	
Conclusion &		

Recommendations	
Action Taken	Decision (Uphold original approval with no further action, Request information, Recommend further action)

6.1.9. Site Visit Reports:

Study No.	
Study Protocol Approval Date	<dd/mm/yyyy>
Site Visit Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Sponsor	
Quorum Status	
Conflict of Interest	
Assessment of Site Visit Report	
Conclusion & Recommendations	
Action Taken	Decision (Uphold original approval with no further action, Request information, Recommend further action)

6.1.10. Study Protocol Non-Compliance (Deviation or Violation) Reports

Study No.	
Study Protocol Approval Date	<dd/mm/yyyy>
Report Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Sponsor	
Quorum Status	
Conflict of Interest	
Assessment of Non-Compliance Report	
Conclusion & Recommendations	
Action Taken	Decision (Uphold original approval with no further action, Request information, Recommend further action to AE Subcommittee)

6.1.11. Early Study Termination Applications

Study No.	
Study Protocol Approval Date	<dd/mm/yyyy>
Application Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Sponsor	
Quorum Status	
Conflict of Interest	
Assessment of risks from early termination	
Conclusion & Recommendations	
Action Taken	Decision (Approval, Request information,

	Recommend further action)

6.1.12. Study Queries, Complaints, or Grievance Reports

Study No.	
Study Protocol Approval Date	<dd/mm/yyyy>
Report Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Sponsor	
Quorum Status	
Conflict of Interest	
Assessment of query, complaint, grievance	
Conclusion & Recommendations	
Action Taken	Decision (Uphold original approval with no further action, Request information, Recommend further action)

6.2. REPORT OF PROTOCOL SUBMISSIONS FOR EXPEDITED REVIEW

6.2.1. Approved Protocols

Study No.	
Study Protocol Approval Date	<dd/mm/yyyy>
Study Protocol Submission Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Sponsor	
ACTION	APPROVAL

6.2.2. Study Protocols for Initial Review

Study No.	
Study Protocol Submission Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Sponsor	
ACTION	Decision (Approval; Major Modification, which require full board deliberation; Minor Modification, which can be expedited at the level of the IECBMHR Chair; Disapproval)

6.2.3. Study Protocols for Modification (or Resubmissions)

Study No.	
Study Protocol Submission Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Sponsor	
Summary of resubmission	(Put PI response to initial review comments)
ACTION	Decision (Approval; Major Modification, which require full board deliberation; Minor Modification, which can be expedited at the level of the IECBMHR

	Chair; Disapproval)

6.2.4. Study Protocol Amendments

Study No.	
Study Protocol Approval Date	<dd/mm/yyyy>
Amendment Submission Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Sponsor	
Amendment requested	
ACTION	Decision (Approval; Minor Modification to the proposed amendment, citing reasons for action, subject to expedited review at the level of the IECBMHR Chair; Major Modification , to the proposed amendment, stating reasons for action, subject to full board review; Disapproval)

6.2.5. Continuing Review Application

Study No.	
Study Protocol Approval Date	<dd/mm/yyyy>
Application Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Sponsor	
Progress reported	
ACTION	Decision (Uphold original approval with no further action, Request information, Recommend further action)

6.2.6. Final Reports

Study No.	
Study Protocol Approval Date	<dd/mm/yyyy>
Report Date	
Study Protocol Title	
Principal Investigator	
Type of Review	
Sponsor	
Results reported	
ACTION	Decision (Approval, Recommend further action)

6.2.7. Study Protocol Deviation/Non-Compliance/Violation Reports

Study No.	
Study Protocol Approval Date	<dd/mm/yyyy>
Report Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Sponsor	
Deviation/Non-Compliance/ Violation Reported	
ACTION	Decision (Uphold original approval with no further action, Request information, Recommend further action, Forward to AE Subcommittee)

6.2.8. Early Study Termination Applications

Study No.	
Study Protocol Approval Date	<dd/mm/yyyy>
Application Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Sponsor	
Reasons for termination	
ACTION	Decision (Approval, Request information, Recommend further action)

7. OTHER MATTERS

8. ADJOURNMENT

Meeting was adjourned at <time>

Prepared by: Date: <dd/mm/yyyy>	Signature over <Title, Name, Surname> IECBMHR Member Secretary
Approved by: Date: <dd/mm/yyyy>	Signature over <Title, Name, Surname> IECBMHR Chair

<dd/mm/yyyy>

<Title, Name, Surname of PI>
Principal Investigator
<Institute>

Ref: <Study Protocol Title with version and date>
Study No: <IECBMHR/ NNN/YYYY>

Sub: Final approval

Dear <Title of PI, Surname>,

This has reference to your above mentioned project. The project was discussed in the Ethics Committee meeting held on dd/mm/yyyy at aa am/pm in the <Seminar Room, ICH> and the following members were present:

<name>
<name>
<name>
<name>
<name>
<name>
<name>
<name>

We wish to inform you that your study protocol has been reviewed and is hereby granted approval for implementation by the IECBMHR-ICH. This ethical clearance and approval is valid until <expiration date>. Your study has been assigned study protocol code <Study No.> which should be used for all communication to the IECBMHR-ICH related to this study.

<You can commence the trial, subject to submission of the following documents:

- Document 1 <version #> <date of document>
- Document 2 <version #> <date of document>

The following submitted documents have likewise been approved for use in the study:

- Study Protocol <version #> <date of document>
- Study Protocol file 1 <version #> <date of document>
- Study Protocol file 2 <version #> <date of document>

You are required to report the following to the Ethics Committee:

- Any changes to or deviation to the protocol approved by the Ethics Committee that you may implement.
- Any changes in the approved Study documents.
- New information that may effect adversely the safety of the subjects or the conduct of the research.
- **Progress of the study at least once in four to six months**
- **Annual Progress Report and Continued IECBMHR Approval application (if study continues for more than one year)**
- **A copy of the final study report at study completion**

It is hereby confirmed that neither you nor any of your study team members have participated in the voting/ decision making matters of the committee.

You are expected to conduct the research conforming to the requirements of Good Clinical Practice (GCP), New Drugs and Clinical Trial Rules 2019 and Indian Council of Medical Research (ICMR) 2017 guidelines, and other local, national and international ethical guidelines published and amended from time to time.

We conform that the Ethics committee constitution and operation is according to requirements of Good Clinical Practice (GCP), New Drugs and Clinical Trial Rules 2019 and Indian Council of Medical Research (ICMR) 2017 guidelines

Thank you.

Yours sincerely,

_____

<name>
Member Secretary – Institutional Ethics Committee For Biomedical & Health Research
Institute of Child Health

<dd/mm/yyyy>

<Title, Name, Surname of PI>
Principal Investigator

Study No: <IECBMHR/NNN/YYYY>

Re: <Study Protocol Title, version, date>

Sub: <Major Modifications prior to Approval/Minor Modifications prior to Approval/Minor Modifications prior to Approval with further processing classified under Expedited Review>

Dear <Title of PI, Surname>,

We wish to inform you that the ICH-Institutional Ethics Committee For Biomedical and Health research reviewed your <study protocol/resubmitted study protocol/proposed amendments> during its regular meeting on <date of full board meeting> and is requesting further clarification. Your study has been assigned study protocol code <Study No.> which should be used for all communication to the IECBMHR-ICH related to this study.

The following members were present:

<name>
<name>
<name>
<name>
<name>
<name>
<name>
<name>

As a result of the review, the IECBMHR action is <Major Modifications prior to Approval/Minor Modifications prior to Approval/Minor Modifications prior to Approval with further processing classified under Expedited Review>. Recommended revisions and/or clarifications are summarized below:

1.

Please note that revisions requested by the IECBMHR-ICH should:

1. Be integrated into a revised Study Protocol and **<IECBMHR-ICH Form 3-B, 2022. *Application Form*/IECBMHR-ICH Form 4-A, 2022. *Study Protocol Amendment Submission Form*>**, and related documents in four (4) printed copies. In the case where only clarification is needed, an explanatory letter would suffice.
2. Be **summarized** in a cover letter indicating in which page of the revised study protocol the respective revision may be found; and
3. Include a footer (in all pages) that indicates both the **date** and **version number** of the resubmitted study protocol.

Please note that the cut-off date for submission of revised study protocol is on <cut-off date>. Should you have any questions or clarification regarding the abovementioned recommendations, please contact the undersigned through the IECBMHR-ICH Secretariat.

The IECBMHR-ICH looks forward to your immediate response and action.

We conform that the Ethics committee constitution and operation is according to requirements of Good Clinical Practice (GCP), New Drugs and Clinical Trial Rules 2019 and Indian Council of Medical Research (ICMR) 2017 guidelines.

Your project has been given number IECBMHR/NNN/YYYY. Kindly quote this number in all future correspondence with Ethics Committee.

Thank you.

Yours sincerely,

<name>
Member Secretary – Institutional Ethics Committee For Biomedical & Health Research
Institute of Child Health

e-mail notification

<dd/mm/yyyy>

<Title, Name, Surname of PI>
Principal Investigator
<Institute>

Ref: <Study Protocol Title with version and date>
Study No: <IECBMHR/ NNN/YYYY>

Sub: <Clarificatory Interview>

Dear <Title of PI, Surname>,

We wish to inform you that the ICH-Institutional Ethics Committee reviewed your <submission> during its regular meeting on <date of IECBMHR meeting>. Upon review, the IECBMHR found issues requiring clarifications such as:

1.

In this regard, the Committee requests for a clarificatory interview with you during the next IECBMHR meeting on <date of next full Board meeting> from <requested time> at the <venue>. Kindly provide a number where you can be reached by telephone.

Should you have any questions or clarifications regarding the above mentioned recommendation, please contact the undersigned through the IECBMHR-ICH Secretariat.

We look forward to your immediate response and action.

Very truly yours,

<Name of IECBMHR, Chair>
Chair, IECBMHR-ICH

e- mail notification

<dd/mm/yyyy>

<Title, Name, Surname of PI>
Principal Investigator
Institute>

Ref: <Study Protocol Title with version and date>
Study No: <IECBMHR/ NNN/YYYY>

Sub: <withdrawal of study protocol application/final report/early study termination approval>

Dear <Title of PI, Surname>,

We wish to inform you that the ICH-Institutional Ethics Committee reviewed the <withdrawal of study protocol application/final report/early study termination application> for the above-named protocol during its meeting on <date of full board meeting>.

Upon review of <IECBMHR-ICH Form 4-D, 2022/ IECBMHR-ICH Form 4-F, 2022>and <submitted document/s>, the IECBMHR **approved** the <withdrawal of study protocol application/final report/early study termination application> and recommended the commencement of archiving procedures. The protocol is now classified as inactive and ethical clearance automatically deemed expired effective <date of full board meeting>. The protocol records will be made available for five years from this date.

Thank you.

Yours sincerely,

_____

<name>
Member Secretary – Institutional Ethics Committee For Biomedical & Health Research
Institute of Child Health

[redacted]

BORROWERS LOG

Control No.					
Borrower's Name	Signature	Date Borrowed	Received By	Date Received
<Title, Name, Surname>				

Confidentiality Agreement for Non-Members Requesting for Copies of IECBMHR-ICH Documents

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

I have received copy/ies of the following IECBMHR-ICH documents:

_____

_____

_____

_____

_____

_____

RECIPIENT

Date: <dd/mm/yyyy>

Signature

_____

Name

_____

IECBMHR SECRETARY Date: *<dd/mm/yyyy>*	Signature _____ Name *<title, name, surname>*
IECBMHR CHAIR Date: *<dd/mm/yyyy>*	Signature _____ Name *<title, name, surname>*

Log of Request for Copies of Documents

Title of Document	Name of Recipient	# of Copies	Reason for the Request	Signature of Recipient	Initials of Secretariat Staff	Date Out	Date In
	<Title, Name, Surname>						

Note: ***This log should be attached to the original documents.***

CERTIFICATION

- This certifies that the Institutional Ethics Committee – Institute of Child Health (IEC-ICH) is constituted and established, and functions in accordance with the requirements set forth by the Governing Body of ICH and in compliance with the standards set by NDCT rules 2019 (Drugs and Cosmetics Act,1940 and Rules, 1945); ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants,2017; ICMR National Ethical Guidelines for Biomedical Research Involving Children, 2017 and other international, national and local guidelines and their amendments as applicable from time to time.

- The current members of the IECBMHR-ICH are in the attached document.

IECBMHR-ICH actions and recommendations are facilitated through consensus. In reference to protocol <Study Protocol Title><Study No.), <Approval/Minor Modifications/Major Modifications/Disapproval> for the aforementioned study protocol and documents specified in the approval package was enacted on <date of meeting>, during which meeting, a quorum was declared, no declaration of conflict of interest was lodged/or declaration of COI was properly lodged and considered, and the attendance of the following members noted, as noted in the IECBMHR-ICH Minutes of the Meeting:

Name 1
Name 2
Name 3
Name 4
Name 5
Name 6
Name 7
Name 8
Name 9

(In case of Minor Modifications, add the paragraph: Final Approval was processed through Expedited Review at the level of the IECBMHR Chair, and issued on <Date of Approval>).

<Name of IECBMHR, Chair>
Chair, IECBMHR-ICH
Date: <dd/mm/yyyy>

This certifies that the following regular members of the Institutional Ethics Committee-Institute of Child Health (IECBMHR-ICH), with appointment until <date of end of appointment>.

Name	Designation IECBMHR	Qualification & Expertise	Institutional Affiliation	Gender	Affiliation with ICH
Name 1					
Name 2					
Name 3					
Name 4					
Name 5					
Name 6					
Name 7					
Name 8					
Name 9					
Name 10					

<Name of IECBMHR,Chair>
Chair, IECBMHR-ICH
Date: <dd/mm/yyyy>

<dd/mm/yyyy>

<Title, Name, Surname of PI>
Principal Investigator

Control No: <IECBMHR/NNN/YYYY>

Re: <Study Protocol Title>

Dear <Title of PI, Surname>,

The ICH- Institutional Ethics Committee acknowledges the receipt of <Continuing Review Application/Study Protocol Non-Compliance Record/SAE Report> dated <date of document>.

The same was discussed in the Ethics Committee meeting held on dd/mm/yyyy at aa am/pm in the <Seminar Room, ICH> and the following members were present:

<name>
<name>
<name>
<name>
<name>
<name>
<name>
<name>

Upon review of <IECBMHR-ICH Form 4-C, 2022. *Continuing Review Application Form*/ IECBMHR-ICH Form 4-E, 2022. *Study Protocol Deviation or Non-Compliance Report* IECBMHR-ICH Form 4-H,2022. *Serious Adverse Event Report Form*> and <submitted document/s, IECBMHR action is Uphold Original Approval with no Further Action. The report is noted and has been included in the protocol file.

Thank you for your continuing compliance with the requirements of the IECBMHR-ICH

Very truly yours,

<Name of IECBMHR, Chair>
Chair, IECBMHR-ICH

Study No: <IEC/ NNN/YYYY>
Study title:

<Title, Name, Surname of PI>

Principal Investigator

Institute>

1	Study Type	
2	Study Objective	
3	EC Submission	
4	EC Meeting	
5	Conditional Approval	
6	Final Approval	
7	DCGI Approval	
8	CTRI Regn No	
9	Sponsor/CRO	
10	Duration of Study	
11	Age and No of Subjects	
12	SIV Date	
13	First Enrollment date	
14	Audit Done on	

15	Interim report	
16	Closeout Report	
17	Annual report	
18	SAE	
19	Any violation	
20	Any deviations	
21	Amended documents	
22	Resubmission	

Date	Event	Follow up

<dd/mm/yyyy>

<Title, Name, Surname of PI>
Principal Investigator

Control No: <IECBMHR/NNN/YYYY>

Re: <Study Protocol Title>

Dear <Title of PI, Surname>,

We wish to inform you that the <progress/final> report for the above named study protocol is due on/had been due since <every six months from date of approval>. Based on the records of the IECBMHR-ICH, there had been no communication regarding the progress of this study, which is still in our active file and has an active ethical clearance. If the study had been concluded or terminated, kindly fill out IECBMHR-ICH Form 4-D,2018, Final Report Form; or if still ongoing, IECBMHR-ICH Form 4-B,2022, Progress Report (submitted six months after the date approval) and IECBMHR-ICH Form 4-C,2022, Continuing Review Application (45 days before the lapse of six months following IECBMHR approval). The forms are attached herein and could also be readily accessed in a previously sent folder (of report forms) to you.

Kindly submit the relevant report/form within thirty days of receipt of this reminder letter. If no submission is received within the indicated period, the committee will be constrained to implement standard procedures for non-compliance with reportorial requirements. This may result in a recommendation for withdrawal of ethical clearance; and the study file subsequently inactive and archived.

Should you have any questions or clarifications regarding the above mentioned recommendations, please contact the undersigned through the IECBMHR-ICH Secretariat.

The IECBMHR-ICH looks forward to your immediate response and action.

Thank you.

Yours sincerely,

_____

<name>
Member Secretary–Institutional Ethics Committee For Biomedical and Health Research
Institute of Child Health

LIST OF ABBREVIATIONS

ADR: Adverse Drug Reaction

AE: Adverse Event

AV: Audio-Visual

CDSCO: Central Drugs Standard Control Organization

Co-I: Co-Investigator

CRA: Clinical Research Associate

CRF: Case Report/Record Form

CRC: Clinical Research Coordinator

CRO: Contract Research Organization

CTRI: The Clinical Trials Registry- India

CV: Curriculum Vitae

DCGI: Drugs Controller General of India

DSMB: Data and Safety Monitoring Board

DHR: Department of Health Research

FDA: The Food and Drug Administration

GCP: Good Clinical Practice

HIV- Human Immunodeficiency Virus

ICD: Informed Consent Documents

ICF: Informed Consent Form

ICH: International Conference on Harmonization

ICMR: Indian Council of Medical Research

IEC: Institutional Ethics Committee

IMP: Investigational Medicinal Product

IND: Investigational New Drug

IP: Investigational Product

IRB: Independent Review Board

PI: Principal Investigator

PIS: Patient Information Sheet

SAE: Serious Adverse Event

SOP: Standard Operating Procedure

SI: Sub-Investigator

Adverse drug reaction	In the pre-approval clinical experience with a new medicinal product or its new usages, particularly as the therapeutic dose(s) may not be established, all noxious and unintended responses to a medicinal product related to any dose should be considered adverse drug reactions. The phrase responses to medicinal product means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility, that is, the relationship cannot be ruled out. Regarding marketed medicinal products, a response to a drug which is noxious and unintended and which occurs at doses normally used in human prophylaxis, diagnosis, or therapy of diseases or for modification of physiological function. *See also adverse event, unexpected adverse event and suspected unexpected serious adverse reaction.*
Adverse event (AE)	Any untoward or undesirable medical occurrence in a patient or participant in clinical investigation after use or administration of an investigational product. The AE may or may not be related to the investigational product.
Amendment to the protocol	A written description of a change(s) to, or formal clarification of a protocol and changes on any other supporting documentation made from the originally approved protocol by the research ethics review body after the study has begun. *See protocol amendment.*
Anonymized sample or data	Biological sample or data that cannot be linked to an identifiable person through destruction of that link to any identifying information about the person who provided the sample or data.
Approved Protocols	Protocols that have been reviewed by the IECBMHR-ICH and *approved without any stipulations* or *after stipulations/recommendations* by the IECBMHR have been complied with.
Archives	A storage for completed studies, inactive files or terminated documents that have not been updated within the last five (5) years.

Assent	Authorization for one's own participation in research given by a minor or another participant who lacks the capability to give informed consent. The assent is a requirement for research, in addition to consent, given by a parent or legal guardian. It is an agreement by an individual not competent to give legally valid informed consent like a child or cognitively impaired to participate in research. *See also child's assent*
Assent forms	Forms asked of minor-aged children who are participants of a research or trial, aside from parent's or legal guardian's consent. The objectives of the study and procedures are explained to the child participants in a language understandable to them.
Audit	A systematic and independent examination of research activities and documents to determine whether the review and approval activities were conducted, data recorded and accurately reported as per applicable guidelines and regulatory requirements.
Autonomy	The ability and capacity of a rational individual to make an independently informed decision to volunteer as a research participant.
Bias	The systematic tendency of any factors associated with the design, conduct, analysis and evaluation of the results of a clinical trial to make the estimate of a treatment effect deviate from its true value.
Biomedical and health research	Research including studies on basic, applied and operational research designed primarily to increase the scientific knowledge about diseases and conditions (physical or socio-behavioural), their detection, cause and evolving strategies for health promotion, prevention, or amelioration of disease and rehabilitation including clinical research.
Beneficence	To try to do good or an action which weighs the risks against benefits to prevent, reduce or remove harm for the welfare of the research participant(s) in any type of research
Caregivers	A caregiver or carer is an unpaid or paid person who helps another individual with illness or impairment with daily activities/performance.
Case record/ report Form (CRF)	Case record form or case report form is a printed, optical or electronic

	document designed to record all the required information in the protocol on each study participant for reporting to the sponsor.
Child's assent	An agreement or expressed willingness of a minor to take part in the research when a child cannot give full consent. Children often can understand some, but not all parts of a study. Assent is the child's way of saying that he/she agrees to take part in the research to the degree that he/she understands it. It differs from consent since consent is the permission given by a parent or guardian to a child to take part in the research. Older children or youth may give their own consent if they are mature enough to completely or totally understand the research, and the consent or decision to participate is freely given with the premise that they are given enough information to make a choice and they understood the information provided to them.
Clinical research	Research that directly involves a particular person or group of people to study the effect of interventions, or uses materials/data from humans indirectly, such as their behavior or samples of their tissue for prevention, treatment and diagnosis of a disease condition/ health disorder
Clinical trial	A planned scientific research or study among human volunteers to determine the effects of treatment or diagnostic test on their safety, efficacy, and its effect on quality of life. It is also a systematic study on pharmaceutical products in human subjects (including patients and other volunteers) in order to discover or verify the effects of and/or identify any adverse reactions to investigational products, and/or to study the absorption, distribution, metabolism, and excretion of the products with the object of ascertaining their efficacy and safety. As per amended NDCT rule 2019, of the Drugs and Cosmetics Rules, 1945, a clinical trial refers to a systematic study of new drugs in human subjects to generate data for discovering and/or verifying the clinical, pharmacological (including pharmacodynamic and pharmacokinetic) and /or adverse effect with the objectives determining safety and/or efficacy of a new drug. The academic clinical trial as per GSR 313 (e) dated 16 March 2016 is a clinical trial intended for academic purposes in respect of approved drug formulations for any new indication or new route of administration or new dose or new dosage form.
Clinical trial Registry	An official platform for registering a clinical trial, such as clinical Trial Registry-India (CTRI)

Clinician	A person with recognized medical qualification and expertise/ training
Cognitive impairment	When a person has trouble remembering, learning new things, concentrating, or making decisions that affect their everyday life
Coercion	An overt or implicit threat of harm to a participant which is intentional to force compliance
Collaborative research	An umbrella term for methodologies that actively engage researchers, communities and/ or policy makers in the research process from start to finish
Compensation	Payment and/or medical care received or provided to subjects injured in research. Payment received by the research participants may include reimbursement for lost earnings, travel costs and other expenses incurred reimbursement for lost earnings, travel costs and other expenses incurred as a study participant, as recompense for inconvenience and time spent. It does not include renumeration for participating in the study.
Competence	Technically, a legal term, used to denote capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice.
Completed Study	A study that was accomplished according to the protocol and where a final report of the study had been submitted and approved.
Confidentiality	The expectation from respondents and research participants that data or information relayed or communicated are kept secret. Also, the non-disclosure of IECBMHR information and documents to other than an authorized individual.
Conflict of interest (COI)	A conflict of interest arises when a member(s) of the IECBMHR holds interests with respect to specific applications for review that may jeopardize his/her ability to provide free and independent evaluation of the research focused on the protection of the research participants. Conflict of interests may arise when an IECBMHR member has financial, material, institutional or social ties to the research. Potential conflicts of interest must be described and managed as per policy.
Contract Research Organization (CRO)	An institution or service organization which represents a sponsor in providing research support/services on a contractual basis nationally or internationally.

Deviation/non-compliance/ violation	Occurs whenever the submitted and approved protocol is not complied with, to the letter, or as approved.
Diagnostic	Procedure or technique used in the identification of a disease or determination of the health status of an individual.
Direct benefits	Gain or advantage or good effect derived by a research subject immediately or closely arising from the use of an experimental substances or device. *See also benefits.*
Disapproval	A negative action of the IECBMHR on the protocol. The study cannot be implemented if it has been disapproved by the Committee.
Disclosure of data:	The giving of information in connection with proposed research undertaking or the sharing of the results of the study especially as they pertain to the individuals or the family's health situation
Distributive justice	Fair distribution of burden, resources and benefits. In research, it means fair selection of participants
Ethicist	One whose judgment on ethics and ethical codes is based on knowledge/ experience through qualification or training
Exploitation	The action or fact of treating someone unfairly in order to benefit from their participation
Discontinuation/ Lost to follow up/ Termination	The deed of terminating participation in a clinical trial by a research subject (dropout) earlier than the completion of all protocol-required terms. In some case, the discontinuation may be initiated by the investigator for a cause or inability to locate or follow up subject or by the sponsor.
Document	Hard copies of studies, proceedings, communications, that include the following: • Study protocols and related documents (such as case report forms, informed consent, diary forms, scientific documents, report, records, expert opinion or reviews); • IECBMHR documents (SOPs, meeting minutes, advice and decisions); • Correspondence with experts, auditors, study participants, principal investigators, officials of the ICH or those of other related institutions, agencies and committees; or • Any other forms of communications such as printed or written papers, hard copies, electronic mails (e-mail), faxes, audio or video tapes, etc.

Drug:	A substance used as medication or used in the diagnosis, cure, mitigation, treatment or prevention of disease.
Ethical clearance	A certification that a research proposal has complied with ethical requirements; action of an ethics or institutional review committee on a research protocol that signifies approval and permission to proceed with the research. *See also approval.*
Ethics review	The evaluation of a research protocol by an ethics review committee to promote the safety and protection of the dignity of human participants. This is a systematic process by which this independent committee evaluates a study protocol to determine if it follows ethical and scientific standards for carrying out biomedical research on human participants. It checks if the protocol complies with the guidelines to ensure that the dignity, rights, safety and well-being of research participants are promoted.
Expedited approval	An IECBMHR approval granted only by the Chair of the IECBMHR or a designated board member (not the full Board) for minor changes to current IECBMHR-approved research activities and for research which involves no more than minimal risk.
Expedited review	An ethics review of research protocol by the IECBMHR chair or a designated voting member or subgroup of voting members rather than by the entire IECBMHR. This is done for some research involving no more than minimal risk and maybe for minor changes in approved research, annual renewals of approved projects, approval of protocol amendments, research conducting health record review, and for confirming changes required by the ethics committee for approval of the protocol.
Full board review	Review of proposed research at a convened meeting at which the quorum is fulfilled. For the research to be approved, it must receive the approval of a majority of those members present at the meeting.
Good clinical practice (GCP) guidelines	An international ethical and scientific quality standards for designing, conducting, recording and reporting trials that involve the participation of human subjects. compliance with these standards provide public assurance that the rights, safety, and well-being of trial subjects are protected, consistent with the principles that have their origin in the International Declaration of Helsinki, and that the clinical trial data are credible. These are standards and procedures for clinical trials that encompass the design, protocol approval, monitoring,

	termination, audit, analyses, reporting, and documentation of human studies. It defines the responsibilities and activities of the sponsor, principal investigators and monitor involved in the clinical trials. The GCP ensures that the studies are scientifically and ethically sound, and all the clinical properties of the product under investigation are properly documented.
Guardian	One who is legally responsible for the care and management of the person or property of an incompetent person or a minor or someone who can make important personal decisions in behalf of another person.
High-risk group	Social group known to have a high prevalence of a health problem because of shared environmental, occupational, nutritional or genetic factors including practices that contribute to ill-health.
Impartial witness	A literate person, who is independent of the research and would not be unfairly influenced by people involved with the study, who attends the informed consent process if the participant and/or their LAR cannot read, and understand the informed consent form and any other written information supplied to the participant.
Independent consultant	An expert who gives advice, comments and suggestions to the EC and has no affiliation to the institute or researchers proposing the research protocols. This individual has no voting power for decision making.
Inducement	A motive or consideration that leads one to action or to additional or more effective actions without considering the harm that may occur.
Informed consent Document (ICD)	Written signed and dated paper confirming a participant's willingness to voluntarily participate in a particular research, after having been informed of all aspects of the research that are relevant for the participant's decision to participate
Incapacity	A person's mental status and means, inability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. Often used as a synonym for incompetence.
Incompetence	Technically, a legal term meaning inability to manage one's own affairs. Often used as a synonym for incapacity.

Independent consultant	An expert who gives advice(s), comment(s) and suggestion(s) upon review of the study protocols with no affiliation to the institute(s) or investigator(s) proposing the research proposal.
Indirect benefits	An unintended or unlikely gain or advantage or good effect from participating in a research.
Informed consent	The process of obtaining approval to participate in an investigative study or permission to a medical intervention. Consent must be freely given in verbal, video or written form. An important part of the process is the adequacy, appropriateness, and timeliness of the information for decision-making; It is "a decision to participate in research, taken by a competent individual who has received the necessary information; who has adequately understood the information; and who, after considering the information, has arrived at a decision without having been subjected to coercion, undue influence or inducement, or intimidation."
Informed Consent Document or Informed Consent Form	A written, signed, and dated form confirming a competent participant's willingness to voluntarily participate in a particular trial or research, after having been informed of all aspects that are relevant to the participant's decision to participate and given time to reflect on the decision.
Initial Review	A first time review of a new protocol for its technical completeness and ethical considerations. This is usually done by three to five individual reviewers of a team in advance of the full IECBMHR meeting. Comments of the reviewers will be reported to the full Board meeting.
Institutional Ethics Committee or Review Board	Ethics review committee organized in a particular institution to ensure that health research is conducted according to international ethical principles, national and institutional guidelines. This is an independent body constituted of medical, scientific, and non-scientific members, whose responsibility it is to ensure the protection of the rights, safety, and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trial protocol and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.
Investigator	A person responsible for the conduct of the clinical trial at a trial site. If trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and

	be called the principal investigator. It is a person responsible for the trial and for the rights, health and welfare of the subjects in the trial. The investigator should have qualifications and competence in accordance with local laws and regulations as evidenced by an up-to-date curriculum vitae and other credentials. Decision relating to, and to provisions of, medical or dental care must always be the responsibility of a clinically competent person legally allowed to practice medicine or dentistry. The investigator must be a qualified scientist who undertakes scientific and ethical responsibility, either on his/her behalf or on behalf of an organization, for the ethical and scientific integrity of a research project at a specific site group of sites. *See principal investigator*
Justice	Pertains to fairness in the way people are dealt with, indicating fair selection and distribution of benefits and risks to participants who should be fully apprised about them.
Lay person science/health related	A literate person who has not pursued a medical career in the last 5 years and is aware of the local language, cultural and moral values of the community.
Legal expert	A person with a basic degree in law from a recognized university, with experience.
Legally acceptable Representative (LAR)	A person, under applicable law or judicial authority, who will give consent on behalf of a prospective participant who, for either legal or medical reasons, is unable to give consent herself/himself to participate in research or to undergo a diagnostic, therapeutic or preventive procedure as per research protocol
Minimal risk	A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination.
Minors	Person who have not yet reached the age of majority, 18 years old.
Monitor	A person appointed by and responsible to the sponsor or contract research organization for monitoring and reporting progress of the trial and for verification of data (WHO, Guidelines for Good Clinical Practice for Trials of Pharmaceutical Products).

Protocol	A document which states the background, rationale, and objectives of the trial (investigation, research, study) and describes its design, methodology, and organization including statistical considerations and the conditions under which it is to be performed and managed. The protocol should be dated and signed by the Principal Investigator.
Protocol amendment	A written description of change(s) to, or formal clarification of a protocol. *See also amendment to protocol.*
Protocol approval by sponsor	The affirmative action of the sponsor on the protocol development when the technical and ethical reviewers have finally approved all the changes of the protocol. This usually act as the signal for the submission of the protocol and the other required documents to an IECBMHR, national regulatory authorities and research sites as applicable. *See also approval.*
Protocol package or protocol dossier	Protocol plus accompanying communications, registration forms and other documents relevant to the protocol.
Quorum	Number of members required to act on any motion presented for action during a meeting. This is usually 5 selected members with a mix of scientific and non scientific backgrounds.
Regulatory requirements	Necessary prerequisites for the approval and conduct of clinical trial by a national regulatory authority. For example, for pharmaceutical and biologic products, it means obtaining a "permit for clinical investigational use" which is a "registration document issued by the FDA for the purpose of allowing the conduct of Phase I, Phase II, and Phase III clinical trials of investigational biologic products in the country".
Rescue medication	Quick-relief or fast-acting medications or procedure used to immediately manage or relieve symptoms when they occur.
Research	Organized set of activities intended to generate data that are generalizable into new knowledge, principle or technology. Investigative work undertaken on a systematic and rigorous basis using quantitative and qualitative methods to generate new knowledge.

Research ethics committee	An independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical professionals and non-medical members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, reviewing and approving/providing favorable opinion on, the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects.
Research participants or subjects	An individual who participates in a biomedical research project, either as the direct recipient of an intervention (e.g., study product or invasive procedure), as a control, or through observation. The individual may be a healthy person who volunteers to participate in the research, or a person with a condition unrelated to the research carried out who volunteers to participate, or a person (usually a patient) whose condition is relevant to the use of the study product or questions being investigated
Research protocol	A document that provides the background rationale and objective(s) of a biomedical research project and describes its design, methodology and organization, including ethical and statistical considerations. Some of these considerations may be provided in other documents referred to in the protocol. *See also protocol.*
Risk	The probability of discomfort or harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Risks to research participants must be justified by the anticipated
Risk factors	Variables or conditions that increase the risk or chances of disease or infection; determinants of disease development. *See also risk*
Scientific review	Also called technical review is the evaluation of the research protocol to ascertain scientific soundness and appropriateness of the objectives and design of the proposed study and the qualifications of the researcher. *See also technical review.*
Serious adverse event	The adverse event is SERIOUS and should be reported when patient outcome is:

	Death - if the death is suspected as being direct outcome of the adverse event *Life-Threatening* - if the patient was at substantial risk of dying at the time of the adverse event or it is suspected that the use or continued use of the product would result in the patient's death *Hospitalization (initial or prolonged)* - if admission to the hospital or prolongation of a hospital stay results because of the adverse event *Disability* - if the adverse event resulted in a significant, persistent, or permanent change, impairment, damage or disruption in the patient's body function/structure, physical activities or quality of life *Congenital Anomaly* – if there are suspicious that exposure to a medical product prior to conception or during pregnancy resulted in an adverse outcome on the child *Requires Intervention to prevent permanent impairment or damage* – Report if you suspect that the use of a medical product may result in a condition which requires medical or surgical intervention to preclude permanent impairment or damage to a patient
Side effect	Undesired effect of a treatment which is either immediate or long- term.
Social scientist:	A person who is an expert on societal and social behaviour with specialization/ experience in the area.
Sponsor	An individual, a company, an institution or an organization which take responsibility for the initiation, management and/or financing of a clinical trial
Standard of care of treatment	Healthcare intervention or regimen that is generally accepted by health practitioners and experts as beneficial to an individual needing such care. Standard treatment is the treatment that is currently thought to be effective in medical practice.
Suspected unexpected serious adverse reaction given a drug, **(SUSAR)**	A serious adverse reaction in research participants who were that may or may not be dose related, but are not expected or anticipated since these reactions are not consistent with the current information about the medicinal product in question. This may occur during clinical trials or clinical care.
Standard Operating	

Procedure (SOP)	Detailed, written instructions, in a certain format, describing all activities and actions undertaken by an organization to achieve uniformity of the performance of a specific function. The aim of the SOPs and their accompanying checklist and forms is to simplify the organization and documentation of operation, while maintaining high standards of Good Clinical Practice.
Stigmatization	Negative perceptions about an individual because of perceived differences from the population at large. It may occur on the basis of physical appearance, race or sex
Surrogate	A substitute or deputy for another person in a specific role.
Technical review	The process of examining, assessing or evaluating a research protocol by technical experts, seasoned researchers, statisticians and other relevant specialist or authority to ensure the scientific soundness and appropriateness of the objective and design of the study and the qualifications of the investigator(s). *See scientific review.*
Termination of research	Ending or discontinuing a research study before its scheduled completion when the safety or benefit of the study participants is doubtful or at risk.
Theologian	A person who is an expert in the study of religious faith(s), including the system of spirituality, practice and experience about the nature of the divine.
Therapeutic Misconception	It is a misconception by participants believing that the purpose of clinical trials/research study is to administer treatment rather than to conduct research
Trial-related expenses	Expenses incurred by the study participants related to their participation in a research study such as transportation, meals, loss of income.
Undue influence	An inappropriate power, pressure or control or domination which may be mental, moral or physical that deprives a person of freedom of judgment, choice and thus, substitutes another's choice or desire in place of its own.
Unexpected adverse event	An adverse reaction that has not been anticipated, nor previously experience, or observed, and is not consistent with the informed consent, information sheets or applicable product information in the investigator's protocol or brochure, product

REFERENCES

Sr.	Guidelines Title
1	Indian Good Clinical Practices
2	ICH- GCP, 1996
3	New Drugs and Clinical Trials Rules 2019 - CDSCO
4	DCGI Registration letter, 2013 & Re-Registration letter of IEC,2017
5	Declaration of Helsinki, (Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964, and its amendments at 64th WMA general Assembly, Fortaleza, Brazil, October 2013).
6	Forum for Ethical Review Committees in Asia and the Western Pacific Region. FERCAP Standard Operating Procedures. 2005
7	International Conference on Harmonization. ICH Harmonized Tripartite Guideline – Guideline for Clinical Practice. 1996
8	Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research Involving Human Subjects. 2002
9	World Health Organization. Operational Guidelines for Ethics Committees that Review Biomedical Research Geneva: WHO; 2011
10	Ethical Guidelines for Biomedical Research on Human Participants, ICMR 2017
11	National Ethical Guidelines for Biomedical Research Involving Children. Indian Council of Medical Research,2017
12	Indian Council of Medical Research (ICMR)Department of Biotechnology (DBT) for stem cell 2017

Web Resources

- Clinical Trials Registry-India. Available from: http://ctri.nic.in
- Central Drugs Standard Control Organization. Available from: http://www.cdsco.nic.in/forms/
- Default.aspx Indian Council of Medical Research. Available from: http://icmr.nic.in/index.html
- Department of Science and Technology. Available from: http://www.dst.gov.in/index.htm
- Department of Biotechnology. Available from: http://dbtindia.nic.in/
- International Clinical Trials Registry Platform. Available from: http://www.who.int/
- National Institutes of Health Clinical Trials Registry. Available from: https://clinicaltrials.gov/
- FDA. Guidelines on good clinical practice. Available from: http://www.fda.gov/
- Clinical Development Services Agency.An extramural unit of Translational Health Science & Technology Institute, Dept. of Biotechnology. Available from: www.cdsaindia.in

- FERCAP The Forum for Ethical Review Committees in the Asian and West Pacific Region www.fercap-sidcer.org

- Naitik.gov.in https://naitik.gov.in/DHR/Homepage