INSTITUTE OF CHILD HEALTH
INSTITUTIONAL ETHICS COMMITTEE (IEC)

IEC Registration Number: ECR/359/Inst/WB/2013/RR-19

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

STANDARD OPERATING PROCEDURES (SOP)

VERSION 6.0

EFFECTIVE DATE: 05th DECEMBER 2022

COPY NUMBER: 01

Approved by
Signature of Chairperson, IEC ICH:

Accepted by
Signature of Director, ICH:

CONTENTS

INTRODUCTION

In 2018, the **INSTITUTIONAL ETHICS COMMITTEE-INSTITUTE OF CHILD HEALTH** evolved from the Ethics Committee (established in 2008) by virtue of ICH Governing Body Order letter no. ICH/Sys-5/106/2018 dated 27 February 2018 and subsequent policy statement issued by the Director of ICH.

The IEC-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 a clinical trial and biomedical research, thereby providing public assurance of that protection.

Registered with the Central Drugs Standard Control Organization (CDSCO) on May 31, 2013 (Registration No.ECR/359/Inst/WB/2013).

Re-registered on February, 02, 2017 (Registration No. ECR/359/Inst/WB/2013); further re-registered on November 11, 2019 (Re-registration No. ECR/359/Inst/WB/2013/RR-19) till 30.05.2024.

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

It has been accredited for Clinical Trials (Ethics Committee) by National Accreditation Board for Hospitals & Healthcare Providers (NABH), a constituent board of Quality Council of India. Accredited with NABH on18.05.2020;valid till 17.05.2023.

SCOPE

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

The scope of research is biomedical research on participants between 0-18 years of age and adults (trials involving mothers etc.)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. For clinical trials, the principal investigator should be a registered medical practitioner with the Medical Council of India having adequate experience in the medical practice of pediatric medicine/ surgery and should be preferably affiliated to Institute of Child Health, Kolkata.

The Standard Operating Procedures (SOPs) written in this booklet describe the procedures for the ethical review of biomedical research protocols established by the IEC-ICH, and intends to demonstrate compliance of the procedures to the requirement of standards put forth in, in the Drugs and Cosmetics Act, 1940 and Rules, 1945 (As amended up to the 31st December, 2017) and standards of National Accreditation for Hospitals & Healthcare Providers (NABH),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 in the amendment sheet provided in the SOP for SOPs.

MANDATE OF THE COMMITTEE

- All 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 IEC shall also review and monitor ongoing projects from time to time.
- 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 IEC 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 IEC 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 IEC will work according to its current established Standard Operating Procedures based on, International Conference on Harmonization - Good Clinical Practices (ICH-GCP) Guidelines,1996; NDCT rule 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.

LOG OF SOP RECIPIENTS

S. No.	Name of recipients	Designation	SOP Copy No.	Date of receipt
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DETAILS OF SUPERSEDED SOPs

Name of Authorized Signatory	Version	Effective Date	Date of becoming Obsolete	Major Changes
Dr. Phalguni Dutta	Version 6.0	5th Dec 2022	NA	See attached summary of changes
Dr. Phalguni Dutta	Version 5.0	20th Apr 2018	4th Dec 2022	• Fifteen SOPs of version 4.0 have been reformatted to five (5) major SOPs in version 5.0 distributing all the existing elements in a logical sequence and adding new elements as required by NABH standards. • SOP1 v4 is rewritten as SOP1v5 (Preparation of SOPs) and has no major changes. • SOP2v4, SOP13v4 and SOP14v4 are merged under separate sections as SOP2v5 (Constitution, Composition, Terms of Appointment, Functions, Role and • Responsibility of IEC members). Additionally, section 10 on Periodic Self Assessment and Root Cause analysis has been added. • SOPs 3; 4; 5a-5d; 6 - v4, and SOP12v4 are merged under separate sections as SOP3v5 (Submission of Proposals for IEC approval) • SOPs 5e; 7a; 7b;8; 9; 11 v4, are merged under separate sections as SOP4v5 (Post approval review) • Part of SOP4 v4 (section 5.4 'After the IEC meeting'), SOP 10 v4, and SOP15v4 are merged under separate sections as SOP5v5 (Documentation & Archiving) • List of Acronyms (& Glossary) has been added in v5 as an Appendix • List of References have been clubbed together and presented as an Appendix. Website references are provided in v5 • Forms have been majorly revised and a list added at the end of each SOP
Dr. Phalguni Dutta	Version 4.0	13th Apr 2016	20th Apr 2018	Introduction of four new SOPs on review Amended protocol / Protocol related documents, Review of study completion reports, Management of Premature Termination, Suspension or Discontinuation of Study, Reviewing Research Studies Involving Vulnerable Participants and minor changes in the existing SOPs. Introduction of SOPs on Financial Policies and Procedures(SOP13), separate SOP on Training for Committee Members (SOP14), and on Communication with different stakeholders (SOP15)
Dr. Samiran Panda	Version 3.0	28th Mar 2015	13th Apr 2016	Major restructuring in SOP presentation – split into 11 separate SOPs with detailing of all essential information and procedures, introduction of routine and for – cause audits of clinical trials and audio visual recording of informed consent process
Dr. Dipika Sur	Version 2.0	21st March 2013	28th May 2015	Introduction of Conditions of appointment-Renewal/Resignation/Termination, Terms of Reference of Chair person and members , Policies to monitor / prevent COI, Elements of Review, SOP on Vulnerable population as research participants, policy on training

Mrs. Krishna Bose	Version 1.0	20th Nov 2008	21st March 2013	NA

Summary of changes

SL.NO.	Page No.	V 5.0	V 6.0
1	Introduction page	Para-4, Re-registered new details Registered with the Central Drugs Standard Control Organization (CDSCO) on May 31, 2013 (Registration No.ECR/359/Inst/WB/2013)	Para-4 Re-registered on February, 02, 2017 (Registration No. ECR/359/Inst/WB/2013/RR-19; Validity from 31.05.2016 to 30.05.19 and 30.05.2019 to30.05.2024)
2	Introduction page	Para-6 It is now committed to achieve accreditation of Clinical Trials (Ethics Committee) by National Accreditation Board for Hospitals & Healthcare Providers (NABH), a constituent board of Quality Council of India.	It has been accredited for Clinical Trials (Ethics Committee) by National Accreditation Board for Hospitals & Healthcare Providers (NABH), a constituent board of Quality Council of India. Accredited with NABH on18.05.2020 valid till 17.05.2023
3	Introduction page	Para-8 The scope of research is biomedical research on participants between 0-18 years of age carried out in the premises of Institute of Child Health	Para-8 The scope of research is biomedical research on Participants between 0-18 years of age and adults (trials involving mothers etc.)
4	Introduction page	Para-9, Schedule Y	Para-9, omitted Schedule Y
5	Introduction page	Para-11, 2nd line omit word "for"	Para-11, 2nd line add word "in"
6	Mandate page	Point-2 Dissertation or thesis, research work of faculty, students (medical, nursing, paramedical, &allied sciences) of this Institute will be reviewed and monitored by this committee	Point-2 Dissertation or thesis, research work of faculty, students (medical, nursing, paramedical, &allied sciences) of this Institute will be reviewed and monitored by this committee-shift to IECBMHR(added)
7	Mandate page	Point-7,third line Schedule Y	Point-7,third line Remove Schedule Y
8	**SOP-1** Page-6, 5th row(under 7.c)	Existing SOPs are reviewed every two (2) 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	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
9	Page-7, 5th	A request for amendment or	A request for amendment or

	row(under 7.e)	revision is accomplished by filling out ***Form IEC – ICH 1-F: Request for Revision of an SOP.*** The IEC-ICH Chair is responsible for initial review of the request, procurement of relevant information, recommendation of further action as follows	revision is accomplished by filling out ***Form IEC – ICH 1-G: Request for Revision of an SOP.*** The IEC-ICH Chair is responsible for initial review of the request, procurement of relevant information, recommendation of further action as follows
10	Page-9, point 15, list of forms	IEC – ICH 1-E, Document History of SOP, 1-F- Details of superseded SOPs merged IEC-ICH 1-G-Request for revision of SOP –Form no changed	IEC – ICH 1-E, Document History of SOP, Details of superseded SOPs, IEC-ICH 1-F-Request for revision of SOP –form no revised
11	SOP-2 Page-5,4.b.i	Schedule Y	Replaced by NDCT rule
12	SOP-2 Page-12,8.a.vi	The fee of independent consultant will be a fixed(Rs-1500/-) amount that covers initial review and subsequent review of submitted documents for approval by the Committee	The fee of independent consultant will be a fixed amount that covers initial review and subsequent review of submitted documents for approval by the Committee
13	SOP-2 Page-15,10.b.ii	Correction action	Corrective action
14	SOP-2, form 2A & 2B	Major revisions and change of formats-Medical/Scientific Member Notification and Appointment, Non-Medical/Lay Member Notification and Appointment	Revised the whole
15	SOP-2, form 2C	Earlier obsolete- *Non-Medical/Lay Member Notification and Appointment*	Revised the whole
16	SOP-3,page-3,para-2,1st line	clinical trials and researches	" and researches"-omitted, refer to IECBMHR SOP version 1.0 dated 18.11.2019
17	SOP-3,page-3,para-2,7th & 8th line	Or research studies by training residents, fellows or consultants	Omitted the entire
18	SOP-3,page-3,point 4, 5th box	Assign primary reviewers, IEC chair	Omit the entire
19	SOP-3,page-4,point 4, 6th box	Present review findings during full committee meeting	Omit the entire
20	SOP-3,page-5,para 9, 2nd point	Research protocols by training residents and fellows, and academic studies conducted by in house researchers for review by the IEC will be exempted from payment of the prescribed institutional fee	Omit the entire
21	SOP-3,page-5,para 10, 2nd point	Initial Review Application for Thesis/ Dissertation	Omit the entire

22	SOP-3,page-6,below para 4,point c, 1st box	Initial Study Protocol review for Thesis/ Dissertation	Initial Study Protocol review –refer to BMHR SOP version 1.0 dated 18.11.2019
23	SOP-3,page-6,below para 4,under point c 1st box	Under section c-i. ii, iii, iv exists 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 **IEC-ICH Form 3H Thesis/ Dissertation Submission Form 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	Initial Study Protocol review –refer to BMHR SOP version 1.0 dated 18.11.2019.
24	SOP-3,page-7,under point d-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 2017; National Ethical Guidelines for Biomedical Research involving Children, ICMR 2017 and Schedule Y, CDSCO regarding the following matters	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 2017; National Ethical Guidelines for Biomedical Research involving Children, ICMR 2017 and NDCT rules 2019 regarding the following matters
25	SOP-3,page-9,under point D-v	Researcher must obtain voluntary written informed consent from the prospective participant for any biomedical and health research involving human participants	Researcher must obtain voluntary written informed consent from the prospective participant
26	SOP-3,page-9,under point D-vii	The ICD has two parts – patient/participant information sheet (PIS)	The ICD has two parts – participant information sheet (PIS)
27	SOP-3,page-22	No procedural details regarding	Details added

		agenda of online meeting	
28	SOP-3,page-23, point e	No procedural details regarding agenda of online meeting	Details added
29	SOP-3,page-22, point e-i	For studies which require the approval of CDSCO, quorum is defined as the presence of at least 5 members with the following representation as per the Schedule Y of the Drugs and Cosmetics (Third Amendment) 2013 Rules	For studies which require the approval of CDSCO, quorum is defined as the presence of at least 5 members with the following representation as per the NDCT rule 2019
30	SOP-3,page-22, point e-i	Determination of quorum	Determination of quorum as per NDCT rule
31	SOP-3,page-24, point g-iii	No procedural details regarding declaration of online details COI	Details added
32	All SOPs(1-5)	"Research"	Replaced by "Trial"
33	All SOPs(1-5)	"Subjects"	Replaced by "Participants"
34	SOP 4,page 5,2nd para, point 5	The Secretariat Staff ensures that sufficient copies for the IEC Members have been submitted by the PI for full board submissions	The Secretariat Staff ensures that sufficient copies for the IEC Members have been submitted by the PI for full board submissions-online process mentioned
35	SOP 4,page 5,7th para, point iii-2	Study protocol amendment packages subject to full board review received within the cut-off period of twenty (20) days before the *IEC* meeting are sent to members ten (10) days before the *IEC* meeting	Study protocol amendment packages/including soft copy subject to full board review received within the cut-off period of twenty (20) days before the *IEC* meeting are sent to members ten (10) days before the *IEC* meeting
36	SOP 4,page 5,9th para, point iii-4	The Reviewers accomplish the review and return the signed **IEC-*ICH* Form 4-A: *Study Protocol Amendment Submission Form*/ IEC-*ICH* Form 4-K: *Additional Material for Study Use for Approval Form*** on the day of the *IEC* meeting together with the Study Protocol Amendment Package.	The Reviewers accomplish the review and return the signed **IEC-*ICH* Form 4-A: *Study Protocol Amendment Submission Form*/ IEC-*ICH* Form 4-K: *Additional Material for Study Use for Approval Form*** on the day of the *IEC* meeting together with the Study Protocol Amendment Package-For online meetings opinion of members are taken and a final decision is recorded by member secretary on form 4A/4K.
37	SOP 4,page 7,10th para, point-10	Thesis / Dissertation projects are exempted from Annual Review by IEC	Refer to IECBMHR SOP
38	SOP 4,page 18,1st para, point-10	Initial and Final Report (Interim Report, if any) as per Appendix XII of Schedule Y	Initial and Final Report (Interim Report, if any) as per NDCT rules 2019
39	SOP 4,page 19, point e-iii	The IEC communicates its decision on the SAE to the DCGI office within 30 days of SAE occurrence in prescribed format	The IEC communicates its decision on the SAE to the DCGI office within 30 days of SAE occurrence in prescribed format-through SUGAM

			portal
40	SOP 4,page 20, box	IEC Chairperson Within 30 calendar days will send the Analysis report of the SAE to CDSCO, Head of Institution	IEC Chairperson Within 30 calendar days will send the Analysis report of the SAE to CDSCO, through SUGAM portal & DCGI email. A separate communication should send to the HOI
41	SOP 4, form 4I, Audit checklist	Form	Major revisions and new format
42	SOP 5, Form 5B	Earlier format modified	Major revisions and new format
43	SOP 5, Form 5D	IEC-ICH Secretariat at 033 2290 5686, 9830897576	IEC-ICH Secretariat at 9073687795
44	SOP 5, Form 5E	Protocol amendment letter	Format modified
45	SOP 5, Form 5F-Submission log		"e-mail notification "added to format
47	SOP 1-5(all cover page-1)	Dr. Sankar Sengupta, Dr. Suparna Chatterjee, Ms. Mamata Sarkar, Mr. Chinmoy Guha Thakurta - resigned	Dr. Sankar Sengupta, Dr. Suparna Chatterjee, Ms. Mamata Sarkar, Mr. Chinmoy Guha Thakurta -names omitted. Dr. Sabnam Ara Begum, Dr .Supriyo Choudhury- names addeded(new appointed)
48	SOP-5, form 5N-submission log		Format revised
49	SOP-5, form 5L	"the Schedule Y (Drugs and Cosmetics Act,1940 and Rules, 1945; As amended up to the 31st December"	Replaced by" NDCT rules, 2019"
50	Reference	Point No. 1- Point No 12	Point No.3a-h omitted
51	SOP-4, Form 4-I	Audit checklist	Format revised
52	SOP-4, page 20	SAE flowchart	"DCGI"-omitted
53	SOP-4,page 17	"As per Appendix XII of Schedule Y"	Replaced by "NDCT rule, 2019"
54	SOP-3,page 22	Not in earlier version	iv. IEC meetings will be conducted on an electronic meeting platform such as Zoom, Webex, Google meet etc. IEC Secretariat will organize the e-meeting. Members will be briefed about the technological requirements necessary. Meeting will be held for a maximum of 90 minutes duration. Agenda will be short and circulated by mail prior to meeting. The frequency of meeting may be increased on a need basis. Meeting ID and password will be communicated to the members 1

			hour before the meeting. E-attendance will be recorded by Member secretary and once quorum is fulfilled discussions will ensue
55	SOP-3,page 23	Not in earlier version	*A conflict of interest arises when a member(s) of the IEC 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 IEC member has financial, material, institutional or social ties to the research.*
56	SOP-3, Form 3-H	Thesis dissertation form	*Refer to SOP, BMHR*
57	SOP-2, form-2A,2B	Old format is obsolete	Entire format is changed
58	SOP-2,page12,point-vi	The fee of independent consultant will be a fixed amount (Rs.1,500) that covers initial review and subsequent review of submitted documents for approval by the Committee.	The fee of independent consultant will be a fixed amount that covers initial review and subsequent review of submitted documents for approval by the Committee.
59	SOP-2,page5,point-i	The composition of this IEC will be as per the **ICMR guidelines for Biomedical research involving human participants, 2017**, and the **Schedule Y** of the **Drugs and Cosmetics Act ,1940 and Rules, 1945 As amended up to the 31st December, 2016**	The composition of this IEC will be as per the NDCT rules 2019 of the **Drugs and Cosmetics Act ,1940 and Rules** and **ICMR guidelines for Biomedical research involving human participants, 2017**

AMENDMENT SHEET

(SOPs of ICH IEC)

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

Preparation of Standard Operating Procedures
SOP Code: SOP 01/V6

Reviewed By

Name and Position in IEC	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	
Dr. Sabnam Ara Begum Basic Medical Scientist; Clinical Pharmacologist	
Mr. Tamal Chatterjee Legal expert	
Ms. Anasuya Basu Layperson	
Ms. Kaberi Mukherjee Theologian	

Approved By

Name and Position in IEC	Signature
Dr. Phalguni Dutta Chairperson	

Accepted By

Name and Position in ICH	Signature
Prof. Apurba Ghosh Executive Director	

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Supersedes	05
Version	06
Authored By	SOP Team
Version Date	17 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 (IEC) 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 IEC-ICH SOP and their amended versions as published and distributed by the IEC-ICH.

3. RESPOSIBILITY

The IEC-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 IEC-ICH Members.

The IEC-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.

IEC-ICH members are responsible for consensus action on the proposed SOP, the outcome of which is approved by the IEC-ICH Chair. The IEC 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 IEC Secretariat.

The IEC-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 IEC and to the administrative head of the Institute **within 14 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 IEC members
- Maintain a record of the investigators to whom SOPs are distributed
- Ensure that all the IEC members and involved administrative staff have access to the SOPs
- Ensure that all the IEC members and involved staff are working according to current versions of the SOP
- Maintain on file all past SOPs of the IEC
- Assist in the formulation of the SOP procedure

DETAILED INSTRUCTIONS

4. IDENTIFY THE NEED FOR NEW OR AMENDING SOP

Any member of the IEC/ 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 **IEC – ICH 1-F** for revision of an SOP. Revision of an SOP made as a formal request will be submitted to the IEC Chairperson.

The Chairperson will inform all the IEC members about this request in a regular full-board IEC meeting. If the IEC 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 IEC members do not agree, no further action will be taken. The Chairperson will inform the person/IEC 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 IEC members with the approval of the Chairperson. This will be logged in **IEC – 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 IEC, CDSCO registration number, 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 and Head of Institute in Font 18(**Form IEC – 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 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 IEC – ICH 1-D, Amendment Sheet Format**).

e. **Eight Page**: This will document the History of the SOPs with the list of Superseded SOPs (**IEC – 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 **(IEC-ICH Form 1-B: SOP Cover Page)** laid out as:
   i. Title with SOP Code
   ii. Name of Reviewers with signature: Reviewed, Approved, and Accepted 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 **sixth one;** hence it will be denoted as"v6". The first SOP of the current version would be ICH IEC SOP01/v6 i.e. it is SOP number 01 of version 06.
   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 IEC-ICH in order to facilitate transparent, clear, and systematic implementation of its functions.

b. New SOPs may be issued in not less than **two-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 IEC-ICH Chair for compilation and processing by respective parties, such as IEC-ICH Members, in preparation for the next round of SOP review.

e. A request for amendment or revision is accomplished by filling out ***Form IEC – ICH 1-F: Request for Revision of an SOP.*** The IEC-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 IEC-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 IEC 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 ***IEC – 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 IEC 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 IEC
- Organize, devise and, name each process
- Make a list of SOPs with coding reference

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

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

b. The IEC-ICH Chair organizes an IEC forum, which is expected to be attended by majority of the IEC members.

c. The IEC-ICH Chair presents the new/revised SOP to the IEC during this forum and presides over deliberation.

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

a. The IEC-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. *Favorable 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 during the forum, in which case, the IEC-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 forum.

12. APPROVAL OF NEW/REVISED SOP FOR IMPLEMENTATION

a. Upon favourable action by IEC-ICH, the SOP is approved by the IEC-ICH Chair and is endorsed to the Director, ICH for final acceptance.

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

c. The **effective date** of the document is reckoned as the date when the Director, ICH signs the document. However, in the interest of continuity of IEC work, SOP documents may be regarded as functionally approved as of the date of favorable action by the IEC-ICH. The approved SOPs will be implemented from the effective date

d. The printed copy of the approved SOPs will be distributed to IEC-ICH Members and ICH authorities (Hospital Director, Chief Administrative Officer) **within thirty (30) days** of approval by the Director, ICH. This will be recorded in the ***Form IEC-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 IEC-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 **IEC – 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 ↓	IEC-ICH Chair on the request of any IEC member/ Stakeholder
Design SOP format, coding and layout ↓	SOP Team
Write new/review existing SOP ↓	SOP Team
Present new/revised SOP to the IEC-ICH ↓	IEC-ICH Chair
Decide on IEC-ICH action ↓	IEC-ICH Members
Approved new/revised SOP ↓	IEC-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

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

INSTITUTE OF CHILD HEALTH
INSTITUTIONAL ETHICS COMMITTEE (IEC)

IEC Registration Number: ECR/359/Inst/WB/2013/RR-19

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, IEC ICH:

Accepted by
Signature of Executive Director, ICH:

Template cover page of each SOP

Title: XXXXX
SOP Code: XX/YY

Reviewed By

Name and Position in IEC	Signature
XXXXXXXXXX	XXXXXXXXXX
XXXXXXXXXX	XXXXXXXXXX
XXXXXXXXXX	XXXXXXXXXX
XXXXXXXXXX	XXXXXXXXXX
XXXXXXXXXX	XXXXXXXXXX
XXXXXXXXXX	XXXXXXXXXX
XXXXXXXXXX	XXXXXXXXXX
XXXXXXXXXX	XXXXXXXXXX
XXXXXXXXXX	XXXXXXXXXX
XXXXXXXXXX	XXXXXXXXXX
XXXXXXXXXX	XXXXXXXXXX

Approved By

Name and Position in IEC	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	XXXXXX	XXXXX		
2	XXXXXX	XXXXX		
3	XXXXXX	XXXXX		
4	XXXXXX	XXXXX		
5	XXXXXX	XXXXX		
6	XXXXXX	XXXXX		
7	XXXXXX	XXXXX		
8	XXXXXX	XXXXX		
9	XXXXXX	XXXXX		
10	XXXXXX	XXXXX		
11	XXXXXX	XXXXX		
12	XXXXXX	XXXXX		
13	XXXXXX	XXXXX		
14	XXXXXX	XXXXX		
15	XXXXXX	XXXXX		
16	XXXXXX	XXXXX		

AMENDMENT SHEET

(SOPs of ICH IEC)

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

Please complete this form whenever a problem or a deficiency in an SOP is identified and maintained with the SOP until an authorized replacement is in place.

SOP/ / (Write the SOP number)	
Title:	
Details of problems or deficiency in the SOP:	
Identified by:	Date (D/M/Y):
Discussed with:	
SOP revision required: ☐ Yes ☐ No	
If yes, to be carried out by whom?	
If no, why not?	
Date SOP re-finalized:	
Date SOP approved:	
Date SOP becomes effective:	

Constitution, Composition, Terms of Appointment, functions, role and responsibility of IEC Members
SOP Code: SOP 02/V6

Reviewed By

Name and Position in IEC	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	
Dr. Sabnam Ara Begum Basic Medical Scientist; Clinical Pharmacologist	
Mr. Tamal Chatterjee Legal expert	
Ms. Anasuya Basu Layperson	
Ms. Kaberi Mukherjee Theologian	

Approved By

Name and Position in IEC	Signature
Dr. Phalguni Dutta Chairperson	

Accepted By

Name and Position in ICH	Signature
Prof. Apurba Ghosh Executive Director	

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Supersedes	05
Version	06
Authored By	SOP Team
Version Date	17 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 Institutional Ethics Committee – Institute of Child Health (IEC-ICH). This Standard Operating Procedure (SOP) describes the Terms of References (TOR), which provide the framework for constitution, responsibilities, and activities of the IEC. 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-IEC, as it carries out its task of providing an independent review of research protocols involving human participants that are submitted to the IEC by consultant-physicians, resident and fellow-trainees, students, hospital staff and employees of the ICH for clinical trials or researches done within the hospital or institution alone.

This SOP describes the basic ethical principles and values on which the ICH-IEC is based, the composition and appointment of the IEC members and the duties and responsibilities of IEC 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 IEC members and staff shall also abide by this SOP.

3. RESPONSIBILITIES

IEC 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 participants.
- 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-IEC under the authority of the Director. The Director is responsible for appointing the IEC 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-IEC Chair, Members and Secretariat Staff to study, comprehend, comply with, and respect the procedures and guidelines set forth by the ICH-IEC.

It is the responsibility of all newly appointed ICH-IEC 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 IEC. 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 IEC to undergo training during the course of his/her appointment. Likewise, existing IEC 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 IEC Members.
It is the responsibility of the Chair and IEC members and the Secretariat to read, understand, follow and respect the SOP set by the Institutional Ethics Committee.

4. CONSTITUTION AND FUNCTIONS

a. Organizational Structure of the IEC-ICH

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

i. The Director appoints the IEC 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 IEC after due process.
iii. Appointment terms for a member
- □ The Chairperson and IEC 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 IEC 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 IEC 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 IEC assignment and make these records available to IEC 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-IEC

i. The composition of this IEC will be as per the NDCT rules 2019 of the **Drugs and Cosmetics Act ,1940 and Rules** and **ICMR guidelines for Biomedical research involving human participants, 2017.**

ii. The IEC shall have at least 7 and a maximum of 15 members. To the end that a quorum will be met during regular IEC 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
3. One or more persons from basic medical science area
4. One or more clinicians from various Institutes
5. Legal expert
6. Social scientist/ representative of non-governmental agency/philosopher/ethicist
7. One or more lay person from community

iii. The IEC 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 laypersons to represent the different points of view. The IEC 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-IEC. The members representing medical 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 IEC.

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 IEC members, in its first meeting, choose among themselves the Vice-Chair and Member Secretary.

ix. The IEC may be supported in its deliberation of specific protocols by Independent Consultants (see **ICH SOP II-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~~ days 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 and 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 and 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 IEC members will elect a replacement for another term in consultation with the Director.

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

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

ii. Members are required to sign ICH-IEC 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 IEC in the course of its work

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

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

e. Specific Duties and Functions of ICH-IEC Personnel

i. ICH-IEC Chair

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

- Assist the IEC Chair in overseeing the review of protocols by IEC 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 IEC-related tasks that may be assigned to him/her by the IEC Chair
- Recommend the development, implementation, and monitoring of IEC policies and procedures to the IEC Chair
- Manage the IEC office under the supervision of the IEC Chair
- Ensure the basic training, orientation, and continuing education of IEC members and staff
- Inform research investigators regarding IEC application processes
- Assist the IEC 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 IEC Chair, schedule and lead the IEC in Site Visits or similar activities
- During IEC 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 IEC-related tasks that may be assigned to him/her by the IEC Chair

iii. ICH-IEC Member

- Make timely and thorough review and decision regarding protocols given to him/her for evaluation (**See SOP III: *Protocol Review*** for timelines)
- Familiarize him/herself with the SOPs of the IEC, his/her terms of reference, and the international and national guidelines on research ethics
- Participate actively in the monthly meetings and other IEC 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 IEC as a review Committee.
- Participate actively in the review of the progress reports, final reports, and other amendments presented during the IEC meeting.
- Participate in Site Visits and similar activities as needed.
- Maintain confidentiality of the documents and deliberations of IEC meetings.
- During IEC meetings, declare any conflict of interest in general and for specific protocols for review.
- Participate in required training as stipulated in **SOP II – 6: *Training of IEC 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 IEC Chair any suggestion, complaint, or grievance of research participants, PIs, and/or sponsors for appropriate discussion during the monthly IEC meeting
- Do other IEC-related duties that may be requested of him/her by the Chair.

iv. ICH-IEC 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-IEC Active Files and Archives, ***Submission Log*** **[IEC –ICH FORM 5-N]**, References and other document files, especially their security and confidentiality
- Organize IEC meetings (see **SOP III-5: *Conduct of Full Committee Meetings***)
- With the IEC Secretary, prepare and maintain meeting agenda and minutes
- Facilitate requisition and procurement of office supplies and materials
- Inform the IEC 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 IEC and they will be supervised by the Member Secretary.

5. CONFIDENTIALITY/CONFLICT OF INTEREST AGREEMENT WORKFLOW

ACTIVITY	RESPONSIBILITY
Prepare *IEC -ICH Form 2-D: Confidentiality Agreement and Conflict of Interest Disclosure* ↓	Secretariat Staff
Accomplish *IEC -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-IEC for Panel Members: The ICH-IEC Secretariat provides a copy of IEC-ICH Form 2-D: *Confidentiality Agreement and Conflict of Interest Disclosure* to new members of the ICH-IEC panel as soon as they are appointed; these are renewed annually.

b. Accomplishment of Forms

i. A copy of IEC-ICH Form 2-D: *Confidentiality Agreement and Conflict of Interest Disclosure* must be filled out and signed by all ICH-IEC personnel. A COI does not necessary disqualify a person from becoming a member of the ICH-IEC for as long as he/she declares it beforehand, understands his/her responsibility as a ICH-IEC 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-IEC personnel reads, signs the forms, and dates his/her signature on the forms then submits them to the ICH-IEC Secretariat Staff

iii. The ICH-IEC 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-IEC Membership Files.

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

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

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

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

6. TRAINING OF ICH-IEC MEMBERS AND PERSONNEL WORKFLOW

ACTIVITY	RESPONSIBILITY
Set training requirements ↓	Chair
Find available training, seminars, lectures, workshops / Conduct in-house training ↓	Members/Secretariat Staff
Signify intention to attend training or the ICH-IEC Chair instructs member/s to attend ↓	Members/Secretariat Staff
Attend training and keep the training record ↓	Members/Secretariat Staff
Store training record in ICH-IEC Membership Files under *Training of ICH-IEC Members*	Secretariat Staff

a. DETAILED INSTRUCTIONS:

Identification of Required Trainings, Seminars, and Workshops

i. The IEC Member Secretary periodically reviews compliance with training requirements for ICH-IEC Chair, Secretary, Members, and Secretariat Staff.

ii. It is the responsibility of the IEC Chairperson with the assistance of Member Secretary to ensure that there is adequate initial and continued training of the IEC members and the Secretariat. The Chairperson is responsible for assessment of all IEC members and to complete a self-assessment exercise at prescribed intervals.

The 2 basic required courses are:

- Basic Research Ethics & Good Clinical Practice
- ICH-IEC Standard Operating Procedures

b. Attendance in the Training

i. The IEC Member Secretary, member, Chairperson will be encouraged to receive continued training by participating in a workshop, conference and/ or retraining

program related to research ethics, as a delegate, faculty, facilitator, etc. at least once every year.

ii. The IEC will conduct workshops on ethics in clinical research and good clinical research practices from time to time to impart training to the IEC Members to the Institutional faculty members.

iii. The Member or Secretariat Staff attends the training and submits proof of attendance to the Coordinator, such as certificate of participation or completion.

iv. The Secretariat verifies validity of submitted documents

v. Attendees are encouraged to echo their experience and disseminate new knowledge and information to the ICH-IEC.

c. Training of new IEC Members

i. Every time a new committee is constituted, the members must undergo initial training on ethics in clinical research and good clinical research and SOPs. One training every year at the minimum should be provided.

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

d. Training of the Secretariat

i. The IEC 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 IEC members' performance is evaluated once a year using **IEC-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-IEC Membership File.

7. SELECTION OF INDEPENDENT CONSULTANTS WORKFLOW

ACTIVITY	RESPONSIBILITY
Invite Independent Consultants to the ICH-IEC ↓	ICH-IEC Chair
Sign conforme and **IEC-ICH Form 2-D: Confidentiality Agreement and Conflict of Interest Disclosure** ↓	Independent Consultant
Appoint the roster of Independent Consultants	ICH-IEC 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:
- **IEC –ICH Form 2-F: *Service Agreement for Independent Consultants***
- **IEC-ICH Form 2-D: *Confidentiality Agreement and Conflict of Interest Disclosure***

ii. .Review assigned protocols that concern his/her specialty using the **IEC-ICH Form 3-C: Study Protocol Assessment Form**

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

iv. Return all protocol-related materials to the ICH-IEC 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-IEC

c. Appointment of Independent Consultants

i. Any member of the ICH-IEC recommends to the IEC 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-IEC Chair

d. Storage of Roster of Independent Consultants

i. The ICH-IEC 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-IEC Chair
Approved Honorarium ↓	Director
Communicate Honorarium Information to Personnel and Independent	Secretariat Staff

Consultants	

a. Recommendation of Honorarium

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

ii. The compensation for IEC 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 IEC 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-IEC related-activities

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

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

c. Communication of Honorarium Information

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

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

9. Financial Policies and Procedures

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

a. **Purpose:** The obligation of IEC 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 IEC budget allocation. It also

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

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 IEC. The IEC 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 IEC 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 IEC 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: IEC 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 IEC 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. IEC Registration and Accreditation Expenditures: Necessary registration and accreditation related expenditures of IEC will be drawn from IEC 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 IEC 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 IEC receives revenue in cheque or bank transfer for the services offered from the sponsors of the research study.

i. The IEC Secretariat will receive the IEC 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 IEC 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 IEC fees to the Institute's account.

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

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

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

ACTIVITY	RESPONSIBILITY
Periodic Self Assessment (Twice a year) ↓	Secretariat Staff
Reviewed in Full Board Meeting ↓	ICH-IEC Chair
System failures addressed, RCA and	Primary Members

CAPA done; documented ↓	
Follow up and Improvements discussed in Full Board Meeting ↓	ICH-IEC Chair
Annual report published (end of calendar year) Copy to Director, ICH	Secretariat Staff

a. Periodic Self Assessment

i. ICH IEC conducts self evaluation twice a year. Evaluation is done by the IEC 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 IEC.

iv. The self assessment review is discussed in the full board IEC 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 (Corrective 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 IEC meeting under the instruction of the Chair.

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

c. Publication of Annual Report

i. IEC Secretariat will prepare an annual activity report of the IEC 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

IEC ICH Form 2A:	Medical / Scientific Member Notification and Appointment
IEC ICH Form 2B:	Non Medical / Lay Member Notification and Appointment
IEC ICH Form 2C:	Curriculum Vitae

IEC ICH Form 2D:	Confidentiality Agreement and Conflict of Interest Disclosure
IEC ICH Form 2E:	Training Record
IEC ICH Form 2F:	Service Agreement for Independent Consultants
IEC ICH Form 2G:	IEC Budget (Financial Year)
IEC ICH Form 2H:	Records of Income (Financial Year)
IEC ICH Form 2I:	Records of Expense (Financial Year)
IEC ICH Form 2J:	Checklist for Periodic Self Assessment
IEC ICH Form 2K:	NC/ CAPA Record
IEC ICH 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 -Institute of Child Health, Kolkata with effect from.....
Brief term & conditions are as mentioned bellow:

SCOPE: The Institutional Ethics Committee -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 -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 -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 -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 of Institutional Ethics Committee-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 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 -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 - 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:

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

Date: .....

Name, Qualification,
Designation
Address

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

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- You shall well versed with the System of Procedure (SOP) of Institutional Ethics Committee -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 of Institutional Ethics Committee - 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 -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 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 -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 -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
f) Your professional indemnity Insurance certificate and other documents you may want to submit.

Thanking You,
Yours faithfully,

For Institutional Ethics Committee -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:

CURRICULUM VITAE

Name :

Date of Birth :

Sex :

Address :

Qualifications :

Designation :

Organization :

Current Affiliation (s) :

Current Work Place :

Current Professional Address:

Contact No. :

Email ID :

Professional Experience :

Publications:

Memberships & Awards:

Signature: _____

Date: _____

INSTITUTIONAL ETHICS COMMITTEE-
INSTITUTE OF CHILD HEALTH
11, Dr. Biresh Guha Street, Kolkata 700017
Telephone No: 033 2290 5686, 9073687795

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 IEC 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 IEC 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 IEC 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 IEC 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 IEC, 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 IEC. Any written information provided to the undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly.

As such, the undersigned agrees to hold all Confidential or Proprietary trade secrets ("information") in trust or confidence and agrees that it shall be used only for contemplated purposes 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 IEC.

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-IEC 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 IEC 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-IEC
- The Undersigned will immediately disclose to the ICH-IEC 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-IEC Member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol
- The request must be in writing and addressed to the Chair. The request must contain evidence that substantiates the claim that a conflict of interest exists with the ICH-IEC 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-IEC 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-IEC, 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
Date:

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

TRAINING RECORD

Surname:	First Name:	Middle Name:

	BASIC COURSES	TRAINING PROVIDER	VENUE	DATE (dd/mm/yyyy)	IEC FUNDED (Yes/No)
1	GCP Training				
2	Research Ethics				
3	Standard Operating Procedures (SOP)				

	CONTINUING ETHICS EDUCATION: Research Ethics Workshops, Conferences, Meetings, Lectures	TRAINING PROVIDER	VENUE	DATE	IEC FUNDED (Yes/No)
1					
2					
3					
4					
5					

	AS RESOURCE PERSON	TRAINING PROVIDER	VENUE	DATE	IEC FUNDED (Yes/No)
1					
2					
3					

Certified Correct:

Secretariat Staff Date: (dd/mm/yyyy)	Name: Signature:
IEC Chair Date: (dd/mm/yyyy)	Name: Signature:

Date (dd/mm/yyyy)

Title, Name

Dear

The ICH-IEC would like to invite you to be an Independent Consultant, in your capacity as a *(area of expertise)*, to provide expert review of study protocols which require scientific or medical expertise not represented in the current composition of the board or those which board has ascertained to require additional expert view.

The responsibilities of an Independent Consultant are as follows:

1. Submission or accomplishment of the following documents
   a. Copy of **IEC - ICH Form 2-C, 2022. *Curriculum Vitae***
   b. Signed **IEC- ICH 2-D, 2022. *Confidentiality Agreement and Conflict of Interest Disclosure***
2. Provision of the following consultation services
   a. Participation during the full board meeting when the study protocol will be discussed, though without decision privileges

Should you agree to this request, please sign the conforme below and submit the documents indicated in 1.a and 1.b above to the IEC office to facilitate processing of your appointment.

Please be informed that the term of office of an Independent Consultant is for a period of three years from the date of appointment.

Thank you and our best regards.

Very truly yours,

_____
Director, ICH

CONFORME:

_____
(Title, Name, Surname) & Signature
Date (dd/mm/yyyy)

Institutional Ethics Committee, Institute of Child Heralth, Kolkata					
Budget Estimate for the year: April..... to March.....					
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 (FINANCIAL 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 (FINANCIAL 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 - IEC composition and qualifications

IEC MEMBER CHARACTERISTICS	
Number of IEC 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 - IEC workload & number of meetings & protocols/documents reviewed

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

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

IIT= Investigator Initiated (Clinical) Trial

REVIEW CHECKLIST FOR PERIODIC SELF ASSESSMENT OF IEC

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

C2. 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
Pharmaceutical sponsored project (regulatory)						
Pharmaceutical sponsored project (non-regulatory)						
IIT (Investigator Initiated Study)						
Academic						
Thesis						

REVIEW CHECKLIST FOR PERIODIC SELF ASSESSMENT OF IEC

D. Annual Evaluation:

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

Year	Pharmaceutical	Academic	IIT	PGT Thesis	Year Wise Total Active
Last 5 years					
Total Active					

INSTITUTIONAL ETHICS COMMITTEE-
INSTITUTE OF CHILD HEALTH
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_____☐
☐ Process non-conformity	☐ Suggestion (improvement)	☐ Others
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 IEC 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 IEC Meetings
SOP Code: SOP 03/V6

Reviewed By

Name and Position in IEC	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	
Dr. Sabnam Ara Begum Basic Medical Scientist; Clinical Pharmacologist	
Mr. Tamal Chatterjee Legal expert	
Ms. Anasuya Basu Layperson	
Ms. Kaberi Mukherjee Theologian	

Approved By

Name and Position in IEC	Signature
Dr. Phalguni Dutta Chairperson	

Accepted By

Name and Position in ICH	Signature
Prof. Apurba Ghosh Executive Director	

TABLE OF CONTENTS

Supersedes	05
Version	06
Authored By	SOP Team
Version Date	17 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 (IEC) manages protocol submissions to the IEC.

2. SCOPE

The ICH-IEC reviews global or local clinical trials conducted on participants 0 – 18 years of age by institution's physicians or other employees. The ICH-IEC, at the present time, does not accept protocols for ethics review if the Study Principal Investigator is not affiliated to ICH. The IEC will also not accept protocols for ethics review if the study is to be done outside the ICH premises even if the Principal Investigator is ICH affiliated. Except in certain cases (collaborative research) deemed appropriate by the Chair and expressly approved by the Committee (e.g. community-based clinical trials the above conditions may be relaxed.

The SOP applies to IEC 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 IEC Chair to decide whether the study protocol is for full Committee (convened) or expedited review.

It is the responsibility of the assigned reviewers 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 forms and informed consent checklist, 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-IEC.

4. INITIAL REVIEW WORKFLOW

ACTIVITY	RESPONSIBILITY
Receive and manage study protocol submissions ↓	IEC Secretariat Staff
Receive the proof of payment of institutional fee (deposited in the ICH Trust Fund) with the submitted protocol ↓	IEC Secretariat Staff
Classify submission as expedited or full Committee review ↓	IEC Chair
Send study protocol package to members with **IEC- ICH Form 3-A1: *Review Checklist for Initial Trial Application*;** **IEC – ICH Form 3-B: *Registration and Application Form;*** **IEC- ICH Form 3-C: *Study Protocol Assessment Form;*** and **IEC- ICH Form 3-D: *Informed Consent Assessment Form***	IEC Secretariat Staff

↓		
Review the protocol and return accomplished **IEC- ICH Form 3-C: *Study Protocol Assessment Form*** and **IEC - ICH Form 3-D: *Informed Consent Assessment Form*** to the Secretariat Staff ↓		Members (Reviewers)
FULL COMMITTEE REVIEW	**EXPEDITED REVIEW**	
Include the protocol in the agenda of the next full Committee meeting ↓		Secretariat Staff
Deliberates on Committee action on the protocol ↓		IEC 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 IEC 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 a clinical trial. It is created to protect the well-being of the participants and to establish the intent of the clinical trial 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 medications and dosages 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 **IEC- ICH Form 3-A: *Review Checklist***.

iii. The Secretariat Staff ensures completeness of submitted forms and documents using the above checklist. All research proposal documents including necessary forms, annexures etc. are to be submitted to the official email ID of IEC-ICH in proper format. If possible **one (2) hard copies** need to be submitted for office records, which can be submitted at a later date. These need to be submitted **at least 10 days** prior to the scheduled meeting date

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 **IEC- ICH Form 3-A: *Review Checklist*** 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 IEC/nnn/yyyy using **IEC-ICH Form 5-N: *Submission Log***.

vii. Payment of the institutional fee 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 of the clinical trial) to the IEC 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-IEC.

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
- ☐ Resubmission of Protocols with corrections
- ☐ Protocol Amendment
- ☐ Continuing Review of Approved Protocols
- ☐ Protocol Termination

ii. The ICH-IEC 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 anonymized or archived samples.
- ☐ Continuing review of clinical trials 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.

c. Initial 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 meetings are included in the agenda.*

ii. Reviewers accomplish **IEC- ICH Form 3-C: *Study Protocol Assessment Form*** and **IEC-ICH Form 3-D: *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 II-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 **IEC- ICH Form 3-C: *Study Protocol Assessment Form*** and **IEC-ICH Form 3-D: *Informed 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 2017; National Ethical Guidelines for Biomedical Research involving Children, ICMR 2017 and NDCT rule 2019 regarding the following matters:

d. Study Protocol Review

1. It is acknowledged that some populations require special protection because of characteristics or situations that render them vulnerable. Research on 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 Xray vis a vis multiple Xrays 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 clinical trials)

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 participants 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.

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 – 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 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 IEC
- Expected duration of the Subject's participation and total number of participants 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 trials)
- Statement describing the financial compensation and medical management as under:
  - In case of any injury occurring to the subject during the clinical trial, 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 clinical trial; whichever is earlier
  - In the event of a trial related injury or death, the Sponsor or his representative, whosoever has obtained permission from the licensing authority for conduct of the clinical trial, shall provide financial compensation for the injury or death
- An explanation about whom to contact for trial related queries in the event of any injury and rights of Participants.
- The anticipated prorated payment, if any, to the Subject for participating in the trial. In particular IEC review payments to determine that:

- The amount of payment and the proposed method and timing of disbursement neither is coercive nor presents undue influence.
- In case any amount paid as a bonus for completion is reasonable and not so large as to unduly induce participants to stay in the study when they would otherwise have withdrawn.
- A description of acceptable and unacceptable payment arrangements for the sponsor, organization, researcher, and those referring research participants, if applicable:
- Address the acceptability of payments in exchange for referrals of prospective participants ("finder's fees" or "referral fees").
- Address payments designed to accelerate recruitment that are tied to the rate or timing of enrolment ("bonus payments").

- Subject's responsibilities on participation in the trial
- 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
- Statement that there is a possibility of failure of investigational product to provide the intended therapeutic effect
- 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.
- 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 Participants 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 is needed for the procedure in the presence of the witness.

Fresh or re-consent is taken in following conditions:

- Availability of new information which would necessitate deviation of protocol.
- 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.
- 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 surrogates consent 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.

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 (CDSCO; July 31, 2015 [G. S. R. 611(E)]). However, IEC will have the discretionary power to exercise A-V consenting in trials 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

- 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 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 behavioural 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

- Recruitment should be voluntary and non-coercive.

- The characteristics of the population from which the research participants will be drawn (including gender, age, literacy, culture, economic status, and ethnicity)
- Vulnerable groups may be recruited after proper justification is provided
- 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.
- students or staff recruitment in research
- recruitment of healthy volunteers.
- 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.
- 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.

J. Advertisements

The IEC reviews advertising to ensure that advertisements do not:

- State or imply a certainty of favourable 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 judgement. No undue inducement must be offered.
- Protocols should provide IECs 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 IEC.
- IEC 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.
- When children are enrolled into drug trials which come under the ambit of DCGI, all rules/guidelines pertaining to regulatory trials apply.
- 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 should examine the processes that are put in place to safeguard participants' privacy and confidentiality.
- Research records to be filed separately than routine clinical records such as in a hospital setting.

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

N. Post trial 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 participants 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 participants after their study participation.

O. 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 [Institute's Clinical Research Center];
- 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 and discharge from the Clinical Research Center. If discharge would jeopardize your health, you have the right to remain under Clinical Research Center care until discharge or transfer is medically advisable;
- To be transferred to another facility when your participation in the Clinical Research Center study is terminated;
- To expect that a medical summary from the Clinical Research Center 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 trial.
- 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 trial at any time without prejudice or loss of future treatment. (Participation is totally voluntary. However, you should intend on completing the trial before enrolling.)
- Ask questions at any time concerning the study drug.
- 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 a research 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 IRB/Ethics Committee at the telephone number in the consent form.
- **Visits, Medications and Records.** To the best of my ability, Iwill 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.

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 IEC 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-IEC.

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 V-8: *Archived (Inactive/Completed/Terminated) Files***

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

xiv. In the event that a PI or the Sponsor decides not to continue the conduct of a clinical trial which has been approved by the IEC, the PI must write a letter stating the reason for the decision and submission of accomplished **IEC- ICH Form 4-F: *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 clinical trial 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 V-8: Archived (Inactive/ Completed/ Terminated) files.

xv. In the event that PI has to resubmit, the following workflow is performed:

e. REVIEW WORKFLOW FOR RESUBMISSION ACTIVITY	RESPONSIBILITY
Receive and manage study protocol resubmissions ↓	IEC Secretariat Staff

Classify submission as expedited or full Committee review ↓		IEC Chair
FULL COMMITTEE REVIEW	**EXPEDITED REVIEW**	
Send study protocol resubmission to Members with □□**IEC- ICH Form 3-A.2: *Review Checklist for Resubmission and Amendment*** □□**IEC- ICH Form 3-F: *Review of Resubmitted Protocol Form*** ↓	Send study protocol resubmission to Chair with □□**IEC - ICH Form 3-A.2: *Review Checklist for Resubmission* and *Amendment*** □□**IEC-ICH Form 3-F: *Review of Resubmitted Protocol Form*** ↓	IEC Secretariat Staff
Review the protocol and return accomplished **IEC –ICH Form 3-F: *Review of Resubmitted Protocol Form*** to the Secretariat Staff ↓		Reviewers/ Chair
Include the protocol in the agenda of the next full Committee meeting ↓		Secretariat Staff
Discuss review findings during full Committee meeting ↓		IEC Members
Deliberates on Committee action on the protocol ↓		IEC Members
1) If approved: send approval letter to P.I. **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 P.I.		Secretariat Staff
	Include in the agenda of the next IEC meeting under the Expedited Review ↓	Secretariat Staff
	Present review findings during full Committee meeting	Chair

5. FULL COMMITTEE MEETING WORKFLOW

ACTIVITY	RESPONSIBILITY
Set regular meeting schedule ↓	IEC Chair and Members/ Secretariat Staff
Distribute meeting agenda	IEC Secretariat Staff

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

5. DETAILED INSTRUCTIONS FOR MEETING SCHEDULE

a. Regular Meeting Schedule

i. The ICH-IEC will have its regular meeting once every two months. The meeting, however, for the last two (2) months of the year 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, 6 meetings per year i.e. once in 2 months are planned. However, frequency of meetings maybe altered at the discretion of Chairperson and/or Member Secretary. Emergency meetings may be 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 limit is placed on the number of items on the agenda. The number of items is based on available expertise (members and consultants), urgency, order of submission to the IEC and IEC workload.

ii. In addition, the IEC administrator will check the agenda prior to the meeting to identify IEC 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 IEC member who has a conflict of interest with regard to a research project that will be reviewed at a convened IEC meeting must notify the IEC office of the conflict prior to the meeting. Once the IEC office receives notice of recuse, the IEC Member Secretary will seek an alternate IEC 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 **IEC – ICH Form 3-E: *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.

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 IEC members by hand or by courier of hard copies and CD/ e-dossier (soft copy) 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 IEC member to verify items of the parcel on receipt and in case of any missing items, intimate the IEC office immediately so that the relevant documents could be made available to the members before the meeting

iv. It is the responsibility of the IEC member to identify any conflict of interest and notify the IEC 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 (**IEC-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 V-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 IEC Members must bring all meeting-related materials sent to them to serve as their reference during the review.

iv. IEC meetings will be conducted on an electronic meeting platform such as Zoom, Webex, Google meet etc. IEC Secretariat will organize the e-meeting. Members will be briefed about the technological requirements necessary. Meeting will be held for a maximum of 90 minutes duration. Agenda will be short and circulated by mail prior to meeting. The frequency of meeting may be increased on a need basis. Meeting ID and password will be communicated to the members 1 hour before the meeting. E-attendance will be recorded by Member secretary and once quorum is fulfilled discussions will ensue.

e. Determination of Quorum

i. For studies which require the approval of CDSCO, quorum is defined as the presence of at least 7 members with the following representation as per NDCT rule 2019 from medical, non-medical, scientific and non-scientific areas with at least-.

- One Lay person from the community
- One woman member
- One Legal Expert
- One independent member from any other field such as social scientist or representative of non-governmental voluntary agency or philosopher or ethcist or theologian
- Clinician
- Social scientist/ representatives of NGO/ Philosopher/ Ethicist/ Theologian or similar person
- Basic medical scientist (preferably pharamocologist)

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

iii. On the appointed meeting time, the IEC Secretary determines quorum viability and informs the IEC 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 IEC Chair, or a designated IEC member in the Chair's absence, calls the meeting to order upon confirmation of quorum by the IEC Secretary. E-Meeting may be digitally recorded with the permission of members. Opening and closing time will be noted.

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

iii. The Secretary documents the proceedings of the meeting, as soon as the meeting is called to order by the IEC 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 V-4: *Minutes of the Meeting.***

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

v. The IEC 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 IEC 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 IEC 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 IEC 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 IEC 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 IEC Chair then declares approval of the Minutes of the previous meeting.

vii. The IEC 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 IEC 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 IEC 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 IEC members who have declared COI be allowed to participate in the decision. For e-meeting-they will declare COI on e-mail which will be kept as record.

iv. For initial review, the IEC Chair calls the reviewers to discuss findings on respective study protocols based on study protocol assessment points specified in **IEC - ICH Form 3-C: *Study Protocol Assessment Form*** and elements detailed **IEC- ICH Form 3-D: *Informed Consent Assessment Form***. The scientific, ethical & legal issues are also used. For online meetings opinions of members are taken and a final decision is recorded by member secretary on form **IEC - ICH Form 3-C: *Study Protocol Assessment Form*** & **IEC- ICH Form 3-D: *Informed Consent Assessment Form.***

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

vi. For review of resubmissions, the IEC Chair discuss with members on the response of the PI to the previous recommendations of the Committee summarized in the **IEC-ICH Form 3-F: *Review of Resubmitted Study Protocol***.

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

- **Approval**

Records will be maintained electronically in the time period

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

viii. If the Chair feels that the present IEC 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 IEC may request comments or clarificatory interview from the PI at another meeting.

ix. The ICH-IEC may allow investigators and other resource persons (such as an independent consultant commissioned by the IEC) of highly specialized areas to attend the part of the IEC 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.

Communication of decision and maintaining records: All communications with Head of Institute, Regulatory bodies, Investigators, Participants etc. will be made through telephone and/or e-mail. Decision letters will be scanned and mailed to the designated PIs' email Id. E-signatures will be used wherever needed.

h. Conduct of Clarificatory Interview

i. If needed, the IEC 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 **IEC - 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 IEC must sign **IEC-ICH Form 3-G: *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 IEC Chair calls for action depending on the type of submission (see **SOP II-4b)** Decisions are based on the IEC's assessment of the PI's response to their queries.

i. Discussion of Post-Approval Submissions

i. The IEC Chair presents, if any, ***Study Protocol Amendment Submission Form*** **(IEC-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 IV-4: *Study Protocol Amendment***. The IEC 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 IEC Chair presents, if any, submissions for Continuing Review of study protocols previously approved through full Committee and any ***Continuing Review Applications Forms*** **(IEC-ICH Form 4-C)** or **Progress Report (IEC-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 IV-4: Continuing Review Application***. The IEC Chair calls for any of the following actions:

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

iii. The IEC Chair presents, if any, ***Final Report Forms*** **(IEC-ICH 4-D)** of completed studies. For details on how Final Reports are processed, refer to **SOP IV-4: *Final Reports***. The IEC 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

iv. The IEC presents, if any, report on ***Serious Adverse Events*** *(SAEs)* submitted by PI's. If there are serious issues related to the report of the adverse events in studies involving already marketed drugs, such reports will be transmitted to obtain experts opinion for information and appropriate action. The details on how Serious Adverse Events Reports are processed are detailed in **SOP IV-4: *Serious Adverse Event Reports***. The IEC Chair then calls on the IEC members to deliberate on the matter and decide on appropriate action such as:

- Uphold original approval with no further action
- Recommend further action
- Forward to obtain experts' opinion

v. The IEC Chair, presents, if any, reports on **Site Visits (IEC –ICH Form 4-G: *Checklist for Site Visit*)**. For details on how Site Visits are conducted and reported, refer to **SOP IV-6: *Site Visit***. The IEC Chair calls on the IEC Members to recommend any of the following action:

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

vi. The IEC Chair presents, if any, ***Study Protocol Deviation or Non-Compliance Report*** **(IEC –ICH 4-E)** of study protocols previously approved through full Committee. Noncompliance may be in the form of noncompliance with post-approval requirements. For details on how Study Protocol Non-Compliance (Deviation or Violation) Records are processed, refer to **SOP IV-4: *Study Protocol Non-Compliance (Deviation or Violation) Report***. The IEC Chair calls on the IEC Members to recommend any of the following actions:

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

vii. The IEC Chair presents, if any, ***Early Study Termination Application Forms*** **(IEC -ICH Form 4-F)** of study protocols previously approved through full Committee. For details on how Early Study Termination Applications are processed, refer to **SOP IV-4: *Early Study***

Termination Application. The IEC Chair calls on the IEC Members to recommend any of the following actions:

- Approval
- Request information
- Recommend further action

viii. The IEC Chair presents, if any, ***Study Participant Queries or Complaints*** (IEC-ICH 4-J). For details on how queries are processed, refer to **SOP IV-4: *Study Participant Queries or Complaints***. The IEC Chair calls on the IEC Members to recommend any of the following actions:

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

j. Review of Results of Expedited Review

i. The IEC 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 III-4**).

k. Discussion of Other Matters: Before closing the meeting, the IEC 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 IEC 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-IEC 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 IEC Chair as he determines the need for such or as it may be proposed by majority of the IEC 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 IEC 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 III-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-IEC Form 3-A1	Review Checklist for Initial Review Application
ICH-IEC Form 3-A2	Review Checklist for Resubmission and Amendment
ICH-IEC Form 3-B	Registration and Application Form
ICH-IEC Form 3-C	Study Protocol Assessment Form
ICH-IEC Form 3-D	Informed Consent Assessment Form
ICH-IEC Form 3-E	Meeting Agenda
ICH-IEC Form 3-F	Review of Resubmitted Study Protocol Form
ICH-IEC Form 3-G	Confidentiality Agreement for Guests or Observers

REVIEW CHECKLIST FOR INITIAL TRIAL APPLICATION

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.*

STUDY PROTOCOL INFORMATION

IEC-ICH Study No.	*(By IEC Secretariat)*	
Study Protocol Title		
Study Protocol Code		
Principal Investigator		Signature:
Date of Submission		
Verified Complete By		

TO THE IEC SECRETARIAT: *CHECK FOR COMPLETENESS UPON SUBMISSION. INDICATE WITH (√) MARK ON THE TICK BOXES, IF APPLICABLE*

Basic Documents (*must submit*)		
	No. of Copies	**Document Submitted**
☐	2	Application Letter to Chairperson-IEC
☐	2	Review Checklist (**IEC- ICH Form 3-A.1**)
☐	2	Printed Registration and Application Form (**IEC-ICH Form 3-B**)
☐	2	Completed Study Protocol Assessment Form (**IEC-ICH Form 3-C**)
☐	2	Completed Informed Consent Assessment Form (**IEC-ICH Form 3-D**) *[Include detailed procedure of obtaining informed consent (who, when, where & how)]*
☐	2	Study Protocol with Synopsis
☐	2	Liability insurance for clinical trial protocols
☐	2	DCGI approval or application/ FSSAI approval/ Any Other
☐	2	Investigator Undertaking, Curriculum Vitae and photocopy of Good Clinical Practice certificate of Principal Investigator and study team members
Study-Specific Documents (*submit as needed*)		
☐	2	Investigator's Brochure (for clinical trials phase I, II, III) or Basic Product Information Document (for clinical trials phase IV)
☐	2	Informed consent form in English (for studies with human participants)
☐	2	Informed consent form in local language (for studies with human participants) ☐Hindi ☐Bengali
☐	2	Audio Visual consent form in English (for studies involving new drug as per Rule 122DA of the Drugs and Cosmetic Rules, 1945)
☐	2	Audio Visual consent form in local language (for studies involving new drug as per Rule 122DA of the Drugs and Cosmetic Rules, 1945) ☐Hindi ☐Bengali
☐	2	Assent form in English (for studies involving minors and relevant populations deemed incompetent to sign an informed consent form)
☐	2	Assent form in local language (for studies involving minors and relevant populations deemed incompetent to sign an informed consent form) ☐Hindi ☐Bengali
☐	2	Data collection forms (including CRFs)
☐	2	Recruitment procedures & advertisements (as needed by the study protocol)
☐	2	Other information or documents for participants (such as diaries, questionnaires, etc.)
☐	2	Authorization from Director, ICH if accessing ICH medical records
☐	2	Clinical Trial Agreement (Tripartite)
☐	2	Laboratory Name, Address, Certificates, SOPs and Reference Material
☐	2	Any other study related material to be used in the conduct of clinical trial
Photocopy of Cheque/NEFT details (Institutional fee payment)		
Kindly provide CD or send a soft copy of the Protocol and other related documents attached (e.g. IEC Forms, Informed Consent, Case Report Form and Investigator's Brochure or Journal Reports, Literature Review for Trainees, Cover Letter etc.) to instecich@gmail.com		

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

REVIEW CHECKLIST FOR RESUBMISSION AND AMENDMENTS

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*

STUDY PROTOCOL INFORMATION

IEC-ICH Study No.		
Study Protocol Title		
Protocol No.		
Principal Investigator		Signature of PI:
Date of Initial Approval *(for amendment)*		☐ Resubmission ☐ Amendment
Date of Submission		
Verified Complete By		

TO THE IEC SECRETARIAT: *CHECK FOR COMPLETENESS UPON SUBMISSION. INDICATE WITH (√) MARK ON THE TICK BOXES, IF APPLICABLE*

	NO. OF COPIES	DOCUMENT SUBMITTED
For resubmission:		
☐	11	Review Checklist for Resubmission or Amendment (**IEC-ICH 3-A2**) – for resubmission
☐	11	Completed Registration and Application Form (**IEC-ICH Form 3-B**) – for resubmission
☐	11	Completed Review of Resubmitted Study Protocol Form (**IEC-ICH Form 3-F**) – for resubmission of new clinical trial or amendment to study protocol, ICF, Patient materials etc.
☐	11	Resubmitted Documents (Study Protocol, Informed Consent Forms, etc.) *Highlight the changes made (Letters in bold and/or underlined)*
For submission of Amendment(s)		
☐	11	Completed Study Protocol Amendment Form (**IEC-ICH Form 4-A**) – for amendment
☐	11	Completed Additional Study Materials for Approval Form **(IEC-ICH Form 4-K)** *Highlight the changes made (Letters in bold and/or underlined)* – for amendment
☐	11	Protocol Amendments (Study Protocol, Informed Consent Forms, Patient Materials, etc.) *Highlight the changes made (Letters in bold and/or underlined)*
☐	01	CD or DVD copy of all documents attached or send a soft copy through email
Photocopy of Cheque (Institutional fee payment)		

**Notes:*

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

2) Make sure that the changes or amendments are highlighted (letters in bold or underlined)

REGISTRATION AND APPLICATION FORM

SECTION I: Application Information	
1. **Study No.**	IEC/
2. **Study Protocol Title**	
3. **Type of Submission**	☐ 2.1. Initial Review ☐ 2.2. Resubmission (responses to initial review recommendations or submission of studies with investigator-initiated changes prior to ethics approval). ***NOTE*: version and date of version must be inserted as a document footer for all resubmissions**
4. **Date of Submission**	
5. **Type of Study**	☐ **5.1. Clinical Trial** ☐ 5.1.1. Drug/ Vaccines ☐ 5.1.2. Device ☐ 5.2.3. Others ☐ **5.2. Non-clinical trial, Specify:** _____ (diagnostics, herbal research, review of medical records, epidemiologic research, health informatics, etc) ☐ 5.2.1. Diagnostics ☐ 5.2.2. Herbal research ☐ 5.2.3. Complementary and alternative medicine research ☐ 5.2.4. Review of medical records ☐ 5.2.5. Epidemiology study ☐ 5.2.6. Socio-behavioural research ☐ 5.2.7. Genetic studies, Recombinant/ Gene therapy ☐ 5.2.8. Bio-banking ☐ 5.2.9. Stem Cell research ☐ 5.2.10. Research with body fluids/ organs/ tissue ☐ **5.3. Pre-clinical Research** **Others (specify):** _____ ☐ **5.3. Clinical Trial Phase** (drug or pharmaceutical trials, diagnostic trials, trials on devices, and other therapy trials) **intended for marketing registration** **(Indicate Phase** : _____) Is it placebo controlled trial? Yes No ☐ **5.4. Academic Investigator Initiated Clinical Trial** (drug or pharmaceutical trials, diagnostic trials, trials on devices, and other therapy trials) **NOT intended for marketing registration** **(Indicate Phase** : _____) ☐ **5.5. Post Marketing Surveillance**
6. **Category of Investigator**	☐ 6.1. ICH Physician, Full-time ☐ 6.2. ICH Physician, Part-time or Visiting ☐ 6.3. ICH Training Fellow or Resident

REGISTRATION AND APPLICATION FORM

	☐ 6.4. Other ICH employees, please specify _____
7. Purpose of study	☐7.1. Academic requirement (Thesis, Dissertation, Training Requirement) ☐7.2. Sponsored clinical trial ☐7.3. Multi-institutional or multi-country collaboration ☐7.4.Others (indicate):_____
8. Study Protocol Synopsis	Please write synopsis (maximum 500 words) of the study in the space provided below based on the specific components, and indicate page where such components may be found in the full study protocol or in annexes/ appendices. If items are not applicable, indicate by N/A. Attach the full study protocol to this application.
9. Study Duration	
10. Study Site	Single centre: Multicentre: Collaboration with other institute:
11. Approvals	☐DCGI (Clinical Trial; Samples to be tested abroad) ☐ FSSAI (Probiotics/ Nutraceuticals etc) ☐ GEAC (Genetic Engineering, Recombinant DNA etc) ☐ DBT (Genetic Engineering, Recombinant DNA etc) ☐ BARC (Ionizing radiations, Radioactive isotopes etc) ☐ HMSC (Foreign Collaborations) ☐ NOC from HEAD OF INSTITUTE (access to medical records, infrastructure of host institute) ☐ MOU/NOC with HEAD of COLLABORATIVE INSTITUTES (for work in collaboration with other centers)
12. Use of special populations or vulnerable groups	Recruitment from ICH: ☐ **YES** ☐ **NO** **If NO: specify site:** _____ Number of participants with age range (study): Number of participants with age range (recruited at site): ☐ 11.1. Children (under 18) ☐ 11.2. Neonates ☐ 11.3. Adolescents ☐ 11.4. Children with HIV ☐ 11.5. Children from low socio-economic background ☐ 11.6. Patients in emergency/ ICU care ☐ 11.7. Children – Homeless/ in Orphanages/ Juvenile Remand ☐ 11.8. Children of Refugees or displaced persons ☐ 11.9. Patients with incurable diseases ☐ 11.10. Others (indicate) ☐ 11.11. Healthy controls (volunteers)
13. Funding Agency	Name:
	Type of Funding Agency: Sponsor/ CRO Information

REGISTRATION AND APPLICATION FORM

	Total Budget: PI fees: Institutional Fees:
14. Investigational Product	☐ 13.1.Drug ☐ 13.2.Vaccines ☐ 13.3.Device ☐ 13.4.Others (specify): **Is it approved and marketed:** ☐ 13.5.In India ☐ 13.6.EU ☐ 13.7.USA ☐ 13.8.Other countries (specify): **Is it a New Drug? (Rule 122DA)** ☐ Yes ☐ No **Does it involve a change in indication, dose, dosage form, route of administration?** ☐ Yes ☐ No
15. Principal Investigator	
16. PI Business Address	
17. PI Telephone/Fax Nos.	
18. PI Mobile No.	
19. PI Email Address	
20. Declaration on Conflict of Interest for PI	☐18.1. I have no conflict of interest in any form (financial, proprietary, professional) with sponsor, the study, Co-Investigator, or the site ☐18.2. I have personal/family financial interest in the results of the study Nature: ☐18.3. I have proprietary interest in the research (patent, trademark, copyright, licensing) Nature:

21. Other investigators with corresponding task description *(add additional rows as applicable)*	Name	Contact Nos.	E-mail Address
	Co-Investigator:		
	Co-Investigator:		
	Study Coordinator:		

22. Submitted by		
	Study designation	
23. PI Signature		

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

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 **IEC 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 IEC 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 "IEC REVIEWER COMMENTS". Please finalize your review/evaluation by indicating your conclusions under "RECOMMENDED ACTION" and signing in the space provided for the primary reviewer.

ESSENTIAL ELEMENTS	To be filled out by the PRINCIPAL INVESTIGATOR			To be filled out by the IEC 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)

MEETING AGENDA

Date: <dd/mm/yyyy>

NOTICE OF MEETING

TO: **<Name of IEC-ICH> Members:**
Name 1
Name 2
Name 3
Name 4
Name 5
Name 6
Name 7
Name 8

Date of Meeting
Time of Meeting
Venue of Meeting

AGENDA:

1. Call to order
2. Determination of quorum and presence of non-institutional members
3. Conflict of interest disclosure
4. Reading and approval of the Minutes of the last meeting
5. Business arising from the Minutes
6. Protocol review

6.1. FULL REVIEW

6.1.1. Study Protocols for Initial Review

Control No.	
Study Protocol Submission Date	<dd/mm/yyyy>
Title	
Name of PI	
Sponsor	
Type of Review	
Primary Reviewers	

6.1.2. Resubmission or Study Protocols for Modification

Control No.	
Study Protocol Submission Date	<dd/mm/yyyy>
Title	
Name of PI	
Sponsor	
Type of Review	
Primary Reviewers	

6.1.3. Study Protocols for Clarificatory Interview

Control No.	
Study Protocol Submission Date	<dd/mm/yyyy>

Title	
Name of PI	
Sponsor	
Type of Review	
Primary Reviewers	

6.1.4. Application for Protocol Withdrawal

Control No.	
Study Protocol Submission Date	<dd/mm/yyyy>
Withdrawal Application Date	<dd/mm/yyyy>
Title	
Name of PI	
Sponsor	
Type of Review	
Primary Reviewers	

6.1.5. Study Protocol Amendments Applications

Control No.	
Study Protocol Approval Date	<dd/mm/yyyy>
Amendment Submission Date	<dd/mm/yyyy>
Title	
Name of PI	
Sponsor	
Type of Review	
Primary Reviewers	

6.1.6. Continuing Review Applications

Control No.	
Study Protocol Approval Date	<dd/mm/yyyy>
Application Date	<dd/mm/yyyy>
Title	
Name of PI	
Sponsor	
Type of Review	
Primary Reviewers	

6.1.7. Final Reports

Control No.	
Study Protocol Approval Date	<dd/mm/yyyy>
Report Date	<dd/mm/yyyy>
Title	
Name of PI	
Sponsor	
Type of Review	
Primary Reviewers	

6.1.8. SAE and Similar Reports (e.g. SUSAR)

Control No.	
Study Protocol Approval Date	<dd/mm/yyyy>

Report Date	<dd/mm/yyyy> (Organize SAEs under one protocol by date)
Title	
Name of PI	
Sponsor	
Type of Review	
Primary Reviewers	

6.1.9. Site Visit Reports:

Control No.	
Study Protocol Approval Date	<dd/mm/yyyy>
Site Visit Date	<dd/mm/yyyy>
Title	
Name of PI	
Sponsor	
Type of Review	
Primary Reviewers	

6.1.10. Protocol Non-Compliance (Deviation or Violation Reports)

Control No.	
Study Protocol Approval Date	<dd/mm/yyyy>
Report Date	<dd/mm/yyyy>
Title	
Name of PI	
Sponsor	
Type of Review	
Primary Reviewers	

6.1.11. Early Termination Application

Control No.	
Study Protocol Approval Date	<dd/mm/yyyy>
Application Date	<dd/mm/yyyy>
Title	
Name of PI	
Sponsor	
Type of Review	
Primary Reviewers	

6.1.12. Study Queries, Complaints, or Grievance Reports

Control No.	
Study Protocol Approval Date	<dd/mm/yyyy>
Report Date	<dd/mm/yyyy>
Title	
Name of PI	
Sponsor	
Type of Review	
Primary Reviewers	

6.2. REPORT OF PROTOCOL SUBMISSIONS FOR EXPEDITED REVIEW

6.2.1. Approved Protocols

Control No.	
Study Protocol Approval Date	<dd/mm/yyyy>
Study Protocol Submission Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Sponsor	
ACTION	

6.2.2. Study Protocols for Initial Review

Control No.	
Study Protocol Submission Date	<dd/mm/yyyy>
Title	
Name of PI	
Sponsor	
Type of Review	
Primary Reviewers	
ACTION	

6.2.3. Study Protocols for Modification (or Resubmissions)

Control No.	
Study Protocol Submission Date	<dd/mm/yyyy>
Title	
Name of PI	
Sponsor	
Type of Review	
Primary Reviewers	
ACTION	

6.2.4. Study Protocol Amendments

Control No.	
Study Protocol Approval Date	<dd/mm/yyyy>
Amendment Submission Date	<dd/mm/yyyy>
Title	
Name of PI	
Sponsor	
Type of Review	
Primary Reviewers	
ACTION	

6.2.5. Continuing Review Application

Control No.	
Study Protocol Approval Date	<dd/mm/yyyy>
Application Date	<dd/mm/yyyy>
Title	
Name of PI	
Sponsor	

Type of Review	
Primary Reviewers	
ACTION	

6.2.6. Final Reports

Control No.	
Study Protocol Approval Date	<dd/mm/yyyy>
Report Date	
Title	
Name of PI	
Sponsor	
Type of Review	
Primary Reviewers	
ACTION	

6.2.7. Protocol Deviation/Non-Compliance/Violation Reports

Control No.	
Study Protocol Approval Date	<dd/mm/yyyy>
Report Date	<dd/mm/yyyy>
Title	
Name of PI	
Sponsor	
Type of Review	
Primary Reviewers	
ACTION	

6.2.8. Early Study Termination Applications

Control No.	
Study Protocol Approval Date	<dd/mm/yyyy>
Application Date	<dd/mm/yyyy>
Title	
Name of PI	
Sponsor	
Type of Review	
Primary Reviewers	
ACTION	

7. Other Matters

8. Adjournment

<TITLE, NAME, SURNAME> and SIGNATURE
Chair, IEC-ICH

Review of Resubmitted Study Protocol Form

INSTRUCTIONS:

To the **PRINCIPAL INVESTIGATOR (PI):** *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 for Principal Investigator the **IEC-ICH query** and your **RESPONSE** to the comment.

To the **IEC REVIEWER**: Please evaluate if the recommendations by the IEC-ICH were appropriately addressed by confirming the submitted information and putting your comments In the space provided for IEC REVIEWER. Please finalize your review/evaluation by indicating your conclusions under "RECOMMENDED ACTION" and signing in the space provided for the primary reviewer.

STUDY PROTOCOL INFORMATION

Study No.					
Study Protocol Title					
Principal Investigator		Signature:			
Date of Resubmission					
Initial Review Date:	2ND Review Date:	LAST Review Date:			
To be filled out by the PRINCIPAL INVESTIGATOR		**To be filled out by the IEC REVIEWER** Were the recommendations met?			
Recommendations from last review of IEC and Response from Principal Investigator (PI)	Indicate page and paragraph where it is found	YES	NO	COMMENT	
A. On the technical aspects of the study protocol: 1. <IEC-ICH query 1> <**Response** from PI:> 2. <IEC-ICH query 2> <**Response** from PI:> 3. <IEC-ICH query 3> <**Response** from PI:> *B. On the ethical aspects of the study protocol:* 1. <IEC-ICH query 1:> <**Response** from PI> 2. <IEC-ICH query 2> <**Response** from PI:> *C. On the informed consent form:* 1. <IEC-ICH query 1> <**Response** from PI:>					

Review of Resubmitted Study Protocol Form

2. <IEC-ICH query 2> <**Response** from PI:>				

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

To be filled out by the PRIMARY REVIEWER

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 PRIMARY REVIEWER	SIGNATURE:	Date:(dd/mmm/yyyy)

Confidentiality Agreement for Guests/Observers

I, _____, understand that I am allowed to attend the IEC-ICH meeting and to have supervised access to the IEC-ICH files as a/an (Guest/Observer) _____. In the course of the meeting of the IEC-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 IEC-ICH Meeting : _____

Purpose of attendance/access

: _____

_____

_____

_____

IEC SECRETARY	Name & Signature _____ Date
IEC CHAIR	Name & Signature _____ Date

Post Approval Review
SOP Code: SOP 04/V6

Reviewed By

Name and Position in IEC	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	
Dr. Sabnam Ara Begum Basic Medical Scientist; Clinical Pharmacologist	
Mr. Tamal Chatterjee Legal expert	
Ms. Anasuya Basu Layperson	
Ms. Kaberi Mukherjee Theologian	

Approved By

Name and Position in IEC	Signature
Dr. Phalguni Dutta Chairperson	

Accepted By

Name and Position in ICH	Signature
Prof. Apurba Ghosh Executive Director	

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Supersedes	05
Version	06
Authored By	SOP Team
Version Date	17 September 2022
Approved By	Dr. Phalguni Dutta
Effective Date	05 December 2022

1. OBJECTIVES

This SOP describes how the ICH-IEC 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 trial participants. IEC members are responsible for reviewing these post-approval submissions related to study protocols for which they are members.

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 IEC 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 PARTICIPANTT 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 IEC Chair to determine classification of review as expedited or full board ↓	Secretariat Staff
IEC Chair, Members reviews submissions classified as expedited review (Expedited Review at the level of the Chair) ↓	IEC Chair AND Members Secretary /Reviewers
Review full board study protocols in *IEC* 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-IEC before an amendment can be implemented in the conduct of a study.

2. A study protocol amendment is facilitated through the submission of **IEC-ICH Form 4-A: *Study Protocol Amendment Submission Form*/IEC-ICH Form 4-K: *Additional Study Material for Approval Form*** with the amended study protocol and/or protocol-related documents by the principal investigator to the ICH-*IEC*, 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*** **(IEC-*ICH* Form 5-N)**.

4. The Secretariat Staff checks the submission for completeness and gives a receiving copy of **IEC-*ICH* Form 4-A: *Study Protocol Amendment***

Submission Form/IEC-ICH* Form 4-K: *Additional Study Materials for Approval Form to the PI or his/her representative.

5. The Secretariat Staff ensures that sufficient copies (including CD/ e-dossier) for the IEC Members have been submitted by the PI for full board submissions.

ii. Classification of Review by the IEC Chair

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

2. A full board review is necessary if the proposed study protocol amendment increases risk to study participants, as assessed by the *IEC* Chair, such as a change in study design, which may include but is not limited to:

   - Additional treatments or the deletion of treatments
   - Any changes in inclusion/exclusion criteria
   - Change in method of dosage formulation, (e.g. oral changes to intravenous)
   - Significant change in the number of participants
   - Significant decrease or increase in dosage amounts

iii. Review by IEC Chair

1. For submission under expedited review, action is finalized at the level of the *IEC* Chair within fifteen (15) calendar days.

2. Study protocol amendment packages/including soft copy participant to full board review received within the cut-off period of twenty (20) days before the *IEC* meeting are sent to members ten (10) days before the *IEC* meeting.

3. The Secretariat Staff places the study protocol amendment request on the agenda for the next *IEC* meeting.

4. The Reviewers accomplish the review and return the signed **IEC-*ICH* Form 4-A: *Study Protocol Amendment Submission Form*/ IEC-*ICH* Form 4-K: *Additional Material for Study Use for Approval Form*** on the day of the *IEC* meeting together with the Study Protocol Amendment Package. For online meetings opinions of members are taken and a final decision is recorded by member secretary on form **IEC-*ICH* Form 4-A: *Study Protocol Amendment Submission Form*/ IEC-*ICH* Form 4-K: *Additional Material for Study Use for Approval Form.***

Additional Material for Study Use for Approval Form on the day of the *IEC* meeting together with the Study Protocol Amendment Package.

iv. Full board review of Study Protocol Amendment Submission Package

1. The Secretariat Staff distributes the following Study Protocol Amendment Package to *IEC* Members along with the meeting agenda:
   - **IEC-*ICH* Form 4-A: *Study Protocol Amendment Submission Form*/IEC-*ICH* Form 4-K: *Additional Study Materials for Approval Form***
   - Amended study protocol or protocol-related documents with amended section clearly indicated
   - Other documents that have been affected by the revision
2. The documents are presented to *IEC* Members when amendments are deliberated on. For detailed information on the conduct of full board review of study protocol amendments, see SOP III, section 5.0

v. Communication of results

1. The PI is notified of the ICH-*IEC* decision noting which amended documents are approved for use through an action letter.
2. The PI may be required to modify or clarify the amendment, provide additional information, or submit additional documents.
3. If the amendment is approved, the PI is requested to submit an amended study protocol or protocol-related document with a new version number and date, if such has not been included in the Study Protocol Amendment Package yet.

vi. Files management

1. The Secretariat Staff receives the amended study protocol or protocol-related documents with a new version number and date and marks it as **"approved"**, then affixes the approval date.
2. The newly approved documents will supersede previous versions of the study protocol or protocol related document.
3. The *IEC* Secretary and *IEC* Chair sign **IEC-*ICH* Form 4-A:*Study Protocol Amendment Submission Form*/ IEC-*ICH* Form 4-K: *Additional Material for Study Use for Approval Form***
4. The Secretariat Staff stores the signed and approved documents in the study protocol folder/binder.

b. Continuing Review Application/Progress Report

i. Receipt and management of the Continuing Review Application/Progress Report package upon submission

1. Ethical clearance or approval is granted for a period of one year. After approval, continuing review is required to be done at least once a year, depending on the risk assessment of the study protocol. The continuing review process is facilitated through the submission of **IEC-*ICH* Form 4-C:*Continuing Review Application Form*** or **IEC-*ICH* Form 4-B: *Progress Report Form***

2. The expiration of approval granted to a protocol and the frequency of continuing review are indicated in **IEC-*ICH* Form 5-B: *Approval Letter to the Study Protocol***, which is provided to the PI upon approval of the study.

3. For ethical clearance or approval approaching the one-year expiry date and requiring a renewal or extension, it is advisable to submit **IEC-*ICH* Form 4-C: *Continuing Review Application Form*** 45 days prior to expiry date.

4. The Secretariat Staff looks through the Study Protocol Database for the titles of study protocols that are due for continuing review at the end of the month.

5. The Secretariat Staff informs the respective PIs at least 30 days in advance of the due date of submission by fax, e-mail or letter and by sending **the IEC-*ICH* Form 5-O: *Reminder Letter for Progress Report or Continuing Review Application***.

6. The continuing review of a study protocol is initiated by the submission by the P.I. of the **IEC-*ICH* Form 4-C: *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 copy of the **IEC-*ICH* 4-C: *Continuing Review Application Form*** to the PI or his/her representative.

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

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

ii. Classification of Review by the IEC Chair

1. The *IEC* 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 IEC Chair and Members

1. The continuing review application package is sent together with a copy of the study protocol to the *IEC* Chair for expedited review study protocols and to the Members and all other *IEC* members. In Full Board Review, the other *IEC* members (who are not members) are provided with the study protocols, too; their opinions are considered during the deliberation process in the *IEC* meeting.

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

3. Continuing review application packages participant to full board review received within the cut-off period of twenty (20) days before the *IEC* meeting are sent to Reviewers as soon as they are received by the *IEC* 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 *IEC* meeting.

5. The Members accomplish the review and return the signed **IEC-*ICH* Form 4-C: *Continuing Review Application Form*** on the day of the *IEC* meeting together with review application package.

iv. Full Board Review of Continuing Review Application

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

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

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 Board may also recommend further action on the continuing review application.

vi. *Files management*

1. The *IEC* Chair and *IEC* Secretary sign **IEC-*ICH* Form 4-C: *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-*IEC* 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 **IEC-*ICH* Form 4-D: *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 copy of **IEC-*ICH* Form 4-D: *Final Report Form***, to PI or his/her representative.

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

ii. Classification of Review by the IEC Chair

1. The *IEC* 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. Review by Members

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

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

3. Final Report packages participant to full board review received within the cut-off period of two (2) weeks or fourteen (14) calendar days before the *IEC* meeting are sent to 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 *IEC* meeting.

5. The Members accomplish the review and return the signed **IEC-*ICH* Form 4-D: *Final Report Form*** to the Secretariat Staff on the day of the *IEC* Meeting together with the final report package.

iv. Full Board Review of Final Report

1. The Secretariat Staff distributes the following final report package to *IEC* Members along with the meeting agenda:

   - **IEC-*ICH* Form 4-D: *Final Report Form***
   - Relevant documents or attachments

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

v. Communication of Results

1. The PI is notified of the *IEC* decision, noting *IEC* 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. If the final report is approved, the PI is informed of the following:

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

vi. Files Management

1. The *IEC* Secretary and *IEC* Chair sign **IEC-*ICH* Form 4-D:*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-*IEC* 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 participants without prior ICH-*IEC* 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 *IEC* within 24 hours (following the timelines of reporting on SAE).

4. Reporting of protocol noncompliance is facilitated by the submission of **IEC-*ICH* 4-E: *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 **IEC-*ICH* 4-E: *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* (IEC-*ICH* 5-N)**.

ii. *Classification of Review by the IEC Chair*

1. The *IEC* 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 IEC Chair And Members*

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

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

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

4. The Members accomplish the review and return the signed **IEC-*ICH* 4-E: *Study Protocol Deviation or Non-Compliance Report*** to the Secretariat on the day of the *IEC* meeting together with the study protocol noncompliance report package.

iv. *Full Board Review of Study Protocol Noncompliance Report*

1. The Secretariat Staff distributes the following Study Protocol Noncompliance Report package to *IEC* Members along with the meeting agenda:

   - **IEC-*ICH* 4-E: *Study Protocol Deviation or Non-Compliance Report***
   - Documents related to the deviation

2. The documents are presented to *IEC* 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 *IEC* Panel can suspend ethical clearance or participant recruitment until noncompliance issues are addressed
4. The *IEC* 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 SOP III.

v. Communication of Results

1. The PI is notified of the *IEC* 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 *IEC* Secretary and *IEC* Chair sign the **IEC-*ICH* 4-E: *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-*IEC* 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 un resolvable but valid complaints or circumstances.

2. Early study termination is facilitated through the submission of **IEC-*ICH* 4-F: *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 of **IEC-*ICH* 4-F: *Early Study Termination Application Form*** to the PI or his/her representative.

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

ii. Classification of Review by the IEC Chair

1. The *IEC* 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 IEC Chair and Members

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

2. Early study termination application packages participant to full board review received within the cut off period of 2 weeks or fourteen (14) days before the *IEC* meeting are sent to Members at least ten (10) calendar days before the meeting.

3. The Secretariat Staff places the early study termination application on the next *IEC* meeting.

4. The Members accomplish the review and return the signed **IEC-*ICH* 4-F: *Early Study Termination Application Form*** to the Secretariat on the day of the *IEC* meeting together with the early study termination application package.

iv. Full Board Review of Early Termination Application

1. The Secretariat Staff distributes the following early study termination application package to *IEC* Members along with the meeting agenda:
   - **IEC-*ICH* 4-F: *Early Study Termination Application Form***
   - Documents related to the early study termination

2. The *IEC* 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 *IEC* 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 III

v. *Communication of Results*

1. The PI is notified of the *IEC* decision, noting Board 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 **IEC-*ICH* Form 4-D: *Final Report Form***.

vi. *Files Management*

1. The *IEC* Secretary and *IEC* Chair sign the **IEC-*ICH* 4-F: *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 *IEC* 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 **IEC-*ICH* Form 4-J: *Study Participant Queries or Complaints***, which has to be accomplished by *IEC* 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 **IEC-*ICH* Form 4-J: *Study Participant Queries or Complaints***, by respective *IEC* personnel, and then forwarded to the Secretariat for processing.

5. The Secretariat Staff logs the query or complaint into the ***Submissions Database*** **(IEC-*ICH* 5-N)**.

ii. *Classification of Review by IEC Chair*

1. The *IEC* 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 IEC Chair and Members.

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

2. Queries and complaints participant to full board review received within the cut-off period of 2 weeks or fourteen (14) days before the *IEC* meeting

3. The Secretariat Staff places the query or complaint in the agenda of the next *IEC* meeting

4. The *IEC* Chair or Members review the information entered in **IEC-*ICH* Form 4-J: *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 **IEC-*ICH* Form 4-J: *Study Participant Queries or Complaints*** to *IEC* members along with the meeting agenda.

2. The *IEC* deliberates on how best to address the study participant's concerns and recommend a course of action.

3. The *IEC* may request information from the PI, invite the PI for clarificatory interview, or require corrective action.

4. For detailed information on full board review of study participant queries or complaints, see SOP III.

v. Communication of Results

1. The *IEC* responds to the study participant in writing after a course of action of appropriate response is identified whether through expedited or full board review.

2. The PI may be requested to provide additional information or submit additional documents in order to fulfill the study participant's concerns.

vi. Files Management

1. The *IEC* Secretary and *IEC* Chair sign the **IEC-*ICH* Form 4-J:*Study Participants Queries or Complaints***

2. The Secretariat Staff stores the early termination application documents in the study protocol file folder.

5. SERIOUS ADVERSE EVENT REPORTS WORKFLOW

ACTIVITY	RESPONSIBILITY
Receive and manage serious adverse event/s report package ↓	Secretariat Staff
Submit serious adverse event report package to the *IEC* Chair and Members for review ↓	Secretariat Staff
Discuss serious adverse event report/s in *IEC* meeting ↓	*IEC* Members
Communicate results of discussion and deliberation to PI ↓	Secretariat Staff
Manage SAE report/s and related files	Secretariat Staff

DETAILED INSTRUCTIONS:

a. Management of the SAE report upon submission

i. Serious adverse events are events temporally associated with the participant's participation in trial that meets any of the following criteria:

- Results in death
- Is life-threatening (places the participant at immediate risk of death from the event as it occurred)
- Requires inpatient hospitalization or prolongation of existing hospitalization
- Results in a persistent or significant disability/incapacity
- Results in a congenital anomaly/birth defect
- Any other adverse event that, based upon appropriate medical judgment, may jeopardize the participant's health and may require medical or surgical intervention to prevent one of the outcomes listed in this definition

ii. The P.I. must report serious adverse event occurring in a patient enrolled in a study approved by the ICH within 24 hours of its occurrence or the knowledge of the PI or any team member of the same.

iii. The SAEs that must be reported to the *IEC* within 24 hours are those which occur in a patient enrolled in a study being conducted in the ICH. A collated report of SAE's which happen in other (national, international) sites should be reported to the *IEC* every three months.

iv. If warranted by concerns of patient safety, the *IEC* reserves the right to obligate the P.I. to make more frequent reporting of SAEs that occur outside the ICH site.

v. Reporting of SAEs is facilitated through the submission of **IEC-*ICH* Form 4-H: *Serious Adverse Event/s Report***, together with a documents deemed relevant by the investigator to clarify information indicated in the report. This comprises the study protocol serious adverse event/s report package.

Package:

- *Initial and Final Report (Interim Report, if any) as per CT rule 2019*
- *Sponsor's Report*
- *Reimbursement details*
- *PI's opinion on relatedness of IP to SAE*

vi. The Secretariat Staff checks the submission for completeness and gives a receiving copy of **IEC-*ICH* Form 4-H: *Serious Adverse Event/s Report*** to the PI or his/her representative.

vii. The Secretariat Staff logs the date of submission on the ***Submissions Log*** **(IEC-*ICH* Form 5-N)**.

viii. The Secretariat Staff collates all the serious adverse event/s report and encodes data in the Serious Adverse Events Database.

b. Review by Reviewers

i. Serious adverse event/s report packages received within the cut-off period of 2 weeks or fourteen (14) days before the *IEC* meeting are sent to the Member Clinician (s) ten (10) calendar days before the *IEC* meeting.

ii. The Secretariat Staff places the serious adverse event report on the agenda for the next *IEC* meeting.

iii. The Members Clinician accomplish the review and return the signed **IEC-*ICH* Form4-H: *Serious Adverse Event/s Report*** to the Secretariat on the day of the *IEC* 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 *IEC* Members along with the meeting agenda:

- ☐ **IEC-*ICH* Form 4-H: *Serious Adverse Event/s Report***
- ☐ Relevant documents or attachment

ii. The documents are presented to *IEC* 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 *IEC* 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 *IEC* 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 *IEC* decision, noting *IEC* 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 IEC communicates its decision on the SAE to the DCGI office within 30 days of SAE occurrence in prescribed format-via SUGAM portal.

f. Files Management

i. The *IEC* Secretary and *IEC* Chair sign the **IEC-*ICH* Form 4-H: *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 reports in participants of Ongoing Regulatory Clinical Trial

SAE in a trial subject in an ongoing clinical trial

↓

Principal Investigator within 24 hours of occurrence of SAE to submit Initial written report to Sponsor, CDSCO, Chairperson of IEC with a copy to the Member Secretary of IEC

↓

Principal Investigator within 14 calendar days of occurrence of SAE to submit detailed follow up and outcome reports to IEC, Sponsor, CDSCO, head of Institution

↓

IEC Chairperson to convene meeting at the earliest

1) Review in details the SAE and its treatment
2) Redress any grievance of the clinical trial participant or his/her legal representative

Decision regarding the following:
1) SAE relatedness (2) Whether it is a Clinical trial related injury (3) Whether appropriate free medical management was given
(4) Whether financial compensation is payable

↓

IEC Chairperson
Within 30 calendar days will send the Analysis report of the SAE to:
CDSCO, Head of Institution through SUGAM portal & e-mail

↓

Archival of all SAE reports and correspondence in SAE file

6. SITE VISIT WORKFLOW (STUDY MONITORING)

ACTIVITY	RESPONSIBILITY
Select study to be audited ↓	*IEC* Chair and Members
Notify PI of date of audit ↓	*IEC* Chair and *IEC* Secretary
Create Site Visit Team ↓	*IEC* Chair and *IEC* Secretary
Conduct Site Visit ↓	Site Visit Team
Present findings during *IEC* meeting ↓	*IEC* Chair
Communicate Results of Site Visit and subsequent *IEC* action to PI ↓	Secretariat Staff
Manage Site Visit documents	Secretariat Staff

DETAILED INSTRUCTIONS:

a. Selection of Study Sites

i. Each study is audited at least once a year (routine monitoring)

ii. Study sites may be selected for Site Visits based on the following criteria (For cause Audit.

- 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. DCGI Inspection

iii. A decision for Site Visit is deliberated on during a full board meeting of the *IEC*

b. Notification of PI of Date of Site Visit

i. The *IEC* Chair, through the Secretariat, informs the PI at least one (1) week before the scheduled visit through a letter (Form 4-I).

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 *IEC* Chair.
iii. The Site Visit Team should be composed of at least two (2) *IEC* members
iv. Each member of the Site Visit Team are informed of their assignment
v. The Secretariat Staff prepares a Study Visit Package for each members of the Site Visit Team, inclusive of the **IEC-*ICH* Form 4-G:*Site Visit Report Form*** and **IEC-*ICH* Form 4-L: *Audit Checklist***
vi. The Site Visit Team prepares for the activity by reviewing the contents of the study file and the requirements of **IEC-*ICH* Form 4-G: *Site Visit Report Form*** and **IEC-*ICH* Form 4-L: *Audit Checklist***

d. Conduct of Site Visit

i. Upon arrival in the study site, the Site Visit Team uses **IEC-*ICH* Form 4-L:*Audit Check List*** 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
- ☐ 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
- ☐ Site Operations
- ☐ Protocol Compliance
- ☐ Informed Consent Documentation
- ☐ Participant Records
- ☐ Safety Monitoring
- ☐ Drug/ Device/ Test Article Accountability

ii. At the end of the visit, the Site Visit Team issues Form 4G: Site Visit Report Form to **IEC-*ICH* Form 4-L: *Audit Check List*** record with observes. It will:
- ☐ Discuss the findings with the trial team
- ☐ Solicit feedback (written compliance report from PI)

e. Presentation of Findings at *IEC* meeting

i. One of the members of Site Visit Team completes **IEC-*ICH* Form 4-G: *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*** **(IEC-*ICH* Form 5-N)**.

iii. The Secretariat Staff places the Site Visit Report in the agenda of the next *IEC* meeting.

iv. During the meeting, the Secretariat Staff distributes the completed **IEC-*ICH* Form4- G: *Site Visit Report Form*** to *IEC* members along with the meeting **agenda**.

The *IEC* 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 III.

f. Communication of Results

i. The PI is notified of the *IEC* 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 *IEC* Secretary and *IEC* Chair sign the **IEC-*ICH* Form4-G: *Site Visit Report Form***.

ii. The Secretariat Staff stores the Site Visit documents in the study protocol file folder.

7. LIST OF FORMS

IEC-ICH Form 4-A:	Study Protocol Amendment Submission Form
IEC-ICH Form 4-B:	Progress Report Form
IEC-ICH Form 4-C:	Continuing Review Application Form
IEC-ICH Form 4-D:	Final Report Form
IEC-ICH Form 4-E:	Study Protocol Deviation or Non-Compliance Report
IEC-ICH Form 4-F:	Early Study Termination Application Form
IEC-ICH Form 4-G:	Site Visit Report Form
IEC-ICH Form 4-H:	Serious Adverse Event(s) Report
IEC-ICH Form 4-I:	Notice of Site Visit
IEC-ICH Form 4-J:	Study Participant Queries or Complaints
IEC-ICH Form 4-K:	Additional Study Material for Approval Form
IEC-ICH Form 4-L:	Audit Checklist

STUDY PROTOCOL AMENDMENT SUBMISSION FORM

A study protocol amendment is a written description of change(s) to or formal clarification of a protocol and/or informed consent documents. Favorable opinion or approval should be obtained from the IEC-ICH that issued the ethical clearance or approval prior to the implementation of an amendment. Please fill up this form and encode all information required in the space provided. Multiple amendments classified under ONE type of review (expedited or full review) can be submitted in one form. Please date and sign this form before submission.

Study No.:		
Study Protocol Title:		
Initial Approval Date: Click here to enter a date.		
Principal Investigator:	**Signature:**	
E-mail:	**Telephone:**	**Mobile:**
Study Site:		
Study Site Address:		
Sponsor:		
Sponsor Contact Person:		
E-mail:	**Telephone:**	**Mobile:**
Amendment Submission Date: *(to be filled out by IEC-ICH)*		
1 **No. of Amendment/s:**		
2 **State Nature of Study Protocol Amendment** *(cite study protocol section and page where amendment is found)*		
3 **Type of Review:** *(for IEC-ICH use ONLY)* 3 ☐ **EXPEDITED** ▪ ▪ ▪ ▪ ▪ ▪ ▪ 3 ☐ **FULL BOARD REVIEW**		

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

To be filled out by the IEC REVIEWER

☐ ☐ ☐ ☐		
D _____		

PROGRESS REPORT FORM

INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR:

- *Should accomplish this form every six (6) months from the time of approval of a protocol. Please provide all required information, date and sign this form before submission.*
- The progress report of a study protocol is initiated by the submission by the P.I. of the **IEC-ICH Form 4-B,** together with the current informed consent documents.
- Please fill up this form and provide all required information then, **date and sign** this form before submission.

Study No.: IEC/		
Study Protocol Title:		
Initial Approval Date: Click here to enter a date.		
Principal Investigator:		
E-mail:	**Telephone:**	**Mobile:**
Study Site:		
Study Site Address:		
Sponsor:		
Sponsor Contact Person:		
E-mail:	**Telephone:**	**Mobile:**
Application Submission Date:		
1. **Start Date:** 1.1. Date of research site initiation: Click here to enter a date. 1.2. Explanation, if not yet initialized as of date of this application: <reason/s>		
2. **Have there been any amendments since the last review/approval?** 2.1. ☐ No 2.2. ☐Yes (Describe briefly and indicate date/s of Study Protocol Amendment Submission/s): *Please use additional pages if necessary*		
3. **Summary of Study Protocol Participants:**		
3.1. No. of study subjects, the Principal Investigator should randomize (ceiling set by PI and Sponsor)		
3.2. Actual No. of Randomized study subjects		
3.3. No. of Randomized study subjects since last review/approval		
3.4. Total No. of enrolled patients since study initiation		
4. **Have there been any changes in the participant population, recruitment or selection criteria since the last review/approval?** 4.1. ☐No 4.2. ☐Yes (Explain changes and indicate date/s of Study Protocol Amendment Submission/s)		
5. **Have there been any changes in the informed consent process or documentation since the last review/approval?** *Attach latest version of participant information sheet and informed consent form/document* 5.1. ☐ No 5.2. ☐Yes (Explain changes and indicate date/s of Study Protocol Amendment Submission/s)		
6. **Has any information appeared in the literature, or evolved from this or similar research participants that might affect the IRB's evaluation of the risk/benefit assessment of human participants involved in this study protocol?** 6.1. ☐No 6.2. ☐Yes (Describe briefly and provide copy of literature cited, including the Investigator's Brochure if applicable)		
7. **Have any unexpected discomforts, complications, or side effects been noted since last review/approval?**		

7.1. ☐No 7.2. ☐Yes (Summarize and indicate date/s of SUSAR report submission/s)
8. **Have any participants withdrawn from this study since the last review/approval?** 8.1. ☐No 8.2. ☐Yes (Explain context surrounding withdrawal and documenting due diligence exerted by the study team in managing these withdrawals)
9. **Have there been any new intervention(s) or methods in the conduct of study that is/are not in the approved protocol?** 9.1. ☐No 9.2. ☐Yes (Describe use and indicate date/s of Study Protocol Deviation/Non-Compliance/ Violation Report Submission/s)
10. **Have any investigators been added or deleted since last review/approval?** 10.1. ☐No 10.2. ☐Yes (Enumerate personnel and indicate date/s of Study Protocol Amendment Submission/s. append CV if not yet submitted to the IEC-ICH Review Panel)
11. **Have any collaborating sites (institutions) been added or deleted since the last review/approval?** 11.1. ☐No 11.2. ☐Yes (Enumerate sites and indicate date/s of Study Protocol Amendment Submission/s)
12. **Have any investigators developed equity or consultative relationship with a party related to this study protocol which might be considered a conflict of interest since the last review/approval?** 12.1. ☐No 12.2. ☐Yes (Append a statement of disclosure)
13. **Have there been changes in study personnel since the last review/approval?** 13.1. ☐None 13.2. ☐Deleted (Enumerate and indicate date/s of Study Protocol Amendment Submission/s) 13.3. ☐Yes (Enumerate and indicate date/s of Study Protocol Amendment Submission/s)
14. **Have there been others changes not mentioned above since the last review/approval? Attach protocol synopsis?** 14.1. ☐No 14.2. ☐Yes (Describe changes and indicate date/s of Study Protocol Amendment Submission/s)
Signature of Principal Investigator:
Date Signed:

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

To be filled out by the IEC REVIEWER

RECOMMENDED ACTION ☐ Uphold original approval with no further action ☐ Request further information: *(indicate information needed)* ☐ Recommend further action: *(indicate action)*		
NAME OF IEC REVIEWER	SIGNATURE:	DATE: (dd/mm/yyyy)

CONTINUING REVIEW APPLICATION FORM

INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR:

- Ethical clearance or approval is typically granted for a period of one year. Continuing review is required to be done at least once a year (as stated on the initial approval letter), corresponding the risk assessment of the study protocol. For ethical clearance or approval approaching the one-year expiry date and requiring a renewal or extension, it is advisable to submit this form **45 days** prior to expiry date.

- The continuing review of a study protocol is initiated by the submission by the P.I. of the **IEC-ICH Form 4-C,** together current informed consent. This comprises the continuing review application package.

- Please fill up this form and provide all required information then, **date and sign** this form before submission.

Study No.: IEC/		
Study Protocol Title:		
Initial Approval Date: Click here to enter a date.		
Principal Investigator:		
E-mail:	**Telephone:**	**Mobile:**
Study Site:		
Study Site Address:		
Sponsor:		
Sponsor Contact Person:		
E-mail:	**Telephone:**	**Mobile:**
Application Submission Date:		
1. **Start Date:** 1.1. Date of research site initiation: Click here to enter a date. 1.2. Explanation, if not yet initialized as of date of this application: <reason/s>		
2. **Action Requested:** 2.1. ☐Renewal: subject enrolment still ongoing 2.2. ☐Renewal: randomized participants follow up visits only 2.3. ☐Early Termination: study protocol discontinued ahead of study indicated duration		
3. **Have there been any amendments since the last review/approval?** 3.1. ☐No 3.2. ☐Yes (Describe briefly and indicate date/s of Study Protocol Amendment Submission/s): *Please use additional pages if necessary*		
4. **Summary of Study Protocol Participants:**		
4.1. No. of study subjects, the Principal Investigator should randomize (ceiling set by PI and Sponsor)		
4.2. Actual No. of Randomized study subjects		
4.3. No. of Randomized study subjects since last review/approval		
4.4. Total No. of enrolled patients since study initiation		
5. **Have there been any changes in the participant population, recruitment or selection criteria since the last review/approval?** 5.1. ☐No 5.2. ☐Yes (Explain changes and indicate date/s of Study Protocol Amendment Submission/s)		
6. **Have there been any changes in the informed consent process or documentation since the last review/approval?** *Attach latest version of participant information sheet and informed consent form/document* 6.1. ☐No 6.2. ☐Yes (Explain changes and indicate date/s of Study Protocol Amendment Submission/s)		
7. **Has any information appeared in the literature, or evolved from this or similar research participants that might affect the IRB's evaluation of the risk/benefit assessment of human participants involved in this study protocol?** 7.1. ☐No 7.2. ☐Yes (Describe briefly and provide copy of literature cited, including the Investigator's Brochure if applicable)		
8. **Have any unexpected discomforts, complications, or side effects been noted since last**		

review/approval? 8.1. ☐No 8.2. ☐Yes (Summarize and indicate date/s of SUSAR report submission/s)
9. **Have any participants withdrawn from this study since the last review/approval?** 9.1. ☐No 9.2. ☐Yes (Explain context surrounding withdrawal and documenting due diligence exerted by the study team in managing these withdrawals)
10. **Have there been any new intervention(s) or methods in the conduct of study that is/are not in the approved protocol?** 10.1.☐No 10.2.☐Yes (Describe use and indicate date/s of Study Protocol Deviation/Non-Compliance/Violation Report Submission/s)
11. **Have any investigators been added or deleted since last review/approval?** 11.1.☐ No 11.2.☐ Yes (Enumerate personnel and indicate date/s of Study Protocol Amendment Submission/s. Append CV if not yet submitted to the IEC-ICH Review Panel)
12. **Have any collaborating sites (institutions) been added or deleted since the last review/approval?** 12.1.☐ No 12.2.☐ Yes (Enumerate sites and indicate date/s of Study Protocol Amendment Submission/s)
13. **Have any investigators developed equity or consultative relationship with a party related to this study protocol which might be considered a conflict of interest since the last review/approval?** 13.1.☐ No 13.2.☐ Yes (Append a statement of disclosure)
14. **Have there been changes in study personnel since the last review/approval?** 14.1.☐ None 14.2.☐ Deleted (Enumerate and indicate date/s of Study Protocol Amendment Submission/s) 14.3.☐ Yes (Enumerate personnel and indicate date/s of Study Protocol Amendment Submission/s. Append CV if not yet submitted to the IEC-ICH)
15. **Have there been others changes not mentioned above since the last review/approval? Attach protocol synopsis?** 15.1.☐ No 15.2.☐ Yes (Describe changes and indicate date/s of Study Protocol Amendment Submission/s)
Signature of Principal Investigator:
Date Signed:

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

To be filled out by the PRIMARY REVIEWER

RECOMMENDED ACTION ☐Uphold original approval with no further action ☐Request further information: *(indicate information needed)* ☐Recommend further action: *(indicate action)*		
NAME OF IEC REVIEWER	SIGNATURE:	DATE: (dd/mm/yyyy)

FINAL REPORT FORM

INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR: *This form is required upon completion of the study or closure of study site. The Principal Investigator is to complete this form and he/she may use additional pages as may be needed. Print the report in A4 size, then* ***date*** *and* ***sign*** *this form before submission.*

Study No.: IEC/		
Study Protocol Title (with version and date):		
Initial Approval Date: Click here to enter a date.		
Principal Investigator:		
E-mail:	**Telephone:**	**Mobile:**
Study Site:		
Study Site Address:		
Sponsor:		
Sponsor Contact Person:		
E-mail:	**Telephone:**	**Mobile:**
Application Submission Date:		
1. Study Arms:		
2. Number of enrolled patients:		
3. Number of randomized patients:		
4. Number of patients who received the study medications:		
5. Number of patients who completed the study:		
6. Number of study drop-outs:		
7. Summary of SAE's: 7.a. Total # of SAE's: 7.b. Enumeration of SAE's:		
8. Summary of documented complaints or grievances by patients in the study:		
9. If terminated early, specify reason for termination:		
Date of Last Review: Click here to enter a date.		
Signature of Principal Investigator:		
Date Submitted: Click here to enter a date.		
Received By:		

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

Recommendations *(for IEC –ICH use only)*

Comments of IEC Reviewer *(i.e. compliance with the terms of the approved protocol including post-approval review requirements, and overall assessment of risks against benefits in the conduct of study)*		
Recommended Action ☐ Approval ☐ Request information: *(specify)* ☐ Recommend further action: *(specify)*		
NAME OF IEC REVIEWER:	SIGNATURE:	DATE: (dd/mm/yyyy)

STUDY PROTOCOL DEVIATION OR NON-COMPLIANCE REPORT

INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR: *Accomplish a copy of this form and include all information required in the space provided information submitted under this form to full board review by the IEC-ICH.* ***Date*** *and* ***sign*** *this form before submission.*

Study No.: IEC/		
Study Protocol Title:		
Initial Approval Date: Click here to enter a date.		
Principal Investigator:		
E-mail:	**Telephone:**	**Mobile:**
Study Site:		
Study Site Address:		
Sponsor:		
Sponsor Contact Person:		
E-mail:	**Telephone:**	**Mobile:**
Report Submission Date: *(to be filled out by IEC-ICH)*		
1. **Nature of Report:** 1.1. ☐ Minor Protocol Deviation *(non-systematic protocol noncompliance with minor consequences, in terms of its effect on the participant's/subject's rights, safety or welfare, or the integrity of study data; includes deviations that are administrative in nature)* 1.2. ☐ Major protocol deviation or protocol Violation *(persistent protocol noncompliance with potentially serious consequences that could critically affect data analysis or put patient's safety at risk)*		
2. **Description of Reported Deviation/Violation:**		
3. **Description of Investigator Corrective Action:**		
4. **Sponsor Assessment of Severity:** 4.1. ☐ Major 4.2. ☐ Minor		
5. **Description of Sponsor Corrective Action:**		
Date of Deviation/Violation: Click here to enter a date.		
Reported By:		
Date of Report: Click here to enter a date.		
Signature of Principal Investigator:		

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

Recommended Action: *(for IEC-ICH use only)* ☐ Uphold original approval with no further action ☐ Request information: *(indicate information)* ☐ Recommend further action: *(indicate action)*		
NAME OF IEC REVIEWER:	SIGNATURE:	DATE: (dd/mmm/yyyy)

EARLY STUDY TERMINATION APPLICATION FORM

INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR: *Obtain an electronic copy of this form and encode all information required in the space provided. Print the application in A4 size paper, then* ***date*** *and* ***sign*** *this form before submission. Approval of this application would require further completion of* **IEC-ICH Form 4-D:** ***Final Report Form***.

Study No.: IEC/		
Study Protocol Title:		
Initial Approval Date: Click here to enter a date.		
Principal Investigator:		
E-mail:	**Telephone:**	**Mobile:**
Study Site:		
Study Site Address:		
Sponsor:		
Sponsor Contact Person:		
E-mail:	**Telephone:**	**Mobile:**
Application Submission Date: *(to be filled out by IEC-ICH)*		
1. **Start Date:** Click here to enter a date.		
2. **Proposed Termination Date:** Click here to enter a date.		
3. **Participants Enrolled to Date:**		
4. **Summary of Results to Date:**		
5. **Reason for Termination with Justification:**		
Signature of Principal Investigator:		
Date of Application: Click here to enter a date.		

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

Recommended Action: *(for IEC-ICH use only)* ☐ Approval with no further action ☐ Request information: *(indicate information)* ☐ Recommend further action: *(indicate action)*		
NAME OF IEC REVIEWER:	SIGNATURE:	DATE: (dd/mm/yyyy)

Site Visit Report Form

INSTRUCTIONS TO THE IEC-ICH Member/Representatives:

A Site Visit is conducted as a result of full board action for purposes of monitoring study protocol compliance in the study site. The visit is limited to the review of study protocol related documents and procedures that have been approved by the IEC-ICH. The visit should not in any way compromise the obligation to protect the privacy and confidentiality of research-related information of study participants/subjects. The IEC Chair should ensure that the Site Visit Team is well-prepared to conduct the visit through a complete review of the study protocol folder prior to the visit. This form should reflect the consensus opinion of the Site Visit Team; the results of which are reported in the next IEC-ICH meeting.

Study No.: IEC/		
Study Protocol Title:		
Approval Date:		
Principal Investigator:		
E-mail:	**Telephone:**	**Mobile:**
Study Site:		
Study Site Address:		
Sponsor:		
Sponsor Contact Person:		
E-mail:	**Telephone:**	**Mobile:**
Site Visit Date: *(to be filled out by IEC-ICH)*		

1. **Total Participants Expected:** (randomized)
2. **Total Participants Enrolled:** (actual)
3. **Are Site Facilities appropriate?**
   - 3.1. ☐ Yes
   - 3.2. ☐ No
   - 3.3. Comments:
4. **Are informed consent documents updated to the version approved by the IEC-ICH?**
   - 4.1. ☐ Yes
   - 4.2. ☐ No
   - 4.3. Comments:
5. **Are there any SAE/SUSAR reports not previously reported to the IEC-ICH?**
   - 5.1. ☐ Yes
   - 5.2. ☐ No
   - 5.3. Comments:
6. **Are there any events of protocol noncompliance not previously reported to the IEC-ICH?**
   - 6.1. ☐ Yes
   - 6.2. ☐ No
   - 6.3. Comments:
7. **Are investigation products and study documents secured adequately?**
   - 7.1. ☐ Yes
   - 7.2. ☐ No
   - 7.3. Comments:
8. **Are all other IEC-ICH-approved documents (e.g. advertisement) used in accordance with the approved study protocol?**
   - 8.1. ☐ Yes
   - 8.2. ☐ No
   - 8.3. Comments:

9. Are there any significant findings found in this visit that could affect participant's/subject's rights, safety or welfare?

9.1. ☐ Yes
9.2. ☐ No
9.3. Comments:

10. Overall, does the study site provide adequate protection for the rights, safety or welfare of participants/subjects?

10.1. ☐ Yes
10.2. ☐ No
10.3. Comments:

11. How well are study participants/subjects protected?

11.1. ☐ Good
11.2. ☐ Fair
11.3. ☐ Not Good
11.4. Comments:

12. Are there further actions or queries resulting from this site visit?

12.1. ☐ Yes
12.2. ☐ No
12.3. Comments:

13. Additional Remarks

COMPLETED BY THE FOLLOWING IEC-ICH MEMBER/REPRESENTATIVES:

Name	Signature	Date
1.		
2.		
3.		

Recommended Action: *(for IEC-ICH use only)*

☐ Uphold original approval with no further action

☐ Request information: *(indicate information)*

☐ Recommend further action: *(indicate action)*

PRIMARY REVIEWER Date: <*dd/mm/yyyy*>	Signature _____ Name <*title, name, surname*>
IEC SECRETARY Date: <*dd/mm/yyyy*>	Signature _____ Name <*title, name, surname*>
IEC CHAIR Date: <*dd/mm/yyyy*>	Signature _____ Name <*title, name, surname*>

Serious Adverse Event(s) Report

INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR: *Obtain an electronic copy of this form and encode all information required in the space provided. This form should be submitted within 24 hours days from SAE occurrence or knowledge of the same.*

Study No.: IEC/
Study Protocol Title:
Initial Approval Date:
Principal Investigator:

SERIOUS ADVERSE EVENT REPORT						
1. Report Type: ☐Initial ☐Follow-up		2. Country:		3. Patient No.:		
4. Date of Patient Randomization: *<dd/mm/yyyy>*						
I. Adverse Event Information						
5. Date of Birth *day month year*	6. Age yrs./mo.	7. Race ☐ Caucasian ☐ Oriental ☐ Black ☐ Other	8. Sex ☐ Male ☐ Female	9. Height cm	10. Weight kg	11. Date of SAE *day month year*
12. Serious Adverse Event(s) in Medical Terms (diagnosis, if possible) 13. Co-Morbidities:				Expedited Reporting Criteria 14. Check All Appropriate to Event ☐ Patient died: *day month year* ☐ Involved or prolonged inpatient hospitalization ☐ Involved persistent or significant disability or incapacity ☐ Life-threatening Other Seriousness Criteria: ☐ Congenital anomaly/birth defect ☐ Other significant medical events:		
Case description of the above SAE (include related signs/symptoms, treatment, course/outcome and suspected cause of the SAE) (continue on P.3 if more space is required): Is the event due to lack of efficacy? ☐ Yes☐ No Is the event due to progression of underlying illness? ☐ Yes☐ No						
I. Trial Drug Information						
15. Trial Drug(s) at or before onset of SAE (If blinded, provide drug package no.) Trial Drug Package No.: Drug Code Broken? ☐ No ☐ Yes Comments (continue on P.3 if more space is required):				16. Last Visit before onset of SAE Visit No.: Week No.:		
17. Doses at or before onset of SAE(total daily dose or specify of other - Add additional pages)		18. Route of Administration		19. Therapy Date (from/to) *day month year*	*day month year*	
20. Trial Indication		21. Therapy Duration Until Onset of First		22. Time Elapsed Between Last Drug Administration and		

	Sign/Symptom of SAE hrs/days/months	Onset of First Sign/Symptom of SAE mins/hrs/days/months

II. History

23. Patient's Past Medical History (e.g. co-existing medical conditions such as disease, allergies, similar experiences)

III. Manufacturer's Information

24. Name and Address of Manufacturer

25. Manufacturer Control No.

26. Concomitant Drugs Relevant to the SAE (exclude therapy to treat SAE)

Drug Name(s)	Dose Route	Unit Schedule	Date Started day month year	Cont. 0 = No 1 = Yes	Date Discontinued day month year	Reason for Use

27. Comments (If adverse event is considered to be cause by a co-medication, please note it here)

28. Action Taken (mark all as appropriate)

☐ No Action Taken
☐ Concomitant medication taken
☐ No drug therapy given **
☐ Trial drug permanently discontinued due to this adverse event
☐ Trial drug dosage adjusted/temporarily interrupted*
☐ Hospitalization/prolonged hospitalization

* If ticked, enter new dosage information in field 12
** If ticked, provide therapeutic measures in field 12

29. Test/Laboratory Findings (enter only those findings necessary for SAE diagnosis or course description)

Test/ Lab Name	Unit	Date day month year	Value	Date day month year	Value	Date day month year	Value

30. Comments on Test/laboratory Findings (Provide normal ranges on pg.3 if not already provided.) (if the SAE is a laboratory abnormality, enter comments on clinical findings and/or treatment in field 11.)

31. Outcome of the Patient/SAE
☐ Completely Recovered Date of recovery: <dd/mmm/yyyy)
☐ Condition still present and unchanged
☐ Condition deteriorated

☐ Recovered with sequelae ☐ Condition improving	☐ Death Yes	Autopsy: ☐ No ☐
32. Assessment of Causality Relationship to study drug ☐ Not suspected ☐ Suspected		
IV. Information Source		
33. Name, Address and Telephone Number of Investigator Signature:	34. Reporting Date by Investigator/Person Reporting Event day month year	
For Additional Information:		

Note: Please fill out this form electronically before printing.

To be filled out by the IEC REVIEWER

RECOMMENDED ACTION

☐ Uphold original approval with no further action

☐ Request information: *(indicate information)*

☐ Recommend further action: *(indicate action)*

NAME OF IEC REVIEWER	SIGNATURE:	DATE: (mm/dd/yyyy)

INSTITUTIONAL ETHICS COMMITTEE - INSTITUTE OF CHILD HEALTH

11, Dr. Biresh Guha Street, Kolkata - 700017

STUDY AUDIT CHECKLIST

Principal Investigator's Name:		GCP Training by Sponsor: Y/N
Co-Investigator(s)Name (Name & affiliation or "None"):		GCP training(others):
Title of Study:		Protocol No: Version: Date:
Name of Sponsor Name of CRO:		Name of laboratories:
Date of IEC Approval		Date of Annual report submitted:
Date of SIV		AR submission date:

STUDY STATUS:	AUDITED BEFORE:
#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
- ☐ 7. Drug/Device/Test Article Accountability

AUDIT WORKSHEET 1

Auditor:		Date:		IEC#	

REGULATORY DOCUMENTATION

1. DCGI application/approval available: Comments:	☐ Yes ☐ No ☐ N/A
2. Protocol, current IEC approved version in study file: Comments:	☐ Yes ☐ No ☐ N/A
3. Informed Consent Documents (ICD), current IEC-approved version in study file: Comments:	☐ Yes ☐ No ☐ N/A
4. Assent Document current IEC-approved version in study file: Comments:	☐ Yes ☐ No ☐ N/A
5. CTRI application no.: Comments:	☐ Yes ☐ No ☐ N/A
6. Investigator Brochure/Device Manual in study file: Comments:	☐ Yes ☐ No ☐ N/A
7. Any other application/approval: Comments:	☐ Yes ☐ No ☐ N/A
8. Required Curriculum Vitae (CV) and IU on file (investigators and sub-investigator listed): Comments:	☐ Yes ☐ No ☐ N/A
9. Clinical laboratory certifications on file: Comments:	☐ Yes ☐ No ☐ N/A
10. Laboratory normals on file: Comments:	☐ Yes ☐ No ☐ N/A
11. Site signature log in study file: Comments:	☐ Yes ☐ No ☐ N/A
12. Subject enrollment screening log in study file: Comments:	☐ Yes ☐ No ☐ N/A
13. Staff training records in study file: Comments:	☐ Yes ☐ No ☐ N/A
14. Sponsor correspondence in study file: Comments:	☐ Yes ☐ No ☐ N/A

15. Sponsor monitoring log/reports in study file: ☐ Yes ☐ No ☐ N/A
Comments:

16. DCGI and all study related correspondence in file: ☐ Yes ☐ No ☐ N/A
Comments:

17. Questionnaire/survey/advertisements/current IEC approved version in study file: ☐ Yes ☐ No ☐ N/A
Comments:

18. All amendments/modifications/addendums to originally approved protocol or ICD in study file:
☐ Yes ☐ No ☐ N/A
Comments:

19. Waiver or modification of consent (IEC approved version) in study file:
☐ Yes ☐ No ☐ N/A
Comments:

20. Annual IEC review obtained: ☐ Yes ☐ No ☐ N/A
Comments:

21. Validity of Insurance: ☐ Yes ☐ No ☐ N/A

AUDIT WORKSHEET 2

Auditor:		Date:		IEC#	

SITE OPERATIONS

1. Documentation of P.I./Co-P.I. involvement in conducting and supervising study: ☐ Yes ☐ No ☐ N/A
Comments:

2. Responsibilities and tasks delegated to qualified personnel: ☐ Yes ☐ No ☐ N/A
Comments:
Screening and admission :
Receipt, handling, administration, return of IP

3. P.I./Co-P.I. directly involved in the ICD process: ☐ Yes ☐ No ☐ N/A
Comments:
Obtaining informed consent for first patient:

4. P.I./Co-P.I. or study personnel delegate available by phone 24 hours/day to study participants: ☐Yes ☐No ☐N/A
Comments:

5. Process in place to maintain study subject confidentiality: ☐ Yes ☐ No ☐ N/A
Comments:

6. All investigators and study personnel completed required research training: ☐ Yes ☐ No ☐ N/A
Comments:

7. Determine site SOP is well established for study activities: ☐ Yes ☐ No ☐ N/A
Comments: Any modifications?

AUDIT WORKSHEET 3

Auditor:		Date:		IEC#	

PROTOCOL COMPLIANCE

1. Inclusion/Exclusion criteria met per IEC approved protocol: ☐ Yes ☐ No ☐ N/A
Comments:

2. Screening, study treatment/procedures, performed per IEC approved protocol: ☐ Yes ☐ No ☐ N/A
Comments:

3. Study administered by IEC authorized personnel only and at approved sites: ☐ Yes ☐ No ☐ N/A
(Look for signatures or notes by personnel not on the list, especially in CRFs)
Comments:

4. Only IEC protocol approved concomitant – treatment or medications administered: ☐ Yes ☐ No ☐ N/A
Comments:

5. Modifications to the study protocol prior to IEC approval or exemption: ☐ Yes ☐ No ☐ N/A
Comments:

6. IEC approved study protocol follow-up procedures performed: ☐ Yes ☐ No ☐ N/A Comments:
7. Drug, Device or test article administration errors: ☐ Yes ☐ No ☐ N/A Comments:

AUDIT WORKSHEET 4

Auditor:		Date:		IEC#	

INFORMED CONSENT DOCUMENTATION

1. IEC approved ICD correct current version used and in study file: Consent obtained prior to study procedures/and or screening as applicable: ☐ Yes ☐ No ☐ N/A Comments:
2. ICD in each patients source document/medical record: ☐ Yes ☐ No ☐ N/A Comments:
3. ICD's signed/thumb impression, personally dated and witnessed: ☐ Yes ☐ No ☐ N/A Date of signing ICF by the first subject: Comments:
4. Signature/details of impartial witness in case of illiterate subject or Illiterate representative ☐ Yes ☐ No ☐ N/A
5. Assent document signed dated and witnessed: ☐ Yes ☐ No ☐ N/A Comments:
6. Consent process documented in source document/progress notes: ☐ Yes ☐ No ☐ N/A Comments:
7. Consent is completed and signed and dated by investigator: ☐ Yes ☐ No ☐ N/A Comments:
8. Subject or legally authorized representative provided with a copy of the consent document: ☐ Yes ☐ No ☐ N/A Comments:
9. All additional consent documents signed, dated and witnessed. (e.g., consent to collect/ take/ store,

specimens, audio/video images): ☐ Yes ☐ No ☐ N/A
Comments:

AUDIT WORKSHEET 5

Auditor:		Date:		IEC #	

PARTCIPANT RECORDS

1. Subject records/source documents organized, readable and secured.: ☐ Yes ☐ No ☐ N/A
How did the investigator identify participants?
Date of enrolment – first and last participant
Comments:

2. Subject case history documented to include information, data, and observations of subjects condition at time of enrollment. ☐ Yes ☐ No ☐ N/A
Comments:

3. Study events and progress notes on the conditions of the subject throughout participation in the study: ☐ Yes ☐ No ☐ N/A
Comments:

4. Data collected in source documents are also recorded on Case Report forms as appropriate or equivalent record: ☐ Yes ☐ No ☐ N/A
Comments:

5. All copies correspondence with the subject is in the official record: ☐ Yes ☐ No ☐ N/A
Comments:

6. Information, data, observation of subjects condition at end of study: ☐ Yes ☐ No ☐ N/A
Comments:

7. Subject withdrawal from research participation including reason documented: ☐ Yes ☐ No ☐ N/A
Comments:

8. Subject compensation is documented and concurs with the IEC approval for compensation in the informed consent document: ☐ Yes ☐ No ☐ N/A
Comments:

AUDIT WORKSHEET 6

Auditor:		Date:		IEC#	

SAFETY MONITORING

1.All Adverse Events (AE) reported to the IEC, sponsor and appropriate regulatory agency within required timeline requirements:
Date of last follow up of any subject: ☐ Yes ☐ No ☐ N/A
Comments:

2. Serious Adverse Events (SAE) followed to resolution, return to baseline, completion, or judged acceptable by the IRBs and Principal Investigator: ☐ Yes ☐ No ☐ N/A
Comments:

3. All adverse events recorded in subjects record, source document, and CRF or equivalent: ☐ Yes ☐ No ☐ N/A
Comments:

4. All protocol deviations reported to the IEC, Sponsor and appropriate regulatory agency within required timeline: ☐ Yes ☐ No ☐ N/A
Comments:

5. All Data Safety Monitoring Board (DSMB) reports sent to the IEC: ☐ Yes ☐ No ☐ N/A
Comments:

6. IEC notified of unanticipated problems involving risk to subjects at site: ☐ Yes ☐ No ☐ N/A
Comments:

7. All External SAE, Safety Reports submitted to the IEC within required timeline: ☐ Yes ☐ No ☐ N/A
Comments:

8. Periodic Progress reports sent to the IEC if applicable: ☐ Yes ☐ No ☐ N/A
Comments:

9. IEC approval of any changes in research activity as required by regulations and guidelines: ☐ Yes ☐ No ☐ N/A
Comments:

10. All correspondence (e.g., e-mail, letters) to and from the IEC on file: ☐ Yes ☐ No ☐ N/A
Comments:

AUDIT WORKSHEET 7

Auditor:		Date:		IEC#	

DRUG/DEVICE/TEST ARTICLE ACCOUNTABILITY

1. Records of receipt of drug/device/test articles in study file: ☐ Yes ☐ No ☐ N/A
Date of first administration of IP:
Comments:

2. All drugs/devices/test articles secured and stored properly (i.e. temperature log, light protections, etc.) Comments:	☐ Yes ☐ No ☐ N/A
3. Inventory Log – organized, completed, available: Comments:	☐ Yes ☐ No ☐ N/A
4. Drug/device/test article name, dosage strength, and form type: Comments:	☐ Yes ☐ No ☐ N/A
5. Lot number Comments:	☐ Yes ☐ No ☐ N/A
6. Expiration date: Comments:	☐ Yes ☐ No ☐ N/A
7. Date and quantity dispensed: Comments:	☐ Yes ☐ No ☐ N/A
8. Amount transferred/returned/destroyed: Comments:	☐ Yes ☐ No ☐ N/A
9. Date and quantity returned by study participant: Comments:	☐ Yes ☐ No ☐ N/A
10. Date and quantity returned to sponsor: Comments:	☐ Yes ☐ No ☐ N/A
11. Chain of custody per regulations or protocol: Comments:	☐ Yes ☐ No ☐ N/A
12. Drug/device/test article used for protocol purposes only: Comments:	☐ Yes ☐ No ☐ N/A
13. Drug/device/test article manual/package insert information in file: Comments:	☐ Yes ☐ No ☐ N/A

Study Participant Queries or Complaints

INSTRUCTIONS: *This form can be accomplished by any IEC-ICH personnel who receive queries, complaints, or grievances from study participants of any study protocol under the responsibility of the IEC-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.: IEC/		
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 (IEC-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 IEC 6.2. ☐ Expedited Review at the level of IEC Chair		
7. **Signature of IEC-ICH Personnel:**		

Recommended Action: *(for IEC-ICH use only)* ☐ Uphold original approval with no further action ☐ Request information: *(indicate information)* ☐ Recommend further action: *(indicate action)*	
IEC SECRETARY Date: *<dd/mm/yyyy>*	Signature _____ Name *<title, name, surname>*
IEC CHAIR Date: *<dd/mm/yyyy>*	Signature _____ Name *<title, name, surname>*

ADDITIONAL STUDY MATERIAL FOR APPROVAL FORM

INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR: *An additional study material is a written description of change(s) to or formal clarification of a protocol and/or informed consent documents. Favorable opinion or approval should be obtained from the IEC-ICH that issued the ethical clearance or approval prior to the implementation of an amendment. Please fill up this form and encode all information required in the space provided. Multiple amendments classified under ONE type of review (expedited or full review) can be submitted in one form. Please date and sign this form before submission.*

Study No.: IEC/		
Study Protocol Title:		
Approval Date:		
Principal Investigator:		
E-mail:	**Telephone:**	**Mobile:**
Study Site:		
Study Site Address:		
Sponsor:		
Sponsor Contact Person:		
E-mail:	**Telephone:**	**Mobile:**
Amendment Submission Date: *(to be filled out by IEC-ICH)* <dd/mm/yyyy>		
1. **No. of Study Material/s Submission:**		
2. **State Nature of Additional Study Material and reason for submission:**		
3. **Type of Review**: *(for IEC-ICH use ONLY)* 3.1. ☐ **EXPEDITED** Review for Amendments that: ▪ Do not involve changes in study populations ▪ Do not involve the collection of stigmatizing information ▪ Do not change approved us of anonymized or archived samples ▪ Do not involve further recruitment of participants ▪ Involve study protocols previously classified under expedited review ▪ Are administrative in nature (such as contact details of study personnel) ▪ Do not materially affect the risk-benefit ratio of the approved protocol or increase risks to study participants 3.2. ☐ **FULL BOARD REVIEW** for any amendments not cited under EXPEDITED REVIEW		
Signature of Principal Investigator:		
Comments/Findings: *(for IEC-ICH use only)*		
Recommended Action: *(for IEC-ICH use only)* ☐ APPROVAL ☐ MINOR MODIFICATION TO THE STUDY PROTOCOL, SUBJECT TO EXPEDITED REVIEW AT THE LEVEL OF THE CHAIR ☐ MAJOR MODIFICATION TO THE STUDY PROTOCOL, SUBJECT TO FULL BOARD REVIEW ☐ DISAPPROVAL		
IEC REVIEWER Date: *<dd/mm/yyyy>*	Signature _____ Name *<title, name, surname>*	

Documentation and Archiving

SOP Code: SOP 05/V6

Reviewed By:

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

Approved By

Name and Position in IEC	Signature
Dr. Phalguni Dutta Chairperson	

Accepted By

Name and Position in ICH	Signature
Prof. Apurba Ghosh Executive Director	

TABLE OF CONTENTS:

Supersedes	05
Version	06
Authored By	SOP Team
Version Date	17 September 2022
Approved By	Dr. Phalguni Dutta
Effective Date	05 December 2022

1. OBJECTIVES

This SOP describes how the IEC- 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 IEC- 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 IEC- ICH approval or undergoing IEC- 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, IEC documents, and correspondences.

3. RESPONSIBILITIES

The Secretariat Staff, under the supervision of the IEC Secretary, has the primary responsibility for study protocol and administrative documentation and archiving. The IEC 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, IEC Secretary
Approve the Minutes ↓	IEC Chair and IEC Secretary
Store the approved Minutes	Secretariat Staff

DETAILED INSTRUCTIONS:

a. Preparation of the Template of the Minutes of the Meeting

i. The IEC Secretary and Secretariat Staff use the **IEC-*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 IEC Secretary within seven (7) days after the meeting for form and content corrections and finalization. The finalized draft is sent to the IEC 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 person who prepared the Minutes Date of completion
- Name and signature of the IEC Secretary to indicate that the contents have been verified and corrected
- Name and signature of the IEC Chair to indicate approval
- Date of approval by the IEC chair

c. Approval of the Minutes

i. The IEC 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 **IEC-ICH 5-B:** ***Approval Letter to Study Protocol within 20 days of IEC meetings.***

2. Action letter or notification letter in response to specific kind of application submitted to the *IEC*

a. **IEC-ICH Form 5-C:** *Action Letter to Study Protocol Submissions/Resubmissions/Amendments*
b. **IEC-ICH Form 5-D:** *Letter for Clarificatory Interview-email communication in format*
c. **IEC-ICH Form 5-E:** *Approval Letter for Study Protocol Amendment Request*
d. **IEC-ICH Form 5-F:** *Notification Letter (Request Information) to Progress Report/Continuing Review Application/Final Report/Deviation- email communication in format*
e. **IEC-ICH Form 5-G:** *Archiving Notification- email communication in format*
f. **IEC-ICH Form 5-H:** *Notification Letter for Site Visit*
g. **IEC-ICH Form 5-M:** Notification Letter (Uphold Approval) for Continuing Review Application, Deviation/Non Compliance/Violation Report/Site Visit Report-hard copy
h. **IEC-ICH Form 5-L** ***:Certification of Board Action*** is issued to study protocols of clinical trial when asked for

d. **Storage of the Minutes**

i. The Secretariat Staff files the original copy of the Minutes in the Minutes Folder

ii. The Secretariat Staff makes copies of the minutes approved by the IEC Chair.

iii. The Minutes approved by the IEC 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 IEC - 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 IEC- 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 trial, 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 singed & 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) Its trial – 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 IEC 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 IEC.

iii. On a study-by-study basis, IEC Secretariat may communicate with site staff (clinical research coordinators) for intimation regarding SIVs, updates, notifications and other pertinent details.

iv. IEC 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. IEC 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 **IEC- ICH** are recorded in the ***Submissions Log*** **(IEC-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 IEC
- Further Action Required

c. Storage of Communication Records

i. Upon completion of the ***Submission Log*** **(IEC-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/*IEC* Chair
Sort and store documents ↓	Secretariat Staff
Dispose unnecessary copies	Secretariat Staff

DETAILED INSTRUCTIONS:

a. Sorting of all communication related to IEC Administration received and issued by the IEC- ICH

i. Communication with the office of DCGI

- IEC communicates to DCGI regarding any change in the composition of Ethics Committee

- The office is also intimated if there is change of PI in any clinical trial.
- SAE causality analysis & compensation (if applicable) within 30 days after receipt of analysis from PI within 14 days is sent to the DCGI.
- These are done through SUGAM portal in prescribed format to the DCGI office. An e-mail is simultaneously sent informing of the changes to the official e-mail of DCGI.

ii. Communication with Head of Institute and other departments of Institute

- The HOI is communicated with matters of IEC 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 clinical trial agreements.
- The HOI is communicated on financial matters such as budget allocation, IEC 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 IEC letterhead or via the official e-mail of the IEC.
- 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.

iii. Internal Communication within members

- The Chairperson/ member secretary communicates with the IEC 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.

iv. **Communication with research participants**

- The IEC 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 IEC SOP **(IEC-ICH Form 4-J, 2022. *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 IEC-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
- IEC- ICH members and staff files (CVs, Appointment letters, Signed
- ***Confidentiality Agreement and Conflict of Interest Disclosure*** **(IEC-*ICH* Form 2-D),** ***Training Records*** **(IEC-*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*** **(IEC-*ICH* Form 5-N)**.

v. Members' and staff files are filed alphabetically by last name.

vi. Only the most recently updated ***Curriculum Vitae*** **(IEC-*ICH* Form 2-C)** are filed in the individual member's or staff's file.

vii. Signed ***Confidentiality Agreement and Conflict of Interest Disclosure*** **(IEC-*ICH* Form 2-D)** and training certificates are filed chronologically under every member's or staff's file.

viii. ***Training Records*** **(IEC-*ICH* Form 2-E)** must be updated as each training certificate is submitted by the member or staff for filing.

ix. Active ICH-*IEC* 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

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-*IEC*
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

ii. Active files are study protocols that have been received by the ICH-*IEC* Secretariat and are either undergoing review (full board or expedited) or has been approved by the respective ICH-IEC Active study files are given a study number upon receipt by the *IEC*. The number is coded as follows IEC/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 *IEC* Secretariat). NNN continues chronologically even at the beginning of each year.

iii. 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
- Sponsor
- Members
- Date Received
- Date of IEC-ICH Review
- Date of Resubmission
- Date of Approval
- Date of Progress Report Submission
- 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
- ☐ 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-*IEC* 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*** **(IEC-ICH Form 4-D)** is approved by the IEC-ICH.

iv. The Secretariat Staff maintains Active Files cabinets under the supervision of the IEC 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 IEC-ICH) final reports, or
   - Study protocols declared Inactive by the Board if no communication is received from the study team for a period of twelve months
   - Study protocols submitted to the *IEC* but withdrawn by the PI or sponsor before approval is obtained
   - Study protocols submitted to and approved by the *IEC* but withdrawn by PI or sponsor before actual study start

ii. Upon receipt of **IEC-*ICH* Form 4-D: *Final Report Form***, the *IEC* reviews it in accordance with **SOP III-7: *Final Reports***.

iii. Upon approval of the **IEC-*ICH* Form 4-D: *Final Report Form***, the Secretariat Staff removes the contents of the entire file form the active study filing area and verifies that all documents are present in an organized manner.

iv. An archived number is assigned to the document by adding the last two digits of the year of archiving to the original control number <<IEC/nnn/yyyy/yy>>

v. Correspondingly, the data about the study and the year when archive should be entered on the Study Protocol Database.

b. Sorting of Archived Administrative Documents

i. The Secretariat Staff should perform inventories of miscellaneous administrative documents yearly.

Administrative documents that are related to any fund or money released by the IEC are required to be archived in a manner that allows easy retrieval for audit purposes. These include documents that specify issuance of honorarium, receipt of paid institutional fee (money which is passed or directly to the institution's Cash Section), approved annual budget and similar expense reports. One set of such documents are stored in the appropriate storage container/cabinet for archived administrative files.

ii. Unnecessary copies are disposed of accordingly (see section 6.d above).

c. Retrieval of Documents

i. Only authorized IEC-ICH Secretariat Staff can retrieve documents either from active study files or from the archives.

ii. Active or inactive study files can be borrowed, upon written request by the PI or the IEC-ICH personnel, and only for room use.

ii. Non-members can access specific documents upon formal request and completion/signing of ***Confidentiality Agreement for Non-Members Requesting Copies of IEC-ICH Documents*** **(IEC-*ICH* Form 5-J)**. The form requires the approval of the *IEC* Chair. Regulatory authorities have full access to ICH-*IEC* files provided it is within said authorities' mandate, and the request made in advance (at least 30 days notice) to make the files available.

iii. All requests for access are recorded by the Secretariat Staff in the ***Log of Request for Copies of Documents*** **(IEC-ICH Form 5-K)** before the documents are releases.

c. Reproduction of Confidential Documents

i. The request to make copies of any confidential documents should have been made in advance and should be approved by the IEC Chair.

ii. The Secretariat makes only the exact number of copies requested.

iii. The recipient signs for the copies requested in the ***Log of Request for Copies of Documents*** **(IEC-ICH Form 5-K)** upon receipt of the copies.

d. Maintenance of Log of Copies

i. The Secretariat Staff ensures the diligent recording of all document copies issued in the ***Log of Request for Copies of Documents*** **(IEC-ICH Form 5-K)**

This log is filed in a separate folder labeled **Log of Copies of Documents Issued.**

10. LIST OF FORMS

IEC-ICH Form 5-A	Format of the Minutes of the Meeting
IEC-ICH Form 5-B	Approval Letter to the Study Protocol
IEC-ICH Form 5-C	Action Letter to Study Protocol Submission/Resubmissions/ Amendments
IEC-ICH Form 5-D	Letter for Clarificatory Interview
IEC-ICH Form 5-E	Approval Letter for Study Protocol Amendment Request
IEC-ICH Form 5-F	Notification Letter (Request Information) to Progress Reports/Continuing Review Application/Final Report/Deviation
IEC-ICH Form 5-G	Archiving Notification
IEC-ICH Form 5-H	Notification Letter for Site Visit (Site Monitoring/Site Audit)
IEC-ICH Form 5-I	Borrowers Log
IEC-ICH Form 5-J	Confidentiality Agreement for Non-Members Requesting for Copies of IEC-ICH Documents
IEC-ICH Form 5-K	Log of Request for Copies of Documents
IEC-ICH Form 5-L	Certification of Board Action
IEC-ICH Form 5-M	Notification Letter (Uphold Approval) for Continuing Review Application,

iii. A ***Borrowers Log*** **(IEC-*ICH* 5-I)** is placed in a pocket on the study file folder cover, and contains the following information:
- Study file code
- Study title
- Date when borrowed
- Borrower
- Signature of borrower
- Signature of Secretariat Staff upon return of document to file box

9. MAINTAINING CONFIDENTIALITY (OF STUDY FILES AND ICH-IEC DOCUMENTS) WORKFLOW

ACTIVITY	RESPONSIBILITY
Classify documents as confidential ↓	IEC-ICH Chair and Members
Request access to ICH-IEC documents ↓	Members, Non-Members
Reproduce confidential documents ↓	Secretariat Staff
Maintain log of copies issued	Secretariat Staff

DETAILED INSTRUCTIONS:

a. Classification of Documents as Confidential

i. Access to confidential documents is restricted by the ICH-IEC to members and staff, but limited access can be provided to non-members who have a legitimate purpose to access the documents.

ii. The ICH-IEC considers the following as confidential:
- Study protocols
- Study protocols-related documents (case report forms, informed consent documents, diary forms, scientific documents, expert opinions or reviews)
- Minutes of meetings
- Decisions, action letters/notification of ICH-*IEC* decision, approval letters
- Study protocol-related communications

b. Access to Confidential ICH-*IEC* Documents

i. All *IEC* members and the staff with a signed ***Confidentiality Agreement and Conflict of Interest Disclosure*** **(IEC-*ICH* Form 2-D)** can have access to *IEC* confidential documents upon request.

	Deviation/Non-compliance/Violation Report/SAE or SUSAR Report/Site Visit Report
IEC-ICH Form 5-N	Submission Log
IEC-ICH Form 5-O	Reminder Letter for Progress/ Final Report(email)

Type of Meeting/
Meeting No nn/yyyy
Date of IEC Meeting:
<dd/mm/yyyy>, Venue, Time

Minutes of the IEC Meeting of <dd/mm/yyyy>

ATTENDANCE

Present
Member 1
Member 2
Member 3
Member 4
Member 5
Member 6
Member 7
Member 8
Member 9

Absent:

Others:
Independent Consultant

1. **CALL TO ORDER**
   <Title, First Name, Surname> IEC 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 IEC Secretary, <Title, First Name, and Surname>.

3. **DISCLOSURE OF CONFLICT OF INTEREST (COI)**
   <Title, First Name, Surname>, IEC Chair, called for the disclosure of the Conflict of Interest (COI) in the protocols scheduled for deliberation on the meeting.

   The following IEC member/s inhibited from participation in the IEC 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 IEC 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 IEC-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 IEC 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 IEC 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 IEC 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 IEC 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	
Primary Reviewers	
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		
Primary Reviewers		
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	
Primary Reviewers	
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	
Primary Reviewers	
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	
Primary Reviewers	
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	
Primary Reviewers	
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	
Primary Reviewers	
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	
Primary Reviewers	
Sponsor	
ACTION	Decision (Approval; Major Modification, which require full board deliberation; Minor Modification, which can be expedited at the level of the IEC 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	
Primary Reviewers	
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 IEC 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	
Primary Reviewers	
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 IEC 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	
Primary Reviewers	
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	
Primary Reviewers	
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	
Primary Reviewers	
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	
Primary Reviewers	
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> IEC Member Secretary
Approved by: Date: <dd/mm/yyyy>	Signature over <Title, Name, Surname> IEC Chair

<dd/mm/yyyy>

<Title, Name, Surname of PI>
Principal Investigator
<Institute>

Ref: <Study Protocol Title with version and date>
Study No: <IEC/ NNN/YYYY>

Sub: Final approval (Direct)

Dear <Title of PI, Surname>,

This has reference to your above mentioned project. The project was discussed in the Ethics Committee e-meeting held on dd/mm/yyyy at aa am/pm in the < ICH> and the following members were present:

SN	MEMBER	QUALIFICATION	DESIGNATION IN EC	GENDER	AFFILIATION WITH THE INSTITUTE
1					
2					
3					
4					
5					
6					
7					
8					
9					

The following documents were reviewed.....

The Ethics Committee hereby grants permission to conduct the clinical study in its presented form. Your study has been assigned study protocol code <Study No.> which should be used for all communication to the IEC-ICH related to this study. ***This ethical clearance is valid for one year from the date of CT approval.***

You can commence the clinical trial from the Institutional Ethics Committee following submission of the necessary documents: .....

You are required to report the following to the Ethics Committee:

- CTRI registration certificate
- 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 IEC 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
Institute of Child Health

<dd/mm/yyyy>

<Title, Name, Surname of PI>
Principal Investigator
<Institute>

Ref: <Study Protocol Title with version and date>
Study No: <IEC/ NNN/YYYY>

Sub: IEC approval (Indirect)

Dear <Title of PI, Surname>,

This has reference to your above-mentioned project. The project was discussed in the Ethics Committee e-meeting held on dd/mm/yyyy, where in certain queries were raised by EC members and communicated to you vide letter ICH/IEC/No/yyyy dated dd/mm/yyyy. Further your responses dated dd/mm/yyyy along with supporting documents were reviewed and approved.
The following documents were reviewed:

.....

The Institutional Ethics Committee hereby grants you permission to conduct the clinical study in its presented form. Your study has been assigned study protocol code <Study No.> which should be used for all communication to the IEC-ICH related to this study.

You can commence the clinical trial *only* after receipt of letter of final approval from the Institutional Ethics Committee following submission of the necessary documents:

- Final executed CTA

You are required to report the following to the Ethics Committee:

- CTRI Registration Certificate
- Any changes to or deviation to the protocol approved by the Ethics Committee that you may implement to eliminate hazards to the trial subjects.
- Any changes in the approved Informed Consent Form and Study documents.
- All Serious Adverse Events (SAE) should be informed by the PI to the Ethics Committee within 24 hours of the SAE.
- New information that may effect adversely the safety of the subjects or the conduct of the trial.
- Progress of the study at least once in four to six months
- Annual Progress Report (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
Institute of Child Health

<dd/mm/yyyy>

<Title, Name, Surname of PI>
Principal Investigator

Study No: <IEC/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 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 IEC-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 IEC 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 IEC-ICH should:

1. Be integrated into a revised Study Protocol and <**IEC-ICH Form 3-B, 2022. *Application Form*/IEC-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 IEC-ICH Secretariat.

The IEC-ICH looks forward to your immediate response and action.

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.

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
Institute of Child Health

<dd/mm/yyyy>

<Title, Name, Surname of PI>
Principal Investigator
<Institute>

Ref: <Study Protocol Title with version and date>
Study No: <IEC/ 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 IEC meeting>. Upon review, the IEC found issues requiring clarifications such as:

1.

In this regard, the Committee requests for a clarificatory interview with you during the next IEC meeting on <date of next full Board meeting> from <requested time> at the <venue>.

Should you have any questions or clarifications regarding the above mentioned recommendation, please contact the undersigned through the IEC-ICH Secretariat.

We look forward to your immediate response and action.

Very truly yours,

<Name of IEC, Chair>
Chair, IEC-ICH

<dd/mm/yyyy>

<Title, Name, Surname of PI>
Principal Investigator
<Institute>

Ref: <Study Protocol Title with version and date>
Study No: <IEC/ NNN/YYYY>

Sub: Approval of Amendments

Dear <Title of PI, Surname>,

This has reference to your above-mentioned project. The amended project was discussed and approved in the Ethics Committee e-meeting dated dd/mm/yyyy>. The following members were present:

	MEMBER	QUALIFICATION	DESIGNATION IN EC	GENDER	AFFILIATION WITH THE INSTITUTE
1					
2					
3					
4					
5					
6					
7					
8					
9					

The following documents were reviewed.

The Ethics Committee hereby grants permission to conduct the clinical study in its presented ***amended*** *form.* Your study has been assigned study protocol code <IEC/ NNN/YYYY>which should be used for all communication to the IEC-ICH related to this study. ***This ethical clearance is valid for one year from the date of CT approval.***

You can commence the clinical trial from the Institutional Ethics Committee following submission of the necessary documents:

You are required to report the following to the Ethics Committee:

- Updated CTRI registration certificate
- 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 IEC 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
Institute of Child Health

Email notification
<dd/mm/yyyy>

<Title, Name, Surname of PI>
Principal Investigator
<Institute>

Ref: <Study Protocol Title with version and date>
Study No: <IEC/ NNN/YYYY>

Sub: < Continuing Review Application/Final Report/Study Protocol Non-Compliance Record/SAE Report/Site Visit Report >

Dear <Title of PI, Surname>,

We wish to inform you that the ICH-Institutional Ethics Committee acknowledged receipt of <Continuing Review Application/Final Report/Study Protocol Non-Compliance Record/SAE Report/Site Visit Report> dated <date of document>.

Upon review of <IEC-ICH Form 4-C, 2022. *Continuing Review Application Form*/ IEC-ICH Form 4-D, 2022. *Final Report Form*/IEC-ICH Form 4-E, 2022. *Study Protocol Deviation or Non-Compliance Report*/IEC-ICH Form 4-H, 2022. *Serious Adverse Event Report Form*/IEC-ICH Form 4-G, 2022. *Site Visit Report*> and <submitted document/s, Board action is <Request Information/Recommendation for Further Action/Forward to AE Subcommittee>.

Recommended revision and or clarifications are summarized below:

1.

Please note that the cut-off date for submission is on <cut-off date>.

The IEC-ICH looks forward to your immediate response and action.

Very truly yours,

<Name of IEC, Member Secretary>
Member Secretary, IEC-ICH

BORROWERS LOG

Control No.

Borrower's Name	Signature	Date Borrowed	Received By	Date Received
<Title, Name, Surname>				

Email

<dd/mm/yyyy>

<Title, Name, Surname of PI>
Principal Investigator
Institute>

Ref: <Study Protocol Title with version and date>
Study No: <IEC/ 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 <IEC-ICH Form 4-D, 2022/ IEC-ICH Form 4-F, 2022>and <submitted document/s>, the IEC **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
Institute of Child Health

[redacted]

Confidentiality Agreement for Non-Members Requesting for Copies of IEC-ICH Documents

I, <Name, Surname> as a non-member of the IEC-ICH, understand that the copy/ies given to me by the IEC -ICH are confidential. I shall use the information only for the indicated purpose as described to the IEC-ICH and shall not duplicate, give or distribute these documents to any person(s) without permission from the IEC-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 IEC-ICH documents:

_____

_____

_____

_____

_____

_____

RECIPIENT

Date: <dd/mm/yyyy>

Signature

_____

Name

_____

IEC SECRETARY Date: *<dd/mm/yyyy>*	Signature _____ Name *<title, name, surname>*
IEC CHAIR Date: *<dd/mm/yyyy>*	Signature _____ Name *<title, name, surname>*

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: <IEC/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 IEC-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 IEC-ICH Form 4-D,2022, Final Report Form; or if still ongoing, IEC-ICH Form 4-B,2022, Progress Report (submitted six months after the date approval) and IEC-ICH Form 4-C,2022, Continuing Review Application (45 days before the lapse of six months following IEC 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 IEC-ICH Secretariat.

The IEC-ICH looks forward to your immediate response and action.

Thank you.

Yours sincerely,

_____

<name>
Member Secretary–Institutional Ethics Committee
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

DSMSC: Data and Safety Monitoring Sub-Committee

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 IEC-ICH and *approved without any stipulations* or *after stipulations/recommendations* by the IEC 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 care 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 behaviour 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 NDCT rules 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 remuneration 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 IEC information and documents to other than an authorized individual .
Conflict of interest (COI)	A conflict of interest arises when a member(s) of the IEC 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 IEC 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 IEC 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); • IEC 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 IEC approval granted only by the Chair of the IEC or a designated board member (not the full Board) for minor changes to current IEC-approved research activities and for research which involves no more than minimal risk.

Expedited review An ethics review of research protocol by the IEC chair or a designated voting member or subgroup of voting members rather than by the entire IEC. 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 IEC 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).
Monitoring visit	An action taken by the ICH-IEC or its representatives which involves going to a study site to assess how the principal investigators and the institute are conducting researches, taking care of participants, recording data and reporting their observations, especially serious adverse events found during the studies.
More that minimal risk	Occurs when the participants in the course of the research would be exposed to more than a remote possibility of a "substantial or prolonged pain, discomfort, distress" or "clinically significant deterioration of a medical condition"
Placebo	A substance that is not biologically active, does not interact with other substances nor is it expected to affect the health status of an individual. It is an inactive pill, liquid, or powder that has no treatment value. In clinical trial, experimental treatments are often compared with placebos to assess the experimental treatment's effectiveness. In some studies, the participants in the control group will receive a placebo instead of an active drug or experimental treatment.
Primary reviewer	A reviewer – member of the Institutional Ethics Committee to whom is assigned the function of full review of a study protocol and all submitted study materials with the aim of effecting a thorough review of them. The primary reviewer presents his/her review of the study protocol at the convened IEC meeting after which, discussion with other IEC members is made and finally, a vote for an action is taken.
Principal investigator	The chief or person primarily responsible for the implementation or a research project. *See also investigator.*
Privacy	The right or claim or state or ability or condition of an individual or group or institution to conceal or seclude or hide themselves or information about themselves and thus reveal or expose themselves selectively. It is a conceptual space defining the individual's boundary as a person, intrusion of which is limited by human rights and by law. It is right to determine when, how, and to what extent information about someone is communicated to others.

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 IEC, 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 information in the investigator's protocol or brochure, product or package inset or summary of product characteristic. *See also adverse event and serious adverse event.*
Voluntary	Free of coercion, duress, or undue inducement; used in the research context to refer to a subject's decision to participate (or to continue to participate) in a research activity.
Vulnerability	A substantial incapacity to protect one's own interest owing to such impediments as lack of capability to give informed consent, lack of alternative means of obtaining medical care or other expensive necessities, or being a junior or subordinate member a hierarchical group.
Vulnerable subjects/ participants/groups	Individuals or groups of individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests. These are also classes of individuals who have characteristics that lessen their capacity to protect their own interests or promote their own welfare; These are "persons whose situation or characteristics may make them unable to provide free and informed consent to participate in research. This group includes children, institutionalized persons, those who have cognitive impairments, and those in a position of inferiority"
Withdraw	Decision of the subject or respondent or patient to discontinue participating

REFERENCES

Sr.	Guidelines Title
1	Indian Good Clinical Practices
2	ICH- GCP, 1996
3	a)Draft Guidelines on Audio-visual recording of ICD process in clinical trial dated 16th January 2014
	b)G.S.R. 292(E)dated 24th April 2014
	c)G.S.R. 889(E) dated 12th December 2014 (SAE Timeline)
	d)G.S.R. 611(E) dated 31st July 2015 (Audio-visual for vulnerable population)
	e)G.S.R. 918 (E) dated 30th November 2015
	f)G.S.R. 313 dated 16th March 2016 (For Academic project)
	g) Draft Guidelines and formula for determining Compensation for Death and other than Death
	h)Guideline for International collaboration /research projects in Health research.
	i) DCGI Order dated 2013-11-19 on Audio Visual recording of Informed Consent.
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