INSTITUTIONAL HUMAN ETHICS COMMITTEE

STANDARD OPERATING PROCEDURES

Version 03.0
1st October 2021

ICMR - NATIONAL INSTITUTE OF EPIDEMIOLOGY

CHENNAI- 600077

PREFACE

In India, all research proposals on biomedical, social and behavioural science for health involving human participants, their biological material and data to be reviewed and approved by an appropriately constituted Ethics Committee to safeguard the dignity, rights, safety and well-being of all research participants according to the 'National ethical guidelines for biomedical and health research involving human participants, 2017'.

The Institutional Human Ethics Committee (IHEC) of ICMR-National Institute of Epidemiology (ICMR-NIE) was established in 2011 to provide independent guidance, advice and decision on health or other specific research protocols involving human participants submitted to the IHEC by the researchers of ICMR-NIE. The IHEC is composed of both scientists and non-scientists. It is independent in its reflection, advice and decision.

The Standard Operating Procedures (SOPs) IHEC of ICMR-NIE has been prepared in compliance with the applicable national and international ethical guidelines. It provides clear, unambiguous instructions to the members of IHEC for conducting activities of the IHEC and to the researchers of ICMR-NIE as guidance for carrying out the research activities in an ethical manner. The document will provide a good check and balance system in research, protect human research participants, and contribute to quality data. The implementation of SOPs is further supported by the Institutional rules/regulations of ICMR-NIE.

This version of SOPs (IHEC/SOP/03.0) is the revision to update the existing SOPs based on latest ICMR guidelines.

Dr. Manoj Murhekar

Director

1st October 2021

Institutional Human Ethics Committee
ICMR- National Institute of Epidemiology

Standard Operating Procedures
Version 03.0, Dated 1st October 2021

Effective Date: 1st October 2021.

Supersedes: SOP for NIE IHEC Functioning 03.0

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Approved by

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List of SOPs

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

SOP/001/03.0
Effective Date: 1st October 2021

1. Purpose

This SOP defines the process for writing, reviewing, distributing, and amending SOPs within the IHEC, ICMR-NIE.

The SOPs will provide clear, unambiguous instructions to conduct activities of the IHEC in compliance with National Ethical Guidelines for Biomedical and Health Research involving Human Participants provided by ICMR-2017, National Guidelines for Ethics Committees Reviewing Biomedical & Health Research During Covid-19 Pandemic (2020) Ethical guidelines provided by ICMR – 2006 and Schedule 'Y" (Drugs and Cosmetics Act 1940), MoHFW (Department of Health) Notifications 20th January 2005 (Requirements and guidelines for permission to import and/or manufacture of new drugs for sale or to undertake clinical trials), 30th January 2013 (Compensation in case of injury or death due to clinical trial), 1st February 2013 (Permission to conduct clinical trials), 8th February 2013 (Registration of Ethics Committee), ICH guidelines and CDSCO GCP Guidelines, Re-Registration of ethics committees on 27th Dec 2016 as per the provisions of rule 122 DD of drugs and cosmetics rules. The projects will also be re viewed with reference to the guidelines/regulations of the country of origin of the sponsor for international studies.

2. Scope

The scope of this SOP will apply to the procedures of writing, reviewing, distributing, and amending SOPs within the IHEC, Secretariat and investigators of ICMR-NIE.

3. Responsibilities

It is the responsibility of the Director, ICMR-NIE to appoint the SOP Team to formulate the SOPs by following the same procedures, format, and coding system when drafting or editing any SOP of the IHEC. The SOP team will prepare the draft SOPs.

3.1 Secretariat of IHEC:

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

3.2 SOP team:

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

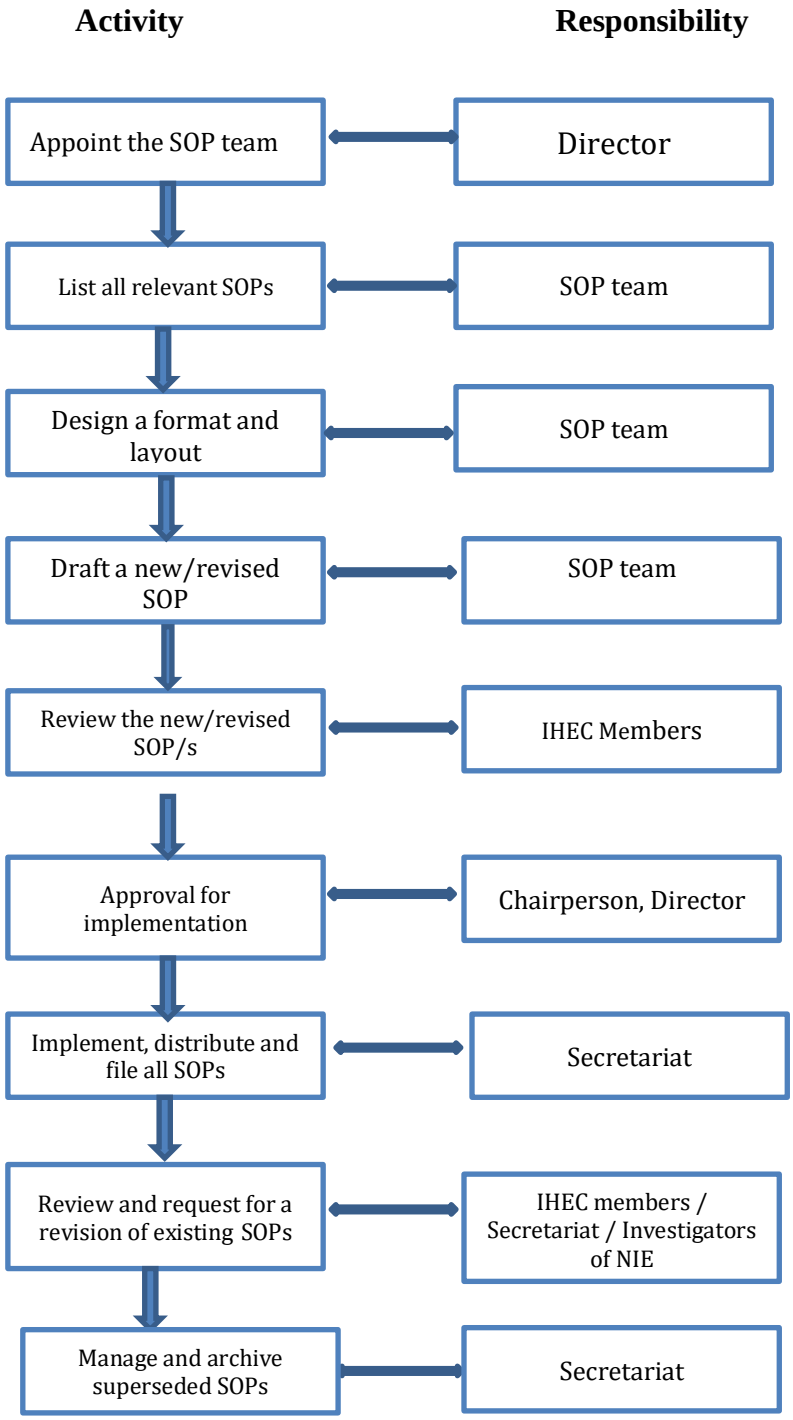
3.3 Chairperson of the IHEC:

a. Reviews and approves the SOPs
b. Signs and dates when receives the approved SOPs

3.4 Ethics Committee Members:

a. Review the draft SOPs when received from the SOP team and provide suggestions/comments on the same
b. Sign and date when they receive the approved SOPs
c. Maintain a file of all SOPs received
d. Return all out-of-date SOPs to the Secretariat upon receipt of the new/revised SOPs

4 Flow Chart


Activity
Responsibility
Appoint the SOP team
Director
List all relevant SOPs
SOP team
Design a format and layout
SOP team
Draft a new/revised SOP
SOP team
Review the new/revised SOP/s
IHEC Members
Approval for implementation
Chairperson, Director
Implement, distribute and file all SOPs
Secretariat
Review and request for a revision of existing SOPs
IHEC members / Secretariat / Investigators of NIE
Manage and archive superseded SOPs
Secretariat

5 Detailed instructions

5.1 Identify the need for new or amendment to the SOP

Any member of the IHEC, secretariat or investigators of NIE, can make a request for designing an entirely new SOP or part of SOP, can put forth his / her request by using the Request Form for Formulation of new SOP/ Revision of an SOP Form (AF 05-001/03.0). This Formulation of new SOP/ Revision of an SOP Form (AF 05-001/03.0)are submitted to the Secretariat. The Secretariat will forward the request to the Chairperson, IHEC and Director, ICMR-NIE. The Chairperson will inform all IHEC members about this request in a regular full board meeting.
If IHEC members agree to the request, the information will be discussed with the Director and he/she will appoint an appropriate SOP team.

5.2 Appoint the SOP Team

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

5.3 List all relevant SOPs

The SOP team will

a. Write down step by step all IHEC procedures.
b. Organize, divide and name each process.
c. Make a list of SOPs with coding reference (Annex 1: AF 01-001/03.0)

5.4 Design a Format and layout

Each SOP should be given a number and a title that is self-explanatory and is easily understood. A unique code number with the format SOP/XXX/YY.W will be assigned to each SOP item by the Secretariat.*XXX* is a three-digit number assigned specifically to the SOP. *YY* is a two-digit number identifying the version of the SOP, and *W* is a one-digit number identifying the version of SOP with minor changes in the SOP. The number of version should be started from 01 and the W should be started with 0, for example, SOP001/01.1 is the SOP number 001 version 01 with one minor revision i.e. 01.1.
Each annex will be given unique code number with the format *AF/BB-XXX/YY.W*. AF is the abbreviation for Annex Form. BB is a two-digit number identifying the number of the annex, for example AF/01-001/01.0 means Annex Form number one of the *SOP/001/01.0*
Each SOP will be prepared according to the template for standard operating procedures (Annex 2 –AF 02-001/03.0*)*.

5.5 <u>Write, Review and Approve new SOP</u>

With reference to section 5.3 and 5.4 the SOP team will prepare the draft SOP. If an SOP supersedes a previous version, indicate the previous SOP version and the main changes in SOP/001/03.0
SOP/001/03.0

The Document History form (Annex 3 – AF 03-001/03.0).

5.6 <u>Reviews by Consultation</u>

The draft SOP should be discussed and consulted with ICMR-NIE scientists before discussion with IHEC members. The draft SOP will be discussed with members of IHEC

during the full board meeting. Members can put forth their suggestions / comments on the draft / revised SOP. The suggestions agreed upon unanimously by all IHEC members will be incorporated and the final draft SOP will be formulated. The final version will be reviewed and approved by the Chairperson, IHEC. The Chairpersons will sign and date the SOP on the first page of the SOP document.
This approved document will then be submitted to the Director, ICMR-NIE for acceptance for implementation in the Institute. This date of approval is declared as the effective date for implementing the SOP.
The SOP team would stand automatically dissolved once the Chairperson IHEC takes the final decision regarding the SOP.

5.7 Implement, distribute and file all SOPs

The approved SOPs will be implemented from the effective date and will be distributed to the IHEC members, and the investigators by the Secretariat according to the distribution list (Annex 4 – AF 04-001/03.0). For public access, two printed and signed copies will be displayed in the library, NIE and the PDF version of the SOP will be published in the NIE website (www.nie.gov.in).
When revised version is distributed, the old version will be retrieved from all persons and destroyed. The old version will be no longer effective. One complete original set of current SOPs will be filed centrally in the SOP Master file, by the Secretariat and keep the file in the Secretariat.
Photocopies made from the paper versions of the SOP will be considered official only if stamped and signed by the Member Secretary. A distribution log should be maintained (AF 04-001/03.0)

5.8 Review and request for a revision of an existing SOP

Any member of the IHEC, Secretariat or investigators of NIE who notices an inconsistency between two SOPs or has any suggestions on how to improve a procedure should use the form in (Annex 5 – AF 05-001/03.0) to make a request. If the IHEC agrees with the request, an appropriate team will be designated by the Director to proceed with the revision process. If the committee does not agree, the Secretariat will inform the person who made the request of the decision.
Revision of the SOPs will be reviewed and approved in the same manner as new SOPs.
The Secretariat will regularly prepare the amendment or addendum (if any) to the existing SOP according to the approved discussion points in the IHEC meetings.The Secretariat will review the SOPs at least every 2years and incorporate the addendum and record the dates of review on the SOP Master file.

5.9 Manage and archive superseded SOPs

Superseded SOPs should be retained and clearly marked “superseded” and archived in the historical file by the Secretariat**.** The process of evolution of previous SOPs of the IHEC will be documented in a defined format (AF 03-001/03.0).

6 References

1. WHO Operational Guidelines for Ethical Review Committee that Review Biomedical Research (Geneva 2000) WHO Operational Guidelines for Ethical Review Committee that Review Biomedical Research (Geneva 2000)
   Retrieved from - *www.who.int/tdr/publications/publications /* accessed 24 March 2008
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) (1996) International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) (1996)
   Retrieved form - *http://www.ich.org/LOB/media/MEDIA482.pdf* accessed on 24 March 2008
3. ICMR Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006)
   Retrieved from - *http://www.icmr.nic.in/ethical guidelines.pdf* accessed 24 March 2008
4. Schedule Y (Drugs and Cosmetic Act 1940; amendment 20th January 2005) Retrieved from - *http://www.cdsco.nic.in/html/Schedule-Y 20 (Amended 20Version- 2005)* accessed 24 March 2008 Schedule Y (Drugs and Cosmetic Act 1940; amendment 20th January 2005) Retrieved from - *http://www.cdsco.nic.in/html/Schedule-Y 20 (Amended 20Version-2005)* accessed 24 March 2008

7 ANNEX

ANNEX 1	AF 01-001/03.0	List of IHEC SOPs
ANNEX 2	AF 02-001/03.0	Template for Standard Operating Procedures
ANNEX 3	AF 03-001/03.0	Document History
ANNEX 4	AF 04-001/03.0	Log of SOP Recipients
ANNEX 5	AF 05-001/03.0	Request for Revision of an SOP

Annexure: AF 01-001/03.0

List of SOPs

Topic No.	Topics/ Standard Operating Procedures (SOPs)	SOP Code
1	Preparing Standard Operating Procedures (SOPs): Writing, Reviewing, Distributing & Amending SOPs for the Institutional Human Ethics Committee (IHEC)	SOP/001/03.0
2	Constitution of Institutional Human Ethics Committee (IHEC)	SOP/002/03.0
3	Management of protocol submissions	SOP/003/03.0
4	Full review of initial study protocols	SOP/004/03.0
5	Continuing review of study protocol report	SOP/005/03.0
6	Expedited Review of Submitted Protocols / Documents	SOP/006/03.0
7	Exemption from ethical review of research projects	SOP/007/03.0
8	Review of amendments of protocols and related documents	SOP/008/03.0
9	Recruiting vulnerable population	SOP/009/03.0
10	Review of serious adverse events (SAE) reports	SOP/010/03.0
11	Board Meeting procedures	SOP/011/03.0
12	Documentation of IHEC Activities	SOP/012/03.0
13	Management of Premature Termination/Suspension/ Discontinuation of the study	SOP/013/03.0
14	Site monitoring	SOP/014/03.0
15	Reporting of protocol deviation, non-compliance and violation	SOP/015/03.0
16	Dealing Participants' Requests/Complaints	SOP/016/03.0
17	Review of Study Completion Reports	SOP/017/03.0
18	Maintenance of active project files, archival/disposal of closed files and retrieval of documents	SOP/018/03.0
19	Online Ethics Committee Meeting Procedures	SOP/019/03.0
20	Review of COVID-19 research proposals	SOP/020/03.0
21	Review of studies on Public health response to outbreaks [PHRO Review]	SOP/021/03.0
22	Formation of subcommittee	SOP/022/03.0

Annexure: AF 02/ 001/**03.0**

Template for Standard Operating Procedures

Name of Institution		
Title:	*Title which is self-explanatory and is easily understood*	
SOP No:	*SOP/xxx/yy.w*	Page: ? of ?

TITLE
Title which is self-explanatory and is easily understood

Effective Date:
Supersedes:

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

Main Text:

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

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

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

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

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

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

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

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

Annexure: AF 03/001/03.0

Document History

Author –	**Version**	**Date**
R. Prabu	0	*11.04.2012*
R. Prabu	1.0	*28.10.2013*
R. Prabu *Tarun Bhatnagar* *P.Manickam* *P. Ganesh Kumar* *R.Ramakrishna Rao* *R. Vijayaprabha*	02.0	*28.10.17*
R. Prabu *Tarun Bhatnagar* *P.Manickam* *P. Ganesh Kumar* *B. Ganesh* *Subhendhu Acharya* *R.Ramakrishna Rao* *R. Vijayaprabha*	0.21	*10.11.2017*
Authors: *Dr. Bhavani Shankara Bagepally, Scientist D/Member Secretary* *Dr. Tarun Bhatnagar, Scientist E* *Dr. P. Manickam, Scientist E* *Dr. P. Ganesh Kumar, Scientist D* *Dr. R. Prabu, Scientist D* *Dr.Jayshree Katheeresan Scientist-D* *Dr.Rizwan Scientist-D* *Dr. Sirshendu Choudary, Consultant* *Dr.Rajalakshmi,Consultant.* *Dr.Meenakumari Natarajan Project Scientist-C* *Mr. R. Ramakrishna Rao, Senior Technical Officer/Coordinator* *Mrs. R. Vijayaprabha, Technical Officer/Coordinator*	03.0	*01.07.2021*

Annexure: AF 04/001/03.0

Table 1: Log of SOP Recipients in IHEC

No.	Name of Recipients	SOP#	#of Copies	Signature	Date
1	*Chairperson*	*SOP/001/03.0* *SOP/002/03.0* *SOP/003/03.0*			
2	*Dr. XXXX*	*SOP/001/03.0* *SOP/002/03.0* *SOP/003/03.0*			

Table 2: Log of other persons receiving SOPs

No.	Name of the recipient with designation	SOP #	# of copies	Signature	Date
1					
2					
3					
4					

Standard Operating Procedures -- Institutional Human Ethics Committee
ICMR- National Institute of Epidemiology

Annexure: AF 05/001/03.0

Request for formulation of new/Revision of an SOP

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

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

Constitution of Institutional Human Ethics Committee (IHEC)

SOP/002/03.0
Effective Date: 1st October 2021

1.Purpose

The IHEC was established to formalize and specify Institution's commitment to the promotion of high scientific and ethical standards in research conducted at & by ICMR-NIE by valuing community interests. The purpose of the IHEC is to protect the dignity, rights, welfare of participants of research. It will also cultivate a pluralistic and democratic exchange of scientific and ethical values and concerns, and to critically analyze them while looking for opportunities to enhance the scientific and ethical integrity of Institution.

2. Scope

This SOP applies to the constitution of the IHEC. The NIE-IHEC will review all research projects undertaken in and by NIE for compliance with National Ethical Guidelines for Biomedical and Health Research involving Human Participants provided by ICMR-2017, Ethical guidelines provided by ICMR – 2006 and MoHFW (Department of Health Research) Notification 20th January 2005 (Requirements and guidelines for permission to import and / or manufacture of new drugs for sale or to undertake clinical trials), 30th January 2013 (Compensation in case of injury or death due to clinical trial), 1st February 2013 (Permission to conduct clinical trials), 8th February 2013 (Registration of Ethics Committee), ICH guidelines and CDSCO GCP Guidelines. Re-Registration of ethics committees on 27th Dec 2016 as per the provisions of rule 122 DD of drugs and cosmetics rules. The projects will also be reviewed with reference to the guidelines/regulations of the country of origin of the sponsor for international studies.

3. Responsibility

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

a. Ensuring the competent review and evaluation of all the scientifis and ethical aspects of research projects received compliance with the appropriate laws, and welfare of participants.
b. Creation, development, revision and implementation of SOPs /guidelines for the IHEC
c. Continuing education and training programs of IHEC members to ensure that they are qualified to perform their specific duties and maintain the quality of review

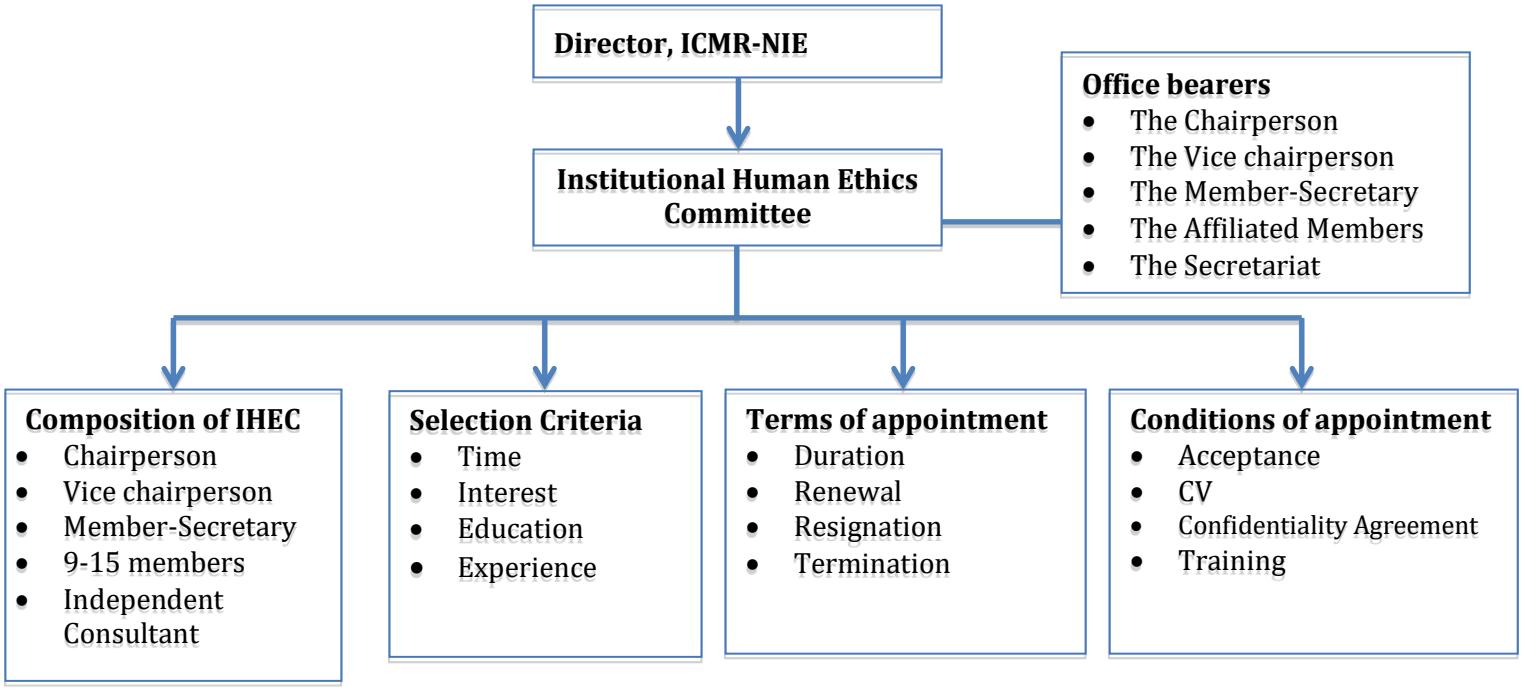
3.1 **Mandate of IHEC**

The IHEC through its Members independently functions for maintaining a consistent scientific and ethical framework for research, integrating ethical values into practice, policy relationships, and organizational activities. related to research

3.2. Terms of Reference

a. Ensure the highest ethical and scientific standards of research at ICMR-NIE
b. Review and approve, proposals for clinical, basic, translational and public health research projects (Intra and Extra mural), in which at least one investigator is a regular employee of ICMR-NIE, for scientific and ethical content.
c. Improve ethical standards and issue guidelines on ethical dilemmas related to human participants' in research projects of NIE
d. Function as a forum to advise the investigators in case of any ethical issues that may arise from human research participants, families or public
e. Maintain ICMR's leadership as a national standard of reference in the fields of public health research
f. Update and revise SOPs and guidelines periodically, for effective functioning of IHEC as and when necessary

4. **Flow Chart**


Director, ICMR-NIE
Institutional Human Ethics Committee
Office bearers
The Chairperson
The Vice chairperson
The Member-Secretary
The Affiliated Members
The Secretariat
Composition of IHEC
Chairperson
Vice chairperson
Member-Secretary
9-15 members
Independent Consultant
Selection Criteria
Time
Interest
Education
Experience
Terms of appointment
Duration
Renewal
Resignation
Termination
Conditions of appointment
Acceptance
CV
Confidentiality Agreement
Training

5. **Ethical basis**
   a. The committee consists of members who collectively have the qualifications and experience to review and evaluate the scientific, and ethical aspects of a proposed research project.
   b. The IHEC recognizes that national and/ or local ethics committees and concerned regulatory bodies to review the approved protocols (and vice versa) prior to their implementation in study settings as specified in the protocol
   c. In evaluating protocols and ethical issues, the IHEC is aware of the diversity of laws, cultures and practices governing research and medical practices in various countries around the world
   d. The IHEC also seeks to be informed, from researchers about the impact of the research projects it has approved.
   e. The IHEC is guided in its reflection, advice and decision by the ethical principles expressed in the Declaration of Helsinki (Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964, and amended by the 29th World Medical Assembly, Tokyo, Japan, October 1975; 35th World Medical Assembly, Venice, Italy, October 1983; 41st World Medical Assembly, Hong Kong, September 1989; 48th World Medical Assembly, Somerset West, Republic of South Africa, October 1996; and the 52nd World Medical Assembly, Edinburgh, Scotland, October 2000; Note of Clarification on Paragraph 29 added by the World Medical Assembly, Washington 2002; Note of Clarification on Paragraph 30 added by the World Medical Assembly, Tokyo 2004, 59th WMA general Assembly, Seoul, October 2008,64th WMA General Assembly, Fortaleza, Brazil, October 2013).
   f. It makes further reference to the International Ethical Guidelines for e.g. The Nuremburg Code (1945), the Council of International Organizations of Medical Sciences (CIOMS), the Belmont Report 1979, the International Ethical Guidelines for Biomedical Research Involving Human Subjects (Geneva 2002), and the European Convention on Human Rights and Biomedicine 1977
   g. The IHEC establishes its own Standard Operating Procedures based on the National Ethical Guidelines for Biomedical and Health Research involving Human Participants provided by ICMR-2017, ICMR guidelines (2006), Schedule Y (Drugs and Cosmetics Act 1940, amendment 20th Jan 2005, 30th January 2013 - Compensation in case of injury or death due to clinical trial, 1st February 2013 - Permission to conduct clinical trials, 8th February 2013 -Registration of Ethics Committee), Operational Guidelines for Ethics Committees that Review Biomedical Research (WHO 2000), and ICH-GCP, 1996. IHEC seeks to fulfill the requirements for international assurances and is established and functions in accordance with the national law and regulations

6. Composition and Constitution of IHEC

IHEC will be multi-disciplinary and multi-sectoral in composition. It is composed of a minimum of 8 and maximum of 15 members. They will collectively possess the qualifications and experience to review and evaluate the scientific, medical and ethical aspects of the proposed projects in NIE.

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

6.1Composition shall be as follows:

a. Chairperson
b. Vice-chairperson

c. At least Two persons from basic medical sciences
d. At least Two clinicians
e. At least One legal expert
f. At least One philosopher/ ethicist/ theologian/Social Scientist
g. At least One lay person from the community
h. Member Secretary

7. Membership

The Director, ICMR-NIE, will appoint all members. including the Chairperson. Director will act as an appellate authority or to handle disputes arise related to ethics committee. The Director, ICMR-NIE will nominate one staff member of ICMR-NIE as IHEC Member-Secretary. The IHEC Member-Secretary will coordinate between IHEC, Investigators and the Director ICMR-NIE to ensure the mandate of IHEC is achieved.

7.1Criteria for selection of members:

a. Members are selected on their personal capacities, based on their interest, ethical and/or scientific knowledge and expertise, experience in the domain field and profile.
b. The qualification of each member is listed as follows

Table 7.1 : IHEC members and Qualification

Member	Number (minimum)	Qualification
Chairperson*	1	A person not affiliated to the institution, from any background should have served or serving member of any human ethics committee elsewhere
Vice-chairperson*	1	A person not affiliated to the institution, from any background should have served or serving member of any human ethics committee elsewhere. She/he will act as chair in the absence of chairperson
Basic medical scientist*	2	One should not be affiliated to the institution. Qualification in basic medical science. One person should have an educational qualification of pharmacology
Clinicians*	2	Either affiliated or non-affiliated person. Qualified medical graduates. One of them is preferred to be a female medical doctor
Legal expert*	1	Basic degree in Law from a recognized university
Social scientist*	1	Social/ behavioral science qualification
One philosopher/ ethicist/ theologian*	1	Possess philosophy/ religious qualification and training
Lay person*	1	Non-affiliated, Literate person from the public or Community. Not pursued a medical science/ health-related career in the last 5 years.

*At least one-third of the members should be females.

c. To avoid conflict of interest while making appointments of IHEC members, list of

selected IHEC members will be circulated widely among the employees of ICMR-NIE as circular, email and displayed in the notice board for a week prior to appointment. Any objections or suggestions could be represented to the Director, NIE with proper justification. The decision of Director, ICMR-NIE in her/his discretion shall be final.

d. New members will be identified according to the requirement i.e. as per the composition specified in table 7.1 of this SOP and provided the potential member fulfills the conditions of appointment as defined in section 11of this SOP.

7.2 The following credentials/qualities are expected in IHEC members:

a. Experience and education
b. Interest and motivation
c. Commitment and availability
d. Respect for divergent opinions
e. Integrity and diplomacy

8. Terms of Appointment

a. Duration

b. The term of IHEC membership will be 4 years from the date of appointment.. The appointment procedure for membership will be followed so that it allows for continuity, development and maintenance of expertise within the IHEC, and the regular input of fresh ideas and approaches.

The members may be reappointed for three more years. No member will serve for 8 years continually. Members will retire in rotation at the end of the tenure.

Selection of Member Secretary and other members should be done at least 3 months and 1 month in advance respectively before the end of tenure. Member Secretary designate should be inducted into the IHEC as an observer for three IHEC meetings before s/he takes on the mantle in the new IHEC.

If a regular member resigns, or ceases to be a member due to disqualification, or death, a new member will be appointed for the remaining term as per the Conditions of appointment stated below – section 11

c. Resignation / Replacement procedure

The members who have resigned may be replaced at the discretion of the Director, ICMR-NIE. IHEC members who decide to resign must provide the written notification of their proposed resignation date at least 30 calendar days prior to the next scheduled meeting to the Director, ICMR-NIE. In case of resignation, Director, ICMR-NIE would appoint a new member, falling in the same category of membership e.g. legal expert. Similar procedure of appointment of new membership should be followed.

d. Termination / Disqualification procedure

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

1. Conduct unbecoming for a member of the IHEC
2. Inability to participate in the meetings on any grounds
3. Failure to attend more than 3 consecutive meetings of the IHEC and subsequent to review of the membership by the IHEC
4. Relocation to another city or any such matter
5. In all such situations/circumstances, Director, ICMR-NIE will serve a letter of termination to the member. Documentation of the termination will be recorded in the minutes of the next duly constituted IHEC meeting and the IHEC membership roster and circulars will be revised.

9. Conditions of appointment of a Member of IHEC

a. Name, age, gender, profession, and affiliation of IHEC members will be publicized. Members must accept the appointment in writing. Members must submit a one page CV and appropriate training certificates be willing to undergo training or update their skills/knowledge during their tenure.

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

c. Members are required to sign the confidentiality agreement (#) at the start of their term. The confidentiality agreement protects the privacy and confidentiality of all parties whose information may be disclosed to the IHEC in the course of its work.

10 . Independent consultants/ Experts

The IHEC may call upon, or establish a standing list of, independent consultants or subject experts who may provide special expertise to the IHEC on proposed research protocols, when the Chairperson / Member secretary or the IHEC members determine that a study requires more insight in that specific subject matter . These consultants may be specialists in ethical or legal aspects, specific diseases or methodologies (e.g. genetic disorders, stem cell research etc.), or they may be representatives of communities, patients, or special interest groups. These consultants must sign the confidentiality agreement regarding meeting, deliberations, and related matters. These consultants or subject experts will not either possess power for decision making or voting rights in IHEC.

11. Office bearers

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

11.1Chairperson

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

11.2 Vice Chairperson

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

11.3 Member Secretary

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

The Member Secretary is responsible for conducting annual training to IHEC members and the staff of the secretariat in the SOPs for IHEC functioning. The duration of Member Secretary is for 2 years, No member secretary will serve for more than 3 years continually.

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

11.4The Affiliated Members

The Affiliated Members of the IHEC will be nominated by the Director, ICMR-NIE for supporting the IHEC secretariat and Member-Secretary in all the IHEC activities. The conditions of appointment, terms of reference, terms of appointment and other relevant conditions lay down for the Members of the IHEC are applicable to the affiliated Members also.

11.5 The Secretariat

The Secretariat is composed of the Member Secretary, affiliated IHEC members and two coordinators. Coordinators of IHEC will be appointed by the Director, ICMR-NIE NIE who will coordinate with member secretary to foster the functioning of the secretariat.

11.6 The secretariat shall have the following functions

a. Provision of necessary administrative support for IHEC related activities to the Member Secretary, IHEC
b. Documentation of IHEC activities including meetings, training, discussions etc in coordination with the member secretary
c. Organization of an effective and efficient tracking procedure for each proposal received
d. Preparation, maintenance and distribution of study files to the IHEC Members
e. Organization of regular IHEC meetings
f. Preparation of the agenda and the minutes of the meetings
g. Maintenance of the IHEC records and archives
h. Communication with IHEC members and PIs
i. Arrangement of training for investigators and IHEC members

11.7 The IHEC Coordinators: Working Rules

a. There will be a two designated permanent staff member, who will be responsible for day to day activities of the IHEC Secretariat.
b. The term for IHEC coordinators will be for four years. After completion of the term, the Director, ICMR-NIE will nominate suitable staff members.
c. Coordinators will report to the Member Secretary, IHEC

12. Roles and Responsibilities of the IHEC members

a. The Committee's primary responsibility will be determining the scientific and ethical validity of the research and the protection of the safety, rights and confidentiality of the research participants.
b. Participate in the IHEC meetings.
c. Review and discuss research proposals assigned for evaluation.
d. Review progress reports and monitor ongoing studies.
e. Monitor SAEs and recommend appropriate action(s).
f. Maintain confidentiality of the documents and deliberations of the IHEC meetings.
g. Declare conflict of interest, if any.
h. Carry out work delegated by the Chairperson.

i. Participate in continuing education activities in biomedical ethics and biomedical research.
j. Provide information and documents related to training obtained in biomedical ethics and biomedical research to the IHEC secretariat.

13. Quorum Requirements

All research projects for approval by the full board of the IHEC shall be reviewed at convened meetings at which a majority of the members of the IHEC are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting. Quorum requirement for any IHEC meeting are as follows.,

- Half of the total IHEC members or Minimum of five members whichever is higher should be present in the meeting
- Both medical and non-medical member should be present in all the meetings
- Presence of one lay person member is mandatory
- Presence of one non-affiliated member is mandatory

According to the Government of India notifications dated 30th January 2013 (Compensation in case of injury or death due to clinical trial), 1st February 2013 (Permission to conduct clinical trials), 8th February 2013 (Registration of Ethics Committee) the quorum requirement for IHEC reviewing a clinical trial protocol is as follows,

a. Basic medical scientist (preferably one pharmacologist)
b. Clinician
c. Legal expert
d. Social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian or a similar person and
e. Lay person from the community

No quorum should consist entirely of members of one profession or one gender.

The members representing medical scientists and clinicians should have post-graduate qualification and adequate experience in their respective fields and aware of their role and responsibilities as committee members.

A quorum should include at least one member whose primary area of expertise is in a non-scientific area (legal expert, NGO representative and Layperson), a clinician, and at least one member who is independent of ICMR-NIE /research site and have no immediate family member affiliated to ICMR-NIE.

If for any reason the Chairperson is unable to attend any meeting, Vice Chairperson will chair that meeting. A written documentation from the Chairperson stating his absence will be obtained and filed. The minutes of such meeting and the decision letters of the study protocols and study related other documents discussed in that meeting would bear the signature of the vice Chairperson. The Vice-Chairperson can chair the sub-committees formed under the IHEC.

14. Decision making

Decisions are arrived at by consensus by the members of IHEC.
The members who are unable to attend the meeting could give their written comments on the protocol/s to the Chairperson and the Member Secretary prior to the proposed meeting. Their views will be taken into consideration, if they have submitted their comments in a written communication either from their email or through a physical document bearing their signature.

Wherever needed, IHEC may invite outside expert/s for guidance to provide opinion/suggestion, in which the IHEC may decide upon. However, this member/s will not be involved in decision-making.

Any committee member with a conflicting interest in a proposal will abstain from deliberations and in the decision-making process on that proposal, except to provide information as requested by the committee. Such abstentions will be recorded in the minutes.

15. Education for IHEC Members

IHEC members have a need for initial and continued education regarding the science and ethics of biomedical research.

All IHEC members must be conversant with National Ethical Guidelines for Biomedical and Health Research involving Human Participants provided by ICMR-2017, ICMR Guidelines for Research involving Human Subjects 2006, Schedule Y of Drugs and Cosmetics Act & respective amendments, ICH-GCP and Indian GCP guidelines.

IHEC members will receive introductory training material in research bioethics and functioning of IHECs and will be exposed to ongoing opportunities for enhancing their capacity for ethical review.

A new member will be requested to undergo introductory training i.e. *online human participant protection course* and training in SOPs of ICMR-NIE-IHEC. The Member-Secretary will impart this.

All the Members will be familiarized in SOPs of ICMR-NIE-IHEC through training/workshop ..etc about once in a year.

The IHEC members will be encouraged to attend to national and international training programmes /conferences/seminars in the field of research ethics to help in improving the ethical conduct of research, Ethics Committee submissions and review. However, the views, presentations, opinions of the IHEC members in such meetings will be of their responsibility and will not carry the endorsement of ICMR-NIE. ICMR-NIE will not provide any financial support to the IHEC members in attending programmes unless it is conducted or supported by the ICMR-NIE.

The IHEC Secretariat will organize workshops from time to time to impart training to the IHEC Members and investigators of ICMR-NIE. The training programmes to be scheduled and spread over the year. All relevant updates on bio-ethics will be brought to the attention of the IHEC Members/ Investigators of ICMR-NIE. It is encouraged that IHEC members/investigators to attend the training and it is mandated that IHEC members should have undergone at least one training within two years from their date of appointment.

16. Annual activity report

The Member Secretary along with the secretariat and affiliated members in Consultation with the Chairperson, IHEC shall prepare an annual activity report of the IHEC for submission to the Director, ICMR-NIE and accreditation. This shall include:

a. A quantitative evaluation of the activities of the committee in a year.
b. List of the research proposals reviewed in the report year.
c. Milestones and Status of each research proposal.

17. Honorarium

All the non-affiliate members of the IHEC will be paid honorarium as per the ICMR rules for attending the IHEC meetings and training programmes/workshops conducted at/by ICMR-NIE.

18. Dissolving of the IEC/IHEC

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

19. Annex

1. Confidentiality undertaking form for IHEC Members
2. Conflict of Interest
3. Confidentiality Agreement Form for Independent Consultants
4. Confidentiality Agreement Form for Observer Attendees

ANNEX 1
(AF 01-002/03.0)

CONFIDENTIALITY UNDERTAKING FORM FOR IHEC MEMBERS

In recognition of the fact, that I, Dr/Mr/Ms. _____ herein referred to as the "Undersigned", have been appointed as a member of the IHEC and would be requested to assess research studies involving human participants in order to ensure that they are conducted in a humane, scientific and ethical manner, with the highest standards of care according to the applied national, local regulations, institutional policies and guidelines, sign the following undertaking in the capacity of Member / Chairperson of IHEC of NIE, Chennai.

Whereas, the appointment of the undersigned as a member of the IHEC is based on individual merits and not as an advocate or representative of a home province/ territory/ community nor as the delegate of any organization or private interest;

Whereas, the fundamental duty of an IHEC member is to independently review research protocols involving human participants and make a determination and the best possible objective recommendations, based on the merits of the submissions under review;

Whereas, the IHEC must meet the highest ethical standards in order to merit the trust and confidence of the communities with respect to the protection of the rights and well being of human participants;

The undersigned, as a member of the IHEC is expected to meet the same high standards of ethical behavior to carry out its mandate.

This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a member of the IHEC. Any written information provided to the Undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly.

As such, the Undersigned agrees to hold all Confidential or Proprietary trade secrets ("information") in trust or confidence and agrees that it shall be used only for contemplated purposes, shall not be used for any other purpose or disclosed to any third party. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the IHEC and shall be returned to the IHEC secretariat after review.

The Undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the Undersigned confirms that his/her performance of this agreement is consistent with NIE's policies and any contractual obligations it may have to third parties.

_____

Undersigned Signature
Date

ANNEX 2
(AF 02-002/03.0)

DECLARATION OF CONFLICT OF INTEREST

It has been recognized that the potential for conflict of interest will always exist but faith and confidence are vested in the IHEC and its Chairperson to manage the issues of conflict so that the ultimate outcome of protection of human participants is achieved.

In accordance of the policy of the IHEC, he/she shall not participate in the review, comment or approval of any activity in which he/she have a conflict of interest, except to provide information as requested by the IHEC.

The Undersigned will immediately disclose to the Chairperson of the IHEC any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the committee, and to abstain from any participation in discussions or recommendations in respect of such proposals.

If an applicant submitting a protocol believes that an IHEC member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol. The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the IHEC member(s) in question. The IHEC may elect to investigate the applicant's claim of the potential conflict.

Examples of conflict of interest cases may be any of the following:

A member is involved in a potentially competing research program. Access to funding or intellectual information may provide an unfair competitive advantage. A member's personal biases may interfere with his or her impartial judgment.

Agreement on Confidentiality and Conflict of Interest

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

_____

Undersigned Signature Date:

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

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

Undersigned Signature Date:

ANNEX 3
(AF 03-002/03.0)

CONFIDENTIALITY AGREEMENT FORM FOR INDEPENDENT CONSULTANTS OR EXPERTS

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

_____
Undersigned Signature Date

_____
Chairperson of IHEC Date

I, _____ (Enter name) acknowledge that I have received a copy of this Agreement signed by Chairperson, IHEC and me.

_____
Signature of the recipient

ANNEX 4
(AF 04-002/03.0)

CONFIDENTIALITY AGREEMENT FORM FOR OBSERVER ATTENDEES

I, _____, understand that I am allowed to observe IHEC activities and attend the IHEC meeting/ scheduled on _____ at _____am/ pm as an Observer.

I understand that the course of the observer ship / meeting of the IHEC some confidential information may be disclosed or discussed.

Upon signing this form, I ensure that to take reasonable measures to keep the information and discussion as confidential and ensure confidential documents will be returned to the Secretariat after completion of the review and IHEC meeting.

_____
Signature of the Observer Date

_____ Date
Member Secretary/Chairperson of IHEC

I, _____ (Enter name) acknowledge that I have received a copy of this Agreement signed by Member Secretary/Chairperson, IHEC and me.

_____
Undersigned Signature Date

ANNEX 5
(AF 05-002/03.0)

Template for One-page Curriculum Vitae for Members of IHEC/ IHEC Secretariat Co-Ordinator

Last Name	First Name	Middle Name
Date of Birth (dd/mm/yyyy):		Sex:
Professional Mailing Address (Include Institution name [if applicable])		
Telephone (Office):		Mobile Number:
Telephone (Residence):		Email:

Academic Qualifications (Most recent qualification first)		
Degree/Certificate	Year	Institution, Country

Professional Experience (most recent position first)		
Month and Year	Title	Institution/Company, Country

Experience to serve on Ethics Committees		
Institution	Role (Member / Chairperson/coordinator)	Period

Area of expertise	Yes	No
1. Basic Medical Science		
2. Clinician		
3. Legal / Regulatory function		
4. Social Science		
5. Philosophy / Ethics / Theology		
6. Lay person		
7. IHEC Secretariat coordinator		

Signature:	Date: Place:

Management of protocol submissions

SOP/003/03.0
Effective Date: 1st October 2021

1. Purpose:

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

2. Scope:

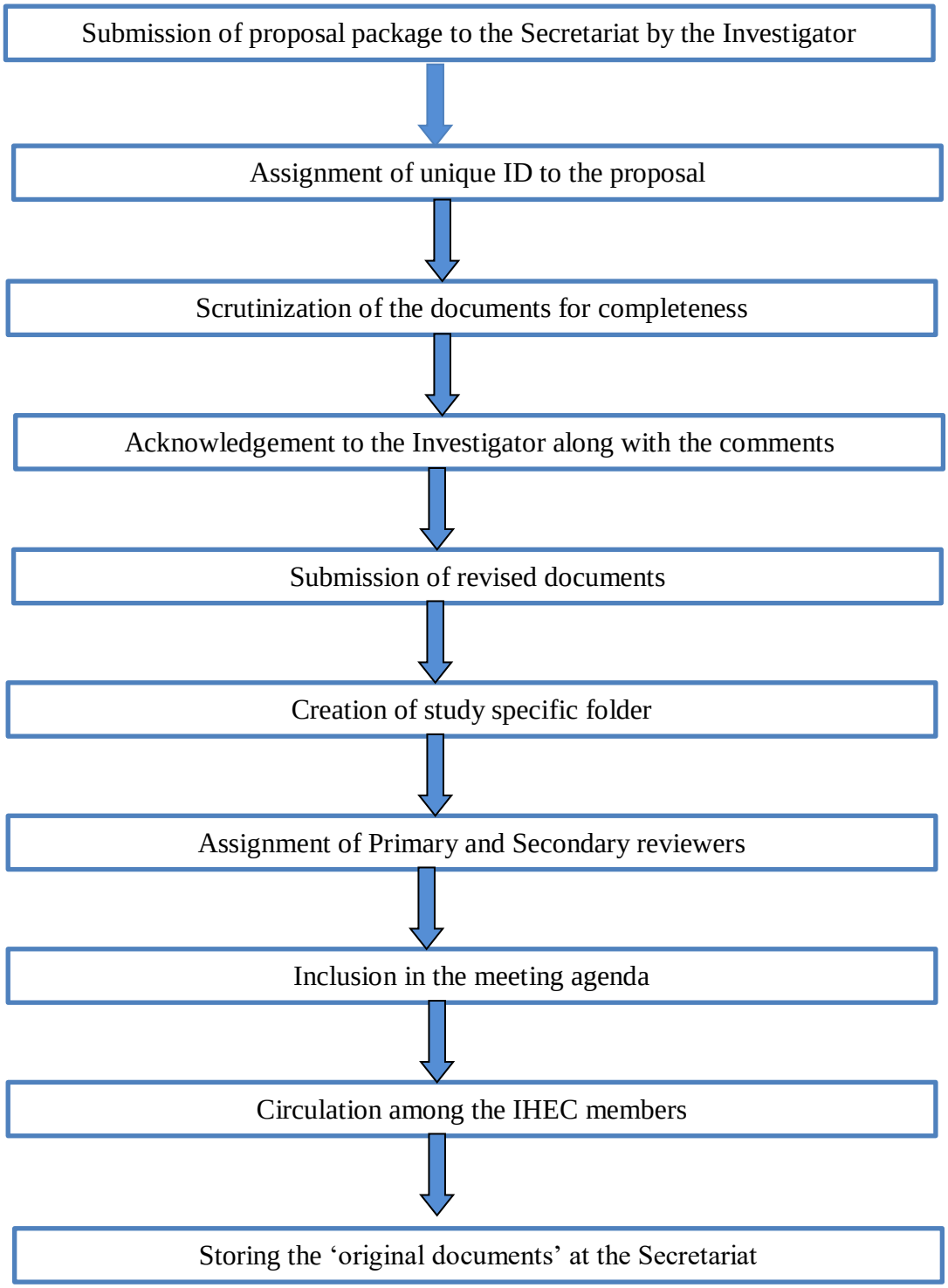
Protocol submissions include:

a. Initial review
b. Expedited review, including student/scholar research reviews.
c. Exemption from review
d. Amendment to the protocol
e. Continuing review of approved protocols
f. Protocol Termination
g. Study completion

3. Responsibility:

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

4. Flow chart on Management of Protocol submission



5.Detailed instructions:

1. Receive submitted packages

a. Initial Review Application

I. Go to SOP/004/03.0

b. Exemption from review of protocols

I. Go to SOP/007/03.0

c. Continuing Review of Approved Protocols

I. Retrieve the previous receipt form from the Secretariat's records.
II. Go to SOP/005/03.0

d. Expedited review of protocols

I. Go to SOP/006/03.0

e. Protocol Amendment

I. Retrieve the previous receipt form from the Secretariat's records.
II. Go to SOP/008/03.0

f. Premature Protocol Termination

I. Retrieve the previous receipt form from the Secretariat's records.
II. Go SOP/013/03.0

g. Study completion reports
I. Go SOP/017/03.0

h. Maintenance of active project files, archival/disposal of closed files and retrieval of documents
I. Go SOP/018/03.0

i. Online Ethics Committee Meeting Procedures
I. Go SOP/019/03.0

j. Review of COVID-19 research proposals SOP/020
I. Go SOP/020/03.0

k. SOP for review of studies on Public health response to outbreaks [PHRO Review]
I. Go SOP/021/03.0

l. SOP for formation of subcommittee.
I. Go SOP/022/03.0

2. Check for submission items

Get relevant forms according to the category of submission mentioned in the section 4.1

a) IHEC accept only the completed submission

b) Check for index/Table of contents each provided in the protocol file.

3. Provide filled in acknowledgement form to the PI (Annex: AF 02/003/03.0)
4. Verify contents of Submitted Package as per the checklist (Annex: AF 01/003/03.0)
5. Create a Protocol Specific File

6. Assign unique project ID No. in the following format: NIE/IHEC/yyyymm/XX, in which yyyy is year in four digits and mm is month in two digits and XX is unique serial number for the submitted protocol for reviewing by the IHEC meeting.

   e.g. NIE/IHEC/201308/01 refers to the protocol submitted to NIE-IHEC in the year 2013 for reviewing in the meeting held on August and last two digits refers to the unique continuous number assigned to the particular protocol.

7. Complete the submission process
   a. Check for completeness of information in the submitted package.
   b. Notify the applicants if a package is incomplete.
   c. State clearly the items missing in the package.
   d. Fill up the related parts and the missing documents.
   e. Stamp the receiving date on the letter and on the first page of the documents.
   f. Initial of the receiver's name on the receiving documents.
   g. Staple the filled checklist (according to the category of the protocol submission) with the protocol submission cover letter.
   h. File a copy of the document receipt form in the "***Protocol Receipt***" folder.
   i. File a copy of the submitted documents with original signatures in the "Submission" Folder.
8. Store the received packages
   a. Bind the packages together appropriately.
   b. Store the dated and initialed original protocol packages on the IHEC submission shelf for review in sequence.
   c. Table of contents for protocol files

Covering letter for study proposal	
Curriculum Vitae of Investigators	
Proposal summary (one page)	
Application of Investigators	
Project proposal	
Copy of advertisements/Information brochures	
Copy of questionnaires and /or other data collection tools	
CPCSEA clearance/SAC approval letter if any	
Participant information sheet (in English and vernacular)	
Informed Consent Form (in English and vernacular)	
Informed ascent form (in English and vernacular)	
Informed parental consent form (In English and vernacular)	
Reviewers' form	
Any other forms	

6. References

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000)
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996 Retrieved from- http://www.ich.org/LOB/media/MEDIA482.
3. MoHFW (Department of Health) Notification 20th January 2005(Requirements and guidelines for permission to import and / or manufacture of new drugs for sale or to undertake clinical trials), 30th January 2013 (Compensation in case of injury or death due to clinical trial), 1stFebruary 2013 (Permission to conduct clinical trials), 8th February 2013 (Registration of Ethics Committee)
4. National Ethical Guidelines for Biomedical and Health Research involving Human Participants provided by ICMR-2017

7. Annexure

Annex: AF 01/003/03.0

Checklist of a Submitted Package

Protocol Number…….

☐ **Initial Review Submitted Package**

- ❑ Covering letter for new study submission
- ❑ Project proposal
- ❑ Curriculum vitae of investigators signed and dated
- ❑ GCP certification applicable for clinical trials
- ❑ Protocol Summary Sheet
- ❑ Application of the Investigators
- ❑ Copy of advertisements (if any)
- ❑ CPCSEA(Committee for the purpose of control and supervision of experiments on Animals)clearance, if any
- ❑ Protocol and Protocol-Related Documents

☐ Study budget ☐ Participant information sheet
☐Case report forms (CRF) ☐ Informed consent/Assent/Parental consent forms
☐Investigator's brochure ☐Others……
☐ Data collection tools☐ SAC and other scientific body approval

- ❑ Reviewer's (Member's comments)form

☐ **Protocol Amendment Submitted Package**

- ❑ Covering letter for Amendment review
- ❑ Original Amendment Submission Form
- ❑ Protocol and Protocol-Related Documents

Note: Changes made to the protocol and protocol-related documents should be clearly marked either with the underlining or highlighting feature of the software package used to prepare the document.

☐ **Annual Continuing Review Package**

- ❑ Covering letter for Annual Continuing Review
- ❑ Original Continuing Review Application Form
- ❑ Current Informed Consent Document (last approved by the IHEC)
- ❑ Protocol summary

☐ **Protocol Termination Package**

- ❑ Covering letter for reviewing study termination
- ❑ Protocol termination Submission form
- ❑ Protocol summary

☐ **Protocol Completion report Package**

- ❑ Covering letter for reviewing study completion
- ❑ Study Completion Report Form
- ❑ Other relevant document like publications, reports, etc.
- ❑ Protocol summary

Annex: AF 02/003/03.0

Document Receipt Form

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

Note: *Please bring this receipt with you when contacting the IHEC Secretariat*

Annexure: AF 03/003/03.0

Application to be filled by the Principal Investigator (PI) for submission of clinical /basic research protocols to IHEC **(for attachment to each copy of the proposal)**

Project ID No: (Will be assigned by the Secretariat)

Proposal Title:

Investigators	Name, Designation& Qualifications	Address Tel & Fax Nos. Email ID	**Signature**
PI			
Co PI/Mentor/Guide			
Co-Investigator			
Co-Investigator			
……			

Sponsor Information :			
1. Indian a) Government ☐	Central ☐	State ☐	Institutional
b) Private ☐			
2. International ☐ Government ☐	Private ☐	UN agencies	
3. Industry ☐ ☐ational ☐	Multinational	NA	
Contact Address of Sponsor:			
Total Budget (in Rs.):			

1.Type of Study: (Tick all applicable)	Basic Sciences ☐	
	Clinical ☐	RCT ☐
	Single center ☐	Multi-centric ☐

2. Status of Review:	New ☐	Revised ☐

3. Clinical Trials:
Drug /Vaccines/Device/Herbal Remedies:

i. Does the study involve use of

☐ Drug ☐ Devices ☐ Vaccines

ii. ☐ian Systems of Medicine/ Alternate System of Medicine ☐	Any other ☐	NA

iii. Is it approved and marketed

In India ☐ UK & Europe ☐ USA ☐ Other countries, specify ☐

	Yes	No
Does the project involve a change in use, dosage, route of administration?		☐
If yes, whether DCGI's /Any other regulatory Authority's permission is obtained?		☐
If yes, Date of permission: (attach a copy)		
v. Is it an Investigational New Drug? **If yes,** IND No:	☐	☐
a) Clinical Study is : Phase I ☐ Phase II ☐ Phase III ☐ Phase IV ☐		
b) Investigator's Brochure submitted	☐	☐
c) *In vitro* studies data	☐	☐
d) Preclinical Studies done	☐	☐
e) Are you aware if this study/similar study is being done elswhere ? **If Yes**, attach details	☐	☐

4. Brief description of the proposal – Introduction, review of literature, aim(s) & objectives, justification for study, methodology describing the potential risks &benefits, outcome measures, statistical analysis and whether it is of national significance with rationale (Attach sheet with maximum 500 words):

5. Subject selection:

i. Number of Subjects:

ii. Duration of study:

	Yes	No
iii. Will subjects from both sexes be recruited	☐	☐
iv. Inclusion / exclusion criteria given	☐	☐
v. Type of participants: Healthy Volunteers ☐ Patients ☐		

vi. Vulnerable subjects Yes ☐ No ☐

(Tick the appropriate boxes)

Pregnant women	☐	Children	☐	Elderly	☐
Fetus	☐	Illiterate	☐	Handicapped	☐
Terminally ill	☐	Seriously ill	☐	Mentally challenged	☐
Economically & Socially backward	☐	Any other	☐		

vii. Special group subjects Yes ☐ No ☐

(Tick the appropriate boxes)

Institutionalized	☐	Employees	☐	Captives	☐
Students	☐	Nurses/dependent staff	☐	Armed forces	☐
Any other	☐				

6. Privacy and confidentiality

i. Study involves - Direct Identifiers ☐

Indirect Identifiers/coded ☐

Completely anonymised / delinked ☐

	Yes	No
ii. Confidential handling of data by staff	☐	☐
7. Use of biological/ hazardous materials i. Use of fetal tissue or aborts	☐	☐
ii. Use of organs or body fluids	☐	☐
iii. Use of recombinant/gene therapy	☐	☐
If yes, has Department of Biotechnology (DBT) approval for DNA products been obtained?	☐	☐
iv. Use of pre-existing/stored/left over samples	☐	☐
v. Collection for banking/future research	☐	☐
vi. Use of ionizing radiation/radioisotopes	☐	☐
If yes, has Bhaba Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained?	☐	☐
vii. Use of Infectious/bio hazardous specimens	☐	☐
viii. Proper disposal of material	☐	☐

ix. Will any sample collected from the patients be sent abroad?	☐	☐
If Yes, does it confirm 1997 Biological Material Transfer Guidelines?	☐	☐
Is Material Transfer Agreement signed	☐	☐
x.Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration?	☐	☐

8. Consent: Written ☐ Oral ☐ Audio-visual ☐

i. Consent form: (Refer to Annexure) (Tick those elements applicable to your project)

Understandable language	☐	Alternatives to participation	☐
Statement that study involves research	☐	Confidentiality of records	☐
Sponsor of study	☐	Contact information	☐
Purpose and procedures	☐	Statement that consent is voluntary	☐
Risks &Discomforts	☐	Right to withdraw	☐
Benefits	☐	Consent for future use of biological material	☐
Compensation for participation	☐	Benefits if any on future commercialization (eg. genetic basis for drug development)	☐
Compensation for study related injury	☐	Healthy volunteers oriented	☐

ii. Who will obtain consent ? PI/Co-PI ☐ Nurse/Counsellor ☐
Research staff ☐ Any other ☐

	Yes	No
9. Will any advertising be done for recruitment of Subjects? (posters, flyers, brochure, websites – if so attach a copy)	☐	☐
10. Risks & Benefits: i. Do the benefits outweigh the risk	☐	☐
ii. Is there likelihood of physical/social/psychological risk/discomfort? If Yes, minimal risk ☐ More than minimum risk ☐ High risk ☐	☐	☐
iii. Is there a benefit a) to the subject? Direct ☐ Indirect ☐ b) Benefit to society ☐		
11. Data Monitoring i. Is there a data & safety monitoring committee/ Board (DSMB)?	☐	☐
ii. Is there a plan for reporting of adverse events? **If Yes,** reporting is done to: Sponsor ☐ Ethics Committee ☐ DSM ☐	☐	☐
iii. Is there a plan for interim analysis of data?	☐	☐
iv. Are there plans for storage and maintenance of all trial databases? **If Yes,** for how long?	☐	☐
12. Is there compensation for participation? **If Yes,** Monetary ☐ In kind ☐ Specify amount and type:	☐	☐
13. Is there compensation for injury? **If Yes,** by Sponsor ☐ by Investigator ☐ by insurance company ☐ by any other ☐	☐	☐
14. Does the PI have conflict of interest? (financial/nonfinancial) **If Yes, specify :**	☐	☐

Covering letter for study proposal	
Curriculum Vitae of Investigators	
Proposal summary (one page)	
Application of Investigators	
Project proposal	
Copy of advertisements/Information brochures	
Copy of questionnaires and /or other data collection tools	
CPCSEA clearance/SAC approval letter if any	
Participant information sheet (in English and vernacular)	
Informed Consent Form (in English and vernacular)	
Informed ascent form (in English and vernacular)	
Informed parental consent form (In English and vernacular)	
Reviewers' form	
Any other forms	

Place: Signature & Designation of PI
Date:

Annexure: AF 04/003/3.0

Application to be filled by the Principal Investigator (PI) for submission of Epidemiological/Social/Operations research protocols to IHEC **(for attachment to each copy of the proposal)**

Project ID No: (Will be assigned by the Secretariat)

Proposal Title:

	Name, Designation & Qualifications	Address Tel & Fax Nos. Email ID	Signature
PI			
Co PI			
Co-Investigator			
Co-Investigator			
…….			

Sponsor Information :

1. Indian a) Government ☐ Central ☐ State ☐ Institutional ☐
   b) Private ☐
2. International Government ☐ Private ☐ UN agencies ☐
3. Industry National ☐ Multinational ☐

Contact Address of Sponsor:

Total Budget :

1.Type of Study : Social / Economic / Behavioral / Operational Research ☐

Epidemiological / Clinical Research: ☐

2. Status of Review:	New ☐	Revised ☐

a). Are you aware if this study/similar study is being done elswhere ? **If Yes**, attach details	Yes	No

3. Brief description of the proposal – Introduction, review of literature, aim & objectives, justification for study, methodology describing the potential risks & benefits, outcome measures, statistical analysis and whether it is of national significance with rationale (Attach sheet with maximum 500 words):

4. Subject selection:						
i. Nature of study : (specify)	Qualitative ☐	Quantitative ☐	Others ☐			
ii. Study Design: (Specify)	Cross Sectional ☐	Cohort ☐	Others ☐			
iii. Study Population:						
iv. Sample Size of the Population:						
v. Duration of study:						
vi. Will subjects from both Genders be included				Yes ☐	No ☐	
vii. Inclusion / Exclusion Criteria given				Yes ☐	No ☐	
viii. Vulnerable subjects (Tick the appropriate boxes)				Yes ☐	No ☐	
Pregnant women ☐ Illiterate ☐ Economically & Socially backward ☐	Children ☐ Elderly ☐ Handicapped ☐ Seriously ill ☐	Mentally Challenged ☐ Terminally ill ☐ Any other ☐ (Specify)				
ix. Special group subjects (If yes, Tick the appropriate boxes)	Yes ☐	No ☐				
Captives ☐ Institutionalized ☐	Staff ☐ Students ☐	Nurses/dependent ☐ Employees ☐ Any other ☐				
6. Privacy and confidentiality						
i. Study involves -	Direct Identifiers ☐ Indirect Identifiers/coded ☐ Completely anonymised / delinked ☐					
ii. Confidential handling of data by staff				Yes	No	

7. Collection of Biological samples		
1. Testing of (Blood/Serum/Blood Components)	Yes	No
2. Testing of tissues	Yes	No
3. Use of pre-existing/stored/left over samples	Yes	No
4. Will any sample collected from the patients be sent abroad?	Yes	No
If Yes, justify with details of collaborators		
a) Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration?	Yes	No

b) Sample will be sent abroad because (Tick appropriate box):

Facility not available in India ☐

Facility in India inaccessible ☐

Facility available but not being accessed. ☐

If so, reasons…

8. Consent :	Written ☐	Audio-visual ☐

i. Consent form:(tick the included elements)

Understandable language	☐	Risks & Discomforts	☐
Alternatives to participation	☐	Right to withdraw	☐
Statement that study involves research	☐	Consent for future use of biological material	☐
Confidentiality of records	☐	Benefits	☐
Sponsor of study	☐	Compensation for participation	☐
Contact information	☐	Benefits if any on future commercialization	☐
Purpose and procedures	☐	Compensation for study related injury e.g. Genetic basis for drug development	☐
Statement that consent is voluntary	☐		

*If written consent is not obtained, give reasons:

ii. Who will obtain consent ?

PI/Co-PI ☐ Research staff ☐

Nurse/Counsellor ☐ Any other(Technical) ☐

9. Risks & Benefits: i. Is the risk reasonable compared to the anticipated benefits to subjects / community / country?	Yes	No
ii. Is there physical / social / psychological risk / discomfort?	Yes	No

☐ **If Yes,** Low risk ☐ Medium risk ☐ High risk		
iii.Is there a benefit a) to the subject ?	Direct ☐	Indirect ☐
b) Benefit to society ☐		
10. Data Monitoring i. Is there a Data & Safety Monitoring Board? (DSMB)?	Yes	No
ii. Is there a plan for sending the raw data files to sponsors of the study abroad?	Yes	No
iii. If yes, is there a measure to protect the confidentiality of data that has been collected from individuals? (Give details in a separate sheet).	Yes	No
vi. Are there plans for storage and maintenance of all Databases related to the study? **If Yes,** for how long?	Yes	No
11. Is there compensation for participation? **If Yes,** Monetary ☐ In kind ☐ Specify amount and type:	Yes	No
12. Is there compensation for injury? **If Yes,** by Sponsor ☐ by Investigator ☐ by insurance company ☐ by any other ☐	Yes	No
13. Do you have conflict of interest?(Financial/nonfinancial) **If Yes, specify:**	Yes	No

Covering letter for study proposal	
Curriculum Vitae of Investigators	
Proposal summary (one page)	
Application of Investigators	
Project proposal	
Copy of advertisements/Information brochures	
Copy of questionnaires and /or other data collection tools	
CPCSEA clearance/SAC approval letter if any	
Participant information sheet (in English and vernacular)	
Informed Consent Form (in English and vernacular)	
Informed ascent form (in English and vernacular)	
Informed Parental consent form (In English and vernacular)	
Reviewers' form	
Any other forms	

Place: Signature & Designation of PI
Date:

Full board review of study protocols

SOP/004/03.0
Effective Date: 1st October 2021

1. Purpose

Every research study involving human participants and other forms of studies, before the research is initiated should be reviewed and approved by the IHEC. The IHEC should evaluate the ethical aspects of the study, which had already approved by the Scientific Advisory Committee of NIE, other scientific bodies such as ICMR-Task Force/ DST/DBT or others. However, the IHEC may also look into the ethical aspects involved in the methodology. The committee should evaluate the possible risks to the participants with proper justification as well as the expected benefits to participants/community. The adequacy of documentation for ensuring privacy & confidentiality should also be reviewed. The purpose of this Standard Operating Procedure (SOP) is to describe how the IHEC members will review an initial submission of the research study for approval using the Reviewers Form (AF 06/004/03.0). The Reviewers Form is designed to standardize the review process and to facilitate reporting, recommendations and comments offered to each study.

2. Scope

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

3. Responsibility

The IHEC Secretariat is responsible for receiving, verifying, and managing the hard/soft copies of the received submission. (Refer SOP 003) In addition, the Secretariat should create a study specific file, distribute the packages and study assessment forms to the IHEC members for review, and communicate the review results to the investigators. The affiliated members to provide necessary support to the secretariat coordinators in delivering their duties if required.

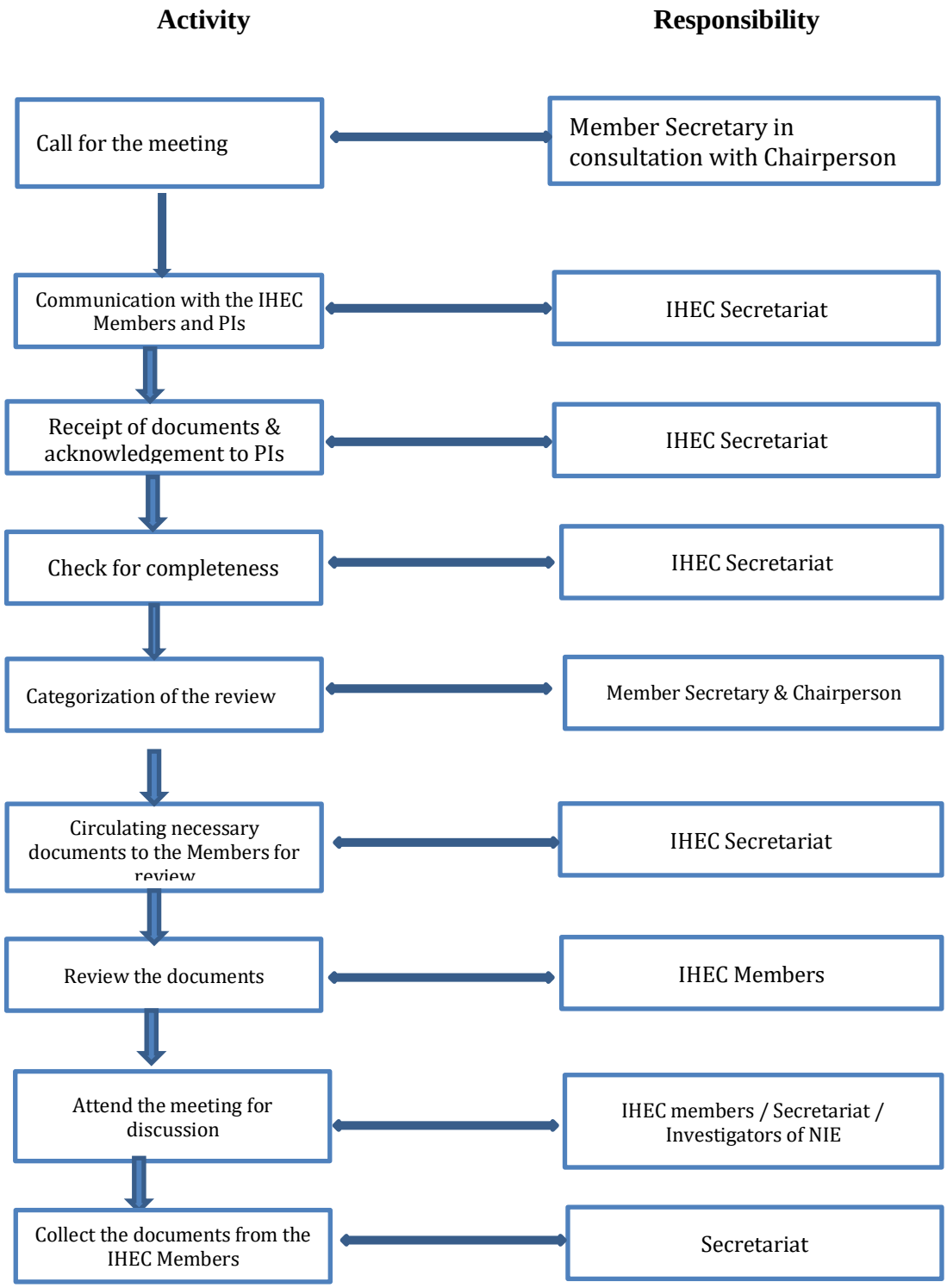
IHEC members are responsible for receiving, verifying, and reviewing the research protocols and providing he review comments/suggestions in writing/email.

3.1 Responsibilities of IHEC members:

I. Check the contents of the packages.
II. Check the meeting date to see if he/she is available to attend the Meeting.
III. Identify the project assigned for review.
IV. Notify the IHEC Secretariat 3 days prior to the convened IHEC meeting regarding the missing documents, if any.

The members must return the packages the IHEC Secretariat on the day of the scheduled meeting. In case an IHEC member is not in a position to attend the scheduled meeting, the responsibility of returning the packages would be that of the respective IHEC member.

4. Flow Chart:


Activity
Responsibility
Call for the meeting
Member Secretary in consultation with Chairperson
Communication with the IHEC Members and PIs
IHEC Secretariat
Receipt of documents & acknowledgement to PIs
IHEC Secretariat
Check for completeness
IHEC Secretariat
Categorization of the review
Member Secretary & Chairperson
Circulating necessary documents to the Members for review
IHEC Secretariat
Review the documents
IHEC Members
Attend the meeting for discussion
IHEC members / Secretariat / Investigators of NIE
Collect the documents from the IHEC Members
Secretariat

5. Detailed instructions
   Project is reviewed by the Members of the IHEC according to the guidelines given the SOPs and in the (Reviewer Form AF 06/004/03.0).
   Distribution of the project documents
   a. The IHEC Secretariat receives the documents to be reviewed by the IHEC from the Principal Investigator / Co – Investigator in the standard submission templates given in the SOPs
   b. The Member Secretary in discussion with the Chairperson categorizes the type of review (Full Board, Expedited, Academic, Exemption or Waiver) and gives guidance to the Secretariat in scrutinizing the submitted documents
   c. The Member Secretary will categorize the scrutinized proposals into the following broad areas of research. The Member Secretary will assign technical primary/Secondary reviewers among the Members of the IHEC for leading the discussion during the IHEC meetings. The Primary reviewer will review the whole study proposal (including ethical aspects) and secondary reviewer will review the ethical aspects and consent related issues in the proposal. However, the proposals will be submitted to all the Members for review for obtaining diverse opinion related to ethical conduct of research. The whole categorization process will be done in consultation with the Chairperson, IHEC.
      I. Public Health/ health/Epidemiological/Emergencies & Disasters research
      II. Clinical research
      III. Laboratory-based research
      IV. Social and Behavioral sciences research
      V. The scrutinized documents will be circulated to the IHEC Members along with the reviewers form and agenda
      VI. If any primary reviewer/s is / are not attending the meeting, his/her comments will be obtained along with the reviewers' form (AF06/004/03.0) before the meeting date for including in the discussion.

   The following timelines will be followed:

Intimation of the arranging the meeting to the Investigators in ICMR-NIE and sending invitations to the IHEC Members	One month in advance of the date of the meeting
Receipt of the proposals from the investigators	21 days in advance
Sending scrutinized proposals along with the agenda and other relevant forms to the IHEC Members/Independent reviewers	10-14 days in advance, (atleast 48-78 hours for expedited review)
Finalization of the minutes of the meeting	Within 14 days from the meeting date
Communicating suggestions/comments to the investigators	Within 2 days from the finalization of the minutes
Obtain of the action taken report/revised documents from the investigators	Within 7 days from the communication of the suggestions/comments
Issue of final decision letter from the IHEC	Within 7 days from the obtaining of action taken report/revised documents by the Secretariat

6. Categorization of protocols

The IHEC Secretariat shall screen the proposals for their completeness and submit to the Member-Secretary (MS). Depending on the risk involved in the research proposals, Member Secretary will categorize them into three types, viz.,

a. Full board review
b. Expedited review
c. Exemption from review

This SOP describes the process of Full board review.

7. Full board Review

All research studies presented with more than minimal risk and which do not qualify for exemption or expedited review, or involve vulnerable populations and special groups, will be subjected to full board review. While reviewing the research studies, the following situations shall be carefully assessed against the existing facilities at the research site for risk/benefit analysis:

7.1. Collection of blood samples by finger prick, heel prick, ear prick, or venipuncture from:

i. Healthy adults and non-pregnant women who weight normal for their age and not more than 500 ml blood is drawn in an 8-week period and frequency of collection is not more than 2 times per week
ii. From other adults and children, where the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected has been considered and not more than 50 ml or 3 ml per kg whichever is lesser, is drawn in an 8-week period and not more than 2 times per week
iii. From neonates depending on the hemodynamics, body weight of the baby and other purposes not more than 10% of blood is drawn within 48 – 72hours. If more than this amount is to be drawn it becomes a risky condition requiring infusion/blood transfusion
iv. Prospective collection of biological specimens for research purposes by non-invasive means for instance
v. Skin appendages like hair and nail clippings in a non-disfiguring manner
vi. Dental procedures - deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction of permanent teeth; supra and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth;
vii. Excreta and external secretions (including sweat)
viii. Un cannulated saliva collected either in an un stimulated fashion or stimulated by chewing gum or by applying a dilute citric solution to the tongue;
ix. Placenta removed at delivery;
x. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
xi. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
xii. Sputum collected after saline mist nebulization and bronchial lavages

7.2. Collection of data through non-invasive procedures routinely employed in clinical practice. Where medical devices are employed, they must be cleared/ approved for marketing, for instance

i. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy;
ii. Weighing or testing sensory acuity;
iii. Magnetic resonance imaging;
iv. Electrocardiography, echocardiography; electroencephalography, thermography, detection of naturally occurring radio activity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow
v. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual

a. Research involving clinical materials (data, documents, records, or specimens)that will be collected solely for non-research (clinical) purposes
b. Collection of data from voice, video, digital, or image recordings made for research purposes;
c. Research on individual or group characteristics or behavior not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior or research employing survey, Interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies;
d. Research involving collection and storage of genetic materials;
e. Research involving gene therapy and gene transfer protocols.

8. Elements of Review

The primary task of the IHEC is to review research proposals and the supporting documents with special attention to the scientific validity, ethical aspects, informed consent and submission form for the suitability and feasibility of the study. The following will be considered as applicable:

8.1 Scientific Design and Conduct of the Study

a. Is the project original and innovative? e.g. 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?
b. Is this an attempt to validate, prove or disapprove the validity of existing knowledge?
c. 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?
d. Relevance of the work in the context of contemporary translation or clinical research:
    1. Does this study address an important research question or is it a predominantly service proposal?
    2. If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced?
e. What will be effect of these studies on the concepts, methods, technologies, treatments, services, or preventive interventions that drive this field?
f. The statistical methodology (including sample size calculation), and the potential for reaching sound conclusions with the smallest number of research participants;
g. The justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants and the concerned communities;
h. The justification for the use of control arms;
i. Potential of the work that would be conducted to lead into a larger and high impact study;
j. Criteria for prematurely withdrawing research participants, and criteria for suspending or terminating the research as a whole;
k. The adequacy of provisions made for monitoring and auditing the conduct of the research, including the constitution of a Data Safety Monitoring Board;
l. Investigator's capability, availability of infrastructure and scientific environment to conduct the study within the time frame and carry it forward;
m. The adequacy of the site, including the support staff, available facilities, and emergency procedures;
n. Study Reporting and publication of the research.

8.2 Care and Protection of Research Participants

a. Required qualifications and experience of the investigators for the proposed study;
b. Any plans to withdraw or withhold standard therapies for the purpose of their search, and the justification for such action;
c. Plans to withdraw participants from the study by the investigator;
d. Medical care to be provided to research participants during and after the course of the research;

e. Adequacy of medical supervision and psycho-social support for the research participants;
f. Steps to be taken if research participants voluntarily withdraw during the course of the research;
g. Criteria for extended access to, the emergency use of, and/or the compassionate use of study products;
h. 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;
i. 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;
j. Rewards and compensations for research participants (including money, services, and/or gifts);
k. 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, DCGI).
l. Insurance and indemnity arrangements.

8.3 Protection of Research Participants' Confidentiality

a. A description of the persons who will have access to personal data of the research participants, including medical records and biological samples;
b. Measures taken to ensure the confidentiality and security of personal information concerning research participants.

8.4 Guidelines for Participant Information Sheet and Informed Consent Form

PARTICIPANT INFORMATION SHEET

1. While the guidelines for participant information sheet (PIS) contain several items, only those applicable or relevant to a particular study should be included in the documents of that study.
2. The PIS is meant for persons who are prospective participants in a study or their guardians/legal representatives. It is meant for them to understand the study, their role in it if they participate, the risks and benefits, possible side effects, the implications of blinding and randomization, etc., in order that they can make an informed decision whether to participate or not. Sample size, inclusion & exclusion criteria in technical terms are not relevant for this purpose.
3. The study protocol, in technical language, should not be cut and pasted on to the PIS. The PIS should be in simple language that a layperson can understand. English and vernacular versions of the PIS should be prepared.
4. As the information is being conveyed by the Investigator/ study personnel, they should explain to the participant 'why you should participate in this study' rather than 'why I should participate'?
5. The prospective participant should be explained the possible risks and complications, even if the chances of such risks /complications are low.
6. The prospective participant should be told that they have the right to NOT participate or to with draw at any time in case of most studies. However, the time up to which such withdrawal is possible should be explained, according to the nature of the study.

7. Financial terms such as Incentives, Inducements, Reimbursement and Compensation should be properly understood by the Investigator and conveyed appropriately to the prospective participant.
8. The prospective participant should be explained about potential benefits directly to him /her and /or to scientific advancement and / or to society at large, according to the nature of the study.
9. The prospective participant should be explained the procedures for maintaining confidentiality of (a) Identity of participant, (especially if photographs are to be taken and published), and (b) personal data.
10. The prospective participant should be told that any outcome of investigations performed as part of the study will be conveyed to him /her automatically.
11. If relevant, the prospective participant should be explained the circumstances under which a study could be terminated prematurely (as may happen in clinical trials).
12. It is not necessary to state in the PIS that 'the study has been reviewed and approved by the Ethics Committee'.
13. In case the investigators themselves are not conversant with the local language, the person who will administer the PIS / convey the information, and seek consent should be identified.
14. The PIS should carry the name of the principal investigator along with Contact Information. In case of item 13 mentioned above, the contact information of the person giving the information on the study should also be stated on the PIS.
15. For the purpose of protecting the rights of the participants /for complaining against unethical practices in carrying out the project /for clarification of queries related to ethical conduct of the project, the contact information of the Chairperson, IHEC should be given along with the telephone number of the IHEC Secretariat.
16. The PIS for Healthy Volunteers or Healthy Controls has to be different from that of prospective participants who have illnesses, as the purpose of their personal benefit in anyway. This has to be explained clearly.
17. One Copy of the PIS should be given to the prospective participants.
18. There is no need for the prospective participant or guardian or a witness to sign on the PIS.

CONSENT FORM (CF)

1. Consent form should be in English and the local language.
2. The content and wording of the CF should be relevant and appropriate for prospective participants/ guardians, for the study in question, and should be customized suitably.
3. The CF for Healthy Volunteers and Healthy controls should also be suitably customized.

4. 'Denial of consent' document should NOT be asked for, and no signatures attesting to refusal to participate or with drawl of consent should be sought.
5. CF should be signed by the participant (or legal guardian where applicable). It should also be signed by a Witness, who should be from the participant's side (and not from hospital staff or those associated with the project/ study. The person obtaining the consent should also sign the CF with name, designation and date). If the prospective participant doesn't want to disclose his / her participation details to others, in view of respecting the wishes of the participant, he / she can be allowed to waive from the witness procedure. This should be properly documented by the Investigator/Interviewer by getting signature from the prospective participant.
6. One copy of the CF, duly signed as above, should be given to the participant/ guardian. Original should be retained as part of the Study Records by the Investigator and produced if required at any time

7. Community Considerations

a. Impact and relevance of the research to the local community and the concerned communities from which the research participants are drawn;
b. Steps taken to consult with the concerned communities during the course of designing the research;
c. Influence of the community on the consent of individuals;
d. Proposed community consultation during the course of the research;
e. Extent to which the research contributes to capacity building, such as the enhancement of local healthcare, research, and the ability to respond to public health needs;
f. A description of the availability and affordability of any successful study product to the concerned communities following the research;
g. The manner in which the results of the research will be made available to there search participants and the concerned communities.

8. Recruitment of Research Participants

a. The characteristics of the population from which the research participants will be drawn (including gender, age, literacy, culture, economic status, and ethnicity);
b. The means by which initial contact and recruitment is to be conducted;
c. The means by which full information is to be conveyed to potential research participants or their representatives;
d. Inclusion criteria for research participants;
e. Exclusion criteria for research participants;
f. Students or staff recruitment in research;
g. Healthy volunteers.

9. Review the Protocol:

Review all elements as per the guidelines given in the SOPs. The protocol will be reviewed by each member as per guidelines to review a study protocol described in refer SOP 003.

10. Use of study assessment forms and reviewers' form

It is the responsibility of the IHEC members to use reviewers' form as a checklist while reviewing each research protocol. The duly filled, signed and dated reviewer's forms need to be returned along with the research protocols to the Secretariat on the day of meeting. The reviewers' form is designed to standardize the review process. The reviewers' form (AF 02/004/03.0) helps to ensure that all elements of research study are reviewed and are accordingly documented during the discussion / meeting. The whole contented reviewed by the primary reviewer and lay person

11.Collection of the reviewers' form

The IHEC Secretariat will collect the reviewers' Forms and the comments from each reviewer and file them in the original set of the study file.

Note! The completed reviewers' form is the official record of the decision reached by the IHEC for the specific protocol

12.At IHEC meeting

The details of the review procedures and communication of the decision is described in section 4, 5 of this SOP

.

13. References

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000)
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996 Retrieved from- http://www.ich.org/LOB/media/MEDIA482.
3. MoHFW (Department of Health) Notification 20th January 2005(Requirements and guidelines for permission to import and / or manufacture of new drugs for sale or to undertake clinical trials), 30th January 2013 (Compensation in case of injury or death due to clinical trial), 1stFebruary 2013 (Permission to conduct clinical trials), 8th February 2013 (Registration of Ethics Committee)
4. National Ethical Guidelines for Biomedical and Health Research involving Human Participants provided by ICMR-2017

Annexure: AF 01/004/03.0
Cover letter for submission

Submission letter format

Letter Head of NIE

Date:

To

The Chairperson,

Institutional Human Ethics Committee,

NIE (ICMR), Chennai

Forwarded through the Director, NIE

Dear Sir / Madam,

A study proposal with the details mentioned below is submitted for review and discussion during the NIE IHEC meeting to be held on _____ at NIE.

Subject: New submission/ Revised submission

Project ID:

Protocol Title:

Protocol Version with date:

Principal investigator:

Thanking You.

Signature the Principal Investigator

Designation,

ICMR-NIE, Chennai

Annexure: AF 02/004/03.0

Protocol Template for submission to IHEC for review

<Title>

Primary Investigator:

Co-Primary Investigator(s) (if any):

Co-investigator(s):

Collaborating institution(s) (if any):

Proposed funding agency:

Background

Significance/Rationale

Objective(s)

Methods

Inclusion /Exclusion/ Withdrawal criteria

Human participants' protection/ Ethical consideration

Expected outcome

Project implementation plan

Timeline

Budget outline

Role and undertaking of investigator

References

Annexure: AF 03/004/03.0
Template for Participant Information Sheet (PIS)

Participant Information Sheet

Title of the study
Name of the research institution

1. **Purpose of the study**
2. **Study Procedures**
3. **Risk of participation**
4. **Benefits of participation**
5. **Confidentiality**
6. **Compensation**
7. **Participant's rights:**
8. **Contacts**

(For queries related to the study: PI, name, contact details incl. phone number)

(For queries related to the rights as a study participant, please write to: The Chairperson, NIE-IHEC, National Institute of Epidemiology (ICMR), 2nd Main Road, Ayapakkam, Chennai – 600077, Ph: 044-26136234)

Annexure: AF 04/004/03.0
Template for Informed Consent Form

Informed Consent Form

Study Title
Participant ID No:
"I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this study and understand that I have the right to withdraw from the study at any time without in any way it affecting my further medical care."

Date	Name of the participant	Signature/thumb impression of the participant

[The literate witness selected by the participant must sign the informed consent form. The witness should not have any relationship with the research team; If the participant doesn't want to disclose his / her participation details to others, in view of respecting the wishes of the participant, he / she can be allowed to waive from the witness procedure (This is applicable to literate participant ONLY). This should be documented by the study staff by getting signature from the prospective participant]

_____

_____

_____

"I have witnessed the accurate reading of the consent form to the potential participant and the individual has had opportunity to ask questions. I confirm that the individual has given consent freely"

Date	Name of the witness	Signature of the witness

Date	Name of the Investigator / person obtaining Consent	Signature of the Investigator / person obtaining Consent

Annexure: AF 05/004/03.0

Template for Informed Assent Form (for obtaining from minors between ≥ 7 years and < 18 years of age)

Informed Assent Form

Study Title

Participant ID No:

"I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this study and understand that I can say NO to taking part in the study, even if my parents have agreed to my participation. I understand I have the right to withdraw from the study at any time without giving any reason, without anyone upset at me, or my medical care or legal rights being affected."

Date	Name of the child participant	Signature/thumb impression of the child participant

[The literate witness selected by the participant must sign the informed consent form. The witness should not have any relationship with the research team; If the participant doesn't want to disclose his / her participation details to others, in view of respecting the wishes of the participant, he / she can be allowed to waive from the witness procedure (This is applicable to literate participant ONLY). This should be documented by the study staff by getting signature from the prospective participant]

_____

_____

_____

"I have witnessed the accurate reading of the consent form to the potential participant and the individual has had opportunity to ask questions. I confirm that the individual has given consent freely"

Date	Name of the witness	Signature of the witness

Date	Name of the Investigator / person obtaining Consent	Signature of the Investigator / person obtaining Consent

Parent/guardian has signed an informed consent: Yes _____ No_____

Initialed by the researcher

Annexure: AF 05A/004/03.0
Template for Informed Parental consent Form (for obtaining below < 7years of age)

Informed Parental Consent Form

Study Title: **Participant ID No:**

"I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction. I give my consent voluntarily to include my child as a participant in this study and understand that I have the right to withdraw from the study at any time without in any way it affecting my further medical care."

- ☐ I give my consent for my child to be included as a participant in this study.
- ☐ I agree to permit storage of my child's blood/serum sample for future analyses
- ☐ I am also aware of my right that I need not agree to take part in the study without assigning any reasons to do so.
- ☐ I agree for my child's participation in the study.

Date	Name of the Child/Participant	Signature/thumb impression of the Parent of the Child/Participant

[The literate witness selected by the participant must sign the informed consent form. The witness should not have any relationship with the research team; If the participant doesn't want to disclose his / her participation details to others, in view of respecting the wishes of the participant, he / she can be allowed to waive from the witness procedure (This is applicable to literate participant ONLY). This should be documented by the study staff by getting signature from the prospective participant]

_____

_____

_____

"I have witnessed the accurate reading of the consent form to the potential participant and the individual has had opportunity to ask questions. I confirm that the individual has given consent freely"

Date	Name of the witness	Signature of the witness
Date	Name of the interviewer	Signature of the interviewer

Annexure: AF 05B/004
Template for Telephonic/Distant Oral Informed Consent script

Telephonic/Distant Oral Informed Consent script

Note to Researcher:

- This script should always be used in conjunction with a Letter of Information when obtaining telephonic/distant oral consent. Remember when seeking oral consent, your Letter of Information/Consent does not need signature lines.
- Please adapt this sample Oral Consent script to match your specific study. Add wording as necessary and delete and/or revise sample wording that does not apply to your study.

Study Title

Participant ID No:

Introduction
Greetings!
We are calling from ICMR-National Institute of epidemiology, Chennai.

Hello. I'm **[insert your name],** I am calling to invite you to participate in **[Research study/ interview/focus group/experiment/etc.]** about the [**provide brief introductory details of study**]. Your participation in this study is completely voluntary. This means that you do not have to participate in this study unless you want to.
Before I start the interview, would you be willing to answer some questions to help me determine if you are eligible for this study?
[Check for study eligibility criteria if any]

[If Not eligible "Thanking message" for their time and end the interview with interview ending message, if eligible then proceed]
Now, kindly let me explain about the purpose of this telephone interview and the study.
[Provide details of Participant Information Sheet details similar to Annexure 3]

- **Purpose of the study**
- **Study Procedures**
- **Risk of participation**
- **Benefits of participation**
- **Confidentiality**
- **Compensation**
- **Participant's rights:**
- **Contacts**

Do you agree to be in this study? Or, Do I have your permission to begin asking you questions?
[if Yes proceed with informed consent]

Informed Consent

Confirm the following to the participant:
[Note to Researcher: Add, delete, or revise statements as needed to fit your study.]

- Your participation in this study is voluntary.
- If you do not want to answer some of the questions you do not have to, but you can still be in the study.
- You can decide to stop at any time, even part-way through the [interview/focus group/experiment/etc.] for whatever reason.
- If you decide to stop during the [interview/experiment], we will ask you how you would like us to handle the data collected up to that point, whether returning it to you, destroying it or using the data collected up to that point.
- This study has been reviewed and cleared by the ICMR-NIE Institutional Human Ethics committee.

Do you have any questions or want me to go over any study details again?

Kindly tick (✔) the relevant option for consenting
( ) I orally consent for the research team to interview and contact me for follow-up relatedto the study
( ) I am also aware of my right that I need not agree to take part in the study withoutassigning any reasons to do so

Date	Name of the participant

Date	Name of the investigator / person obtaining consent	Signature of theinvestigator / person obtaining consent

Signature of Interviewer (with date):

Annexure: AF 06/004/03.0

Reviewers' form

Comments of the Reviewer Member

(For attachment to the copy of the proposal to be sent to primary/secondary reviewer)

Name of the Member (reviewer): To be written by the Reviewer

***Project ID No:** To be assigned by the IHEC Secretariat

***Proposal title: To** be written by the Investigator

***Investigator(s):** To be written by the Investigator

1	**Review of competence of the investigator**			
a.	Competence of the investigator	**Yes**	**No**	
b.	Conflict of interest of the investigator *Comments (if any.)*_____	**Yes**	**No**	
c.	Whether the investigator's capability, availability of infrastructure and scientific environment to conduct the study within the time frame, described appropriately? *Comments (if any.)* _____	**Yes**	**No**	
2.	**Review of scientific content**	**Yes**	**No**	**NA**
a	Is the project original and innovative? *Comments (if any.)* _____	**Yes**	**No**	**NA**
b	Is this an attempt to validate, prove or disapprove the validity of existing knowledge? *Comments (if any.)*_____	**Yes**	**No**	**NA**
c	Does the project have appropriate study design, work plan and structure to achieve the stated objectives? *Comments (if any.)* _____	**Yes**	**No**	**NA**

d	Does the proposal describe the relevance of the work in the context of contemporary translation or clinical research? *Comments (if any.)* _____ _____ _____	**Yes**	**No**	**NA**
e	The statistical methodology (including sample size calculation), and the potential for reaching sound conclusions with the smallest number of research participants are appropriately described? *Comments (if any.)* _____ _____ _____	**Yes**	**No**	**NA**
f	Whether appropriate justification for the use of control arms given in the proposal? *Comments (if any.)* _____ _____ _____	**Yes**	**No**	**NA**
g	Whether the potential of the work that would be conducted to lead into a larger and high impact study has been described? *Comments (if any.)* _____ _____ _____	**Yes**	**No**	**NA**
h	Whether the criteria for prematurely withdrawing research participants, and criteria for suspending or terminating the research as a whole described appropriately? *Comments (if any.)* _____ _____ _____	**Yes**	**No**	**NA**
i	Whether the provisions made for monitoring and auditing the conduct of the research, including the constitution of a Data Safety Monitoring Board are adequate? *Comments (if any.)* _____ _____ _____	**Yes**	**No**	**NA**
j	Whether the policy on study reporting and publication of the research described? *Comments (if any.)* _____ _____	**Yes**	**No**	**NA**

_____

3. **Review of ethical issues**

a Risks of participation in the study for the participants

i. Individual

Yes **No**

Comments (if any.)

_____
_____
_

ii. Societal / Community

Yes **No**

Comments (if any.)

_____
_____
_

iii. Is the overall risk/benefit ratio

Acceptable Unacceptable

Comments (if any.)

_____
_____

b Benefits

i. Direct

Reasonable Undue None

Comments (if any.)

_____
_____

ii. Indirect

Improvement in science/knowledge Any other

Comments (if any.)

_____
_____

c Subject selection

i. Are Inclusion / exclusion criteria appropriate?

Yes No

Comments (if any.)

_____
_____

ii. Vulnerable subjects (women, child, mentally challenged, seriously or terminally ill, foetus, economically or socially backward and healthy volunteers) adequately protected?

Yes No NA

Comments (if any.)

_____
_____

iii. Adequate protection for special group of participants, if involved — Yes / No / NA

Comments (if any.)

_____

_____

d Is description of measures to protect privacy & confidentiality adequate? — Yes / No

Comments (if any.)

_____

_____

4 **Review of informed consent related issues**

a Participant information sheet — Adequate / Inadequate

b Consent form components addressed adequately? If not please explain — Yes / No

_____

_

c Reimbursement, (if applicable) addressed adequately? — Yes / No

Comments (if any.)

_____

_

_____

_

d Is any reimbursement proposed for incidental expenses in participation? — Yes / No

If yes, — Appropriate / Inappropriate

If inappropriate, please comment

_____

_____

Recommendation of review — Please tick one

Approval ☐

Minor Revision ☐

Major Revision ☐

Disapproval ☐

Any other remarks / suggestions:
Reviewer's name
Signature and dat

Annexure:AF 07/004/03.0

Decision letter format for Full board review of the protocol

(Letter head of NIE Institutional Human Ethics Committee)

Members	Participation
1. Prof. ThangamMenon Chairperson thangam56@gmail.com	☐
2. Dr. C.RamachandraBhat Pharmacologist bhatcr@gmail.com	☐
3. Ms. Swapna Sundar Legal Representative swapna@ipdome.in	☐
4. **Dr. M. S. Jawahar** Clinician shaheedjawahar@gmail.com	☐
5. Dr. Saradha Suresh Clinician drsaradhasuresh@gmail.com	☐
6. **Dr. Rema Mathew** Pediatrician remamathew@yahoo.com	☐
7. Dr. V.P. Karthik Pharmacologist dr_karthikvp@yahoo.in	☐
8. Prof. Gabriel Merigala Social Scientist/Ethicist gabrielmerigala@gmail.com	☐
9. Mr. M. Somasundaram Lay person (Community) somumeena@ymail.com	☐
10. Dr. Rajkumar Prabu Member Secretary prahar82@gmail.com	☐
11. Dr.K. Jeyashree (Affiliated) Clinician jshreek@gmail.com	☐
12. Ms. P. Sharly Devi (Affiliated) Member sharlydevi@gmail.com	☐
13. Dr. Bhavani Shankara Bagepally (Affiliated) Clinician/Member Secretary bshankara@gmail.com	☐

To Date:

Name and address of the PI / Co PI

Dear Dr./Mr./Ms._____,

Sub: IHEC review of research proposals.

Ref: Your letter dated dd/mm/yyyy

Type of review:	
IHEC Project ID	
Project Title:	
Version No. & Date:	
Principal Investigator	

Thank you for submitting your application which was considered at the Institutional Human Ethics Committee meeting on dd/mm/yyyy at NIE and the below mentioned documents have been reviewed and discussed.

a. Trial Protocol (including protocol amendments), dated _____ Version no (s). _____
b. Patient Information Sheet and Informed Consent Form (including updates if any) in English and/or vernacular language.
c. Investigator's Brochure, dated_____, Version no._____
d. Proposed methods for patient accrual including advertisement (s) etc. proposed to be used for the purpose.
e. CV of PI / Co-PI
f. Insurance Policy / Compensation for participation and for serious adverse events occurring during the study participation.
g. Investigator's Agreement with the Sponsor.
h. Investigator's Undertaking (Appendix VII of Schedule Y)
i. Other related documents

The decision of the IHEC is as under:

(Approved*, Disapproved ,Major revision, Minor revision)

The Committee gave the following suggestions:

1.
2.
3.

* The approval letter is valid for _____. The amendments to the proposal, SAE reports, protocol deviation and violation reports need to be submitted to IHEC for review and approval should be sought before implementation. The progress/completion report should be submitted to IHEC for review before expiry of this approval, failing which the approval stands withdrawn.

Best Wishes

Annexure: AF 08/004/03.0
One-page CV for the Investigators

One-page Curriculum Vitae of Investigators

Last Name	First Name	Middle Name
Date of Birth (dd/mm/yy)		Sex
Study Site Affiliation (e.g. Principal Investigator, Co-Investigator, Coordinator)		
Professional Mailing Address (Include Institution name)		Study Site Address (Include Institution name)
Telephone (Office):		Mobile Number:
Telephone (Residence):		Email
Academic Qualifications (Most recent qualification first)		
Degree/Certificate	Year	Institution, Country
Current and previous positions (most recent position first)		
Month and Year	Title	Institution/Company, Country
Brief summary of relevant research experience:		
Current project/s at hand:		
Signature:		Date: Place:

Continuing review of study progress reports

SOP/005/03.0

Effective Date: 1st October 2021

1. Purpose

The purpose of continuing review is to monitor the progress of the study, which was previously approved; not only for the changes but to ensure continued protection of the rights and welfare of research participants.

2. Scope

This SOP applies to conducting continuing review of research studies at intervals appropriate to the degree of risk but not less than once a year.

Depending upon the degree of risk to the participants, the nature of the study, the vulnerability of the study participants and duration of the study, IHEC may choose to review the study more frequently.

3. Responsibility

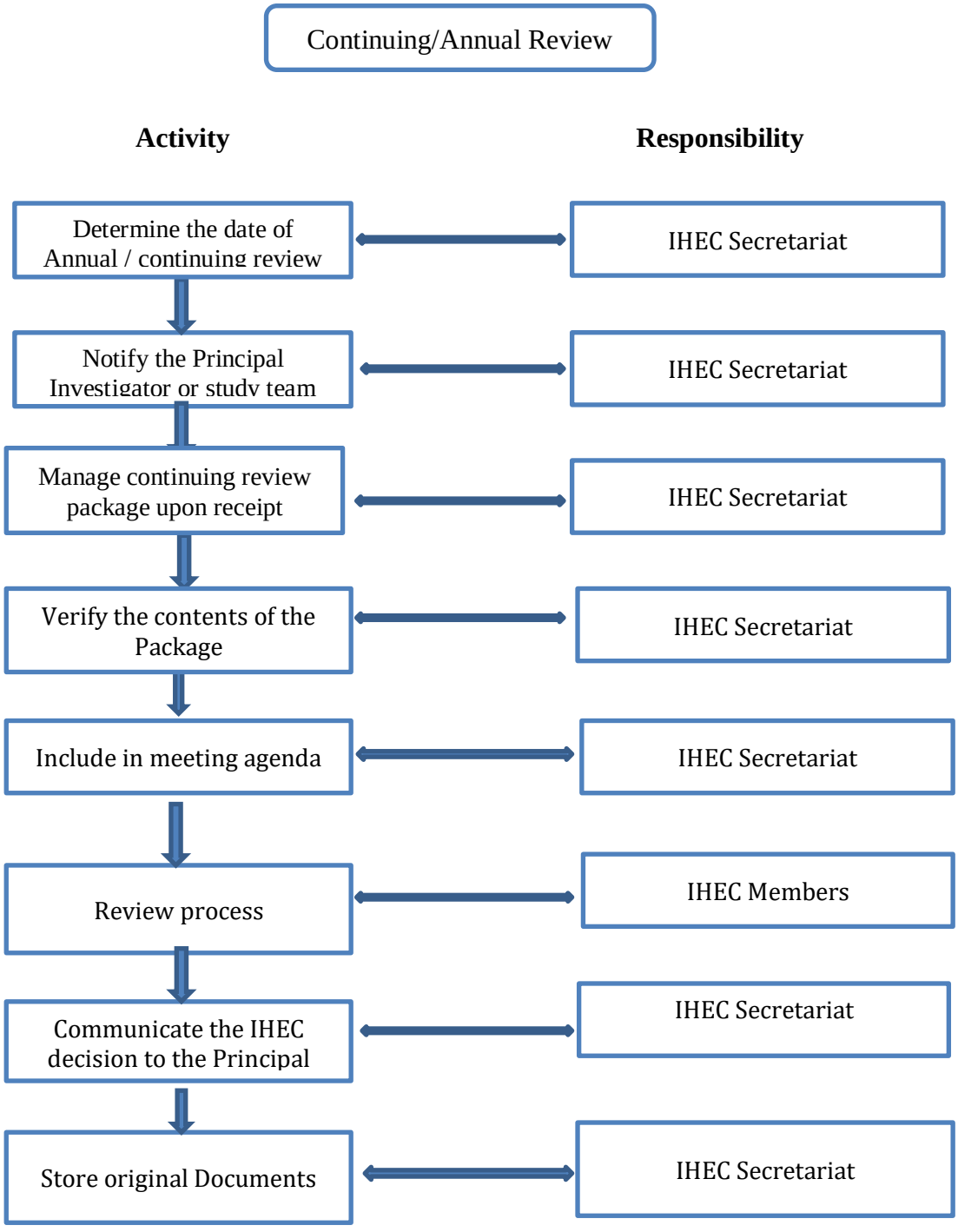
It is the responsibility of the IHEC Secretariat to send reminders (AF 03/005/03.0) to PIs regarding the submission of Continuing Review Application/Annual Status Report.

All the approved studies will be reviewed annually. The IHEC is responsible for determining the date of continuing review if the project will be reviewed more frequently in the year. This decision is taken during the IHEC meeting wherein the project is finally approved and the same should be clearly mentioned in the decision letter issued to the investigator Clinical trials under the purview of a licensing authority must comply with all regulations applicable to SAEs.

IHEC is responsible for reviewing the study progress, the occurrence of unexpected events or problems, and the rate of accrual of participants. The protocol, informed consent documents and assent documents are examined to ensure that the information remains accurate.

The IHEC has the same options for decision making on a continuing review application as for an initial review application. The decision is made as, approval to continue the study; revision or disapproval.

4. Flow Chart


Continuing/Annual Review
Activity
Responsibility
Determine the date of Annual / continuing review
IHEC Secretariat
Notify the Principal Investigator or study team
IHEC Secretariat
Manage continuing review package upon receipt
IHEC Secretariat
Verify the contents of the Package
IHEC Secretariat
Include in meeting agenda
IHEC Secretariat
Review process
IHEC Members
Communicate the IHEC decision to the Principal
IHEC Secretariat
Store original Documents
IHEC Secretariat

5. Deatiled Instrucrions

5.1 Determine the date of continuing review

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

5.2 Notify the Principal Investigator or Co Investigator

Reminders in email are sent from IHEC secretariat to the Principal Investigators for submission of an annual status of reports/Continuing review applications for projects that were approved by IHEC1.5 months before expiry of the final IHEC approval. The timeline for submission of the relevant documents will be followed as mentioned in the section 7 of SOP/004/03.0

Principal Investigator should submit 12 hard copies of the report.

5.3 Manage continuing review application upon receipt

a. The Secretariat will receive the Continuing Review Application submitted by the Principal Investigator for each approved study.
b. Upon receipt of the Continuing Review Application, the Secretariat of the IHEC will perform the following:
   i. Verify the contents of the package
   ii.Continuing review applications will be checked by the IHEC Secretariat for completeness before submission to IHEC

5.4. Review of Continuing Review Application

The Member Secretary will review the Continuing review Application and will record his/her comments on the application and the same will be forwarded to the IHEC. In case of previously approved and not initiated studies due to non-obtention of funds or non-conducive field conditions or any other valid reasons, the concerned investigator should submit the progress report (AF 02/005/03.0) along with other necessary documents as mentioned in the SOP, however the same will be communicated by the Member-Secretary in the IHEC meeting and the decision of the Committee will be communicated to the investigator. The annual review for not-initiated studies may be permitted up to a period of three years from the initial approval. If the investigator prefers to obtain the approval from the IHEC for continuation the study after three years, he/she should present the study with recent literature review and provide justification for continuation.

In case any clarifications or queries are raised by the Member Secretary the same will be intimated to PI and reply will be obtained. The Member-Secretary will present the progress to the IHEC as per the details given in the progress report for all studies. If the due for continuing review falls on the date of regular IHEC meeting, the same will be presented in the same meeting. Ordinarily the continuing review of the studies will be done during the Expedited Review Committee meetings

5.5. Prepare meeting agenda

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

5.6. Review Process

The IHEC members will use the Continuing Review Application Form (AF 02/005/03.0) to guide the review and deliberation process. The IHEC members could arrive at any one

of the following decisions at the IHEC meeting:

a. Noted and the project can be continued without any modifications
b. Revisions recommended - Studies for which modifications have been suggested by the IHEC might not proceed until the conditions set by the IHEC have been met. Studies should be amended and submitted to the IHEC within one month for re-review by an Expedited Review Committee
c. Disapproved.
d. The decision regarding the approval/recommended modifications/disapproval will be noted and documented in the minutes of the meeting is recorded by the Member Secretary
e. The IHEC Secretariat will maintain minutes of the meeting relevant to the continuing review as part of the official record of the review process.

5.7. Store original documents

a. The IHEC secretariat will file the documents pertaining to continuing review in master file of the concerned research study.

5.8 Communicate the IHEC decision to the Principal Investigator

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

Format for reporting continuing review

Title of the study	**Date of initial review**	**IHEC Approved date**	**Progress made**	**Any Modification ?(If yes provide details)**	**Require Continuation? (Yes/ No, if yes provide reasons)**

6.References

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

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

3. ICMR Ethical guidelines, 2016

4. National Ethical Guidelines for Biomedical and Health Research involving Human Participants provided by ICMR-2017,

Annexure: AF 01/005/03.0
Application for submitting the Progress report

Submission letter format

Letter Head of NIE

Date:

To

The Chairperson,
Institutional Human Ethics Committee,
NIE (ICMR), Chennai

Forwarded through the Director, NIE

Dear Sir / Madam,

A study proposal with the details mentioned below is submitted for continuing/annual review and discussion during the NIE IHEC meeting to be held on dd/mm/yyyy at NIE.

Project ID:

Protocol Title:

Protocol Version:

Date of Initial approval:

Date (s) of continuing approval (if any)**:**

Principal investigator:

Thanking You.

Signature & Name of the Principal Investigator

Designation,

NIE, Chennai

Annexure: AF 02/005/03.0

Format of the Progress Report

Date:

1. **Full Protocol Title:**
2. **Version & Date:**
3. **Principal Investigator/Co-investigators**
4. **Funding Agency:** ICMR / non ICMR; if non ICMR, name of the agency:
5. **Date of IHEC approval:**
6. **Date of Study initiation:**
7. **Aims/Objective:**

8. **Project status** (tick any one)**:** Implemented / Awaiting funds / Yet to be implemented

If yet to be implemented: Any preparatory work has been carried out? If yes, give details in brief

9. **Comments / observations of the committee during the last review:**

10. What steps have been initiated to address the comments / observations made by the EC during last meeting?

11. Being implemented in the following study sites/Not applicable
    -
    -
12. Recruitment/Not applicable
    a. Summary of Study Participants:
    b. Number of the Participants approved by the NIE IHEC:
    c. Number of the Participants Enrolled till date:
    d. Number of the Participants Enrolled in the last year:
    e. Number of the Participants at present on Follow-up:
    f. Number of the Participants lost to Follow-up/Death:
    g. Number of the Participants Completed the study:

13. Was any participant withdrawn from this study during the last year?

    No ☐

    Yes ☐

    NA ☐

14. Has there been any amendment to the protocol/Informed Consent document since the last review?

No ☐

Yes ☐

15. Have any SAEs or unexpected adverse events been noted since last review at our site?

No ☐

Yes ☐

NA ☐

(Discuss in the narrative summary – No. of the participants who had SAE, whether reports of SAEs at our site have been submitted to the NIE IHEC, whether reports of SAEs at other sites have been submitted to the NIE IHEC, types of adverse events, severity, seriousness, relatedness to the study drugs)

Sr. No.	PID Number	Onset Date	Related & Not related to study drugs	Submitted to EC & Date	Outcome

16. Is report of interim data analysis available?

No ☐

Yes ☐

17. Any Protocol deviation or Protocol Violation occurred?

No ☐

Yes ☐

(If Yes, Provide details)

Sr. No.	Protocol Violation/ Protocol Deviation – Report	Submitted to IHEC and Date	Action Taken

18. Summary of progress (during the period of report):

19. Proposed work for the next year:

20. Any Publication:

_____Signature & Date of The Principal Investigator

Annexure: AF 03/005/03.0
Decision letter format for continuing/annual review of the protocol

Members	Participation
1. Prof. Thangam Menon Chairperson thangam56@gmail.com	☐
2. Dr. C.RamachandraBhat Pharmacologist bhatcr@gmail.com	☐
3. Ms. Swapna Sundar Legal Representative swapna@ipdome.in	☐
4. Dr. M. S. Jawahar Clinician shaheedjawahar@gmail.com	☐
5. Dr. Saradha Suresh Clinician drsaradhasuresh@gmail.com	☐
6. Dr. Rema Mathew Pediatrician remamathew@yahoo.com	☐
7. Dr. V.P. Karthik Pharmacologist dr_karthikvp@yahoo.in	☐
8. Prof. Gabriel Merigala Social Scientist/Ethicist gabrielmerigala@gmail.com	☐
9. Mr. M. Somasundaram Layperson (Community) somumeena@ymail.com	☐
13. Dr. Rajkumar Prabu Member Secretary prahar82@gmail.com	☐
11. Dr.K. Jeyashree (Affiliated) Clinician jshreek@gmail.com	☐
12. P. Sharly Devi (Affiliated) Member sharlydevi@gmail.com	☐
13. Dr. Bhavani Shankara Bagepally (Affiliated) Clinician/Member secretary bshankara@gmail.com	☐

To Date:
Name and address of the PI / Co PI

Dear Dr./Mr./Ms._____,
Sub: Annual / Continuing review of research proposals by IHEC.
Ref: Your letter dated dd/mm/yyyy

Type of Review:	
Project ID:	
Project Title:	
Version No. & Date:	
Principal Investigator	

Thank you for submitting the annual/continuing review application which was considered at the Institutional Human Ethics Committee meeting on dd/mm/yyyy at NIE.The below mentioned documents have been reviewed and discussed.

j.
k.
l.
m.
n.

The decision of the IHEC is as under:
(Approved*,, disapproved ,Major Revision, Minor Revision)

The Committee gave the following suggestions:

1.
2.
3.

* The approval letter is valid for _____. The amendments to the proposal, SAE reports, protocol deviation and violation reports need to be submitted to IHEC for review and approval should be sought before implementation. The progress/completion report should be submitted to IHEC for review before expiry of this approval, failing which the approval stands withdrawn.

Expedited Review of Submitted Protocols / Documents

SOP/006/03.0
Effective Date: 1st October 2021

1. Purpose

The purpose of this SOP is to provide criteria for those research studies that qualify for expedited review by IHEC.

2. Scope

This SOP applies to the review and approval of research studies and documents that qualify for expedited review by IHEC.

3. Responsibility

It is the responsibility of the Member Secretary to identify which research studies or documents are eligible for expedited review according to the guidelines given in this SOP.

4. Categorization of protocols

The Member Secretary in consultation with the Chairperson, IHEC will screen the study for its completeness and depending on the risk involved in the research study categorize it into three types, viz.

a. Full committee review
b. Expedited review, including Academic reviews
c. Exemption from review

An investigator cannot categorize his/her study in to the above three types. This SOP describes expedited review in detail.

An investigator may apply for expedited review for the study protocol using Request Form No. AF 01/006/0Revised giving appropriate justification. However, decision to accept the request, will be made by the Member Secretary, and Chairperson or Vice-Chairperson designated member of the Committee or Subcommittee of IHEC.

5. Expedited Review

Expedited review is a procedure through which certain kinds of research proposals may be reviewed and approved by a subcommittee (refer section 6.2) without convening a meeting of the full Board.

This subcommittee should be part of the main committee and comprise Chairperson/ Vice chairperson, Member Secretary and one to two appropriate designated members. Sub-committee members should be communicated prior at least 48 hours before the meeting about the proposals and related documents submitted for expedited review.

Constitution of Sub-committee: Sub-committee consists of four members

1. Chairperson or Vice-Chairperson
2. Member Secretary or Alternate member secretary from Affiliated memebers
3. Two designated members in which one will be a non-affiliated, non-medical member

Proposals involving minimal risk to research participants may be subjected to expedited review or Academic studies.

- Minimal risk: Probability of harm or discomfort anticipated in the research is temporary or is not greater than that ordinarily encountered in routine daily life activities of an average healthy individual/ general population or
- during the performance of routine tests where occurrence of serious harm or an adverse event (AE) is unlikely.
- Academic studies: where the student/scholar of ICMR-NIE, such as but not

limited MPH or PhD Scholar thesis/dissertation related research work related to only for the academic purpose as requirement of their respective course curriculum towards qualifying them to get the respective degrees.

Examples:

- research involving routine questioning or history taking,
- observing,
- non-invasive physical examination,
- Plain chest X-ray, ultrasonogram, Plain MRI exposure without contrast medium
- obtaining body fluids without invasive intervention, such as hair, saliva or urine samples, etc
- at a time when tissues samples are being taken for non-research (clinical)purpose, for example during a surgical operation, taking small additional tissue sample
- blood banks, left over clinical samples, tissue banks.

5.1. An expedited review may be conducted only if the research activities that involve only procedures listed in one or more of the following categories:

a. Activity is limited to data analysis or health record research
b. Academic research of students/scholars of ICMR-NIE, with research leading to degree with minimal/no-risk as mentioned above. However, Academic studies involving more-than minimal risk to the study participants to be reviewed by the full board.
c. Anonymous surveys and retrospective chart reviews;
d. Research involving clinical materials (data, documents, records or biological specimens) that have been collected for non-research (clinical) purposes.
e. Study related documents which would be considered for expedited review are as follows but may not restrict to:
    i. Minor deviations from originally approved protocol
    ii. Inclusion or deletion of name/s of co-investigator/s
    iii. Request for change in PI or hand over of trials or projects
    iv. Minor amendments in the protocol, CRF, or eCRF
    v. Minor corrections in budget
    vi. Other administrative revisions like change in the name, address of sponsor, change in contact details of PI
    f. When in emergency situations like serious outbreaks or disasters a full review of the research is not possible, prior written permission of IHEC may be taken before use of the test intervention. Such research can only be approve d for pilot study or preliminary work to study the safety and efficacy of the intervention and the same participants should not be included in the clinical trial that may be initiated later based on the findings of the pilot study.

5.2. Ethics review procedures in emergency situation

Research during humanitarian emergencies, pandemics and disasters can be reviewed through an expedited review/scheduled/unscheduled full committee meetings and this may be decided by the Member Secretary on a case-to-case basis depending on the urgency and need. If an emergency review is done, full ethical review should follow as soon as possible. Meticulous documentation and archiving are required to enable future application in similar situations.

Suggestions to expedite the review process are given below:
• Measures such as virtual or tele-conferences should be attempted when face-to face meetings are not possible.
• In exceptional situations, preliminary research procedures including but not restricted to data/sample collection that are likely to rapidly deteriorate or perish may be allowed while the review process is underway.
• Available protocol templates could be reviewed to expedite the process.
• Re-review should be done if the emergency situation changes.
• In situations where members of local IHECs are unavailable due to the emergency, the ethics review may be conducted by any other recognized EC within India for initiating the study, until the local IHEC is able to convene its meeting. IHECs can develop procedures to ensure appropriate and timely review and monitoring of the approval for such research. On a case-by-case basis, some protocols may require re-review as the emergency situation may change with time and circumstances.

Research on interventions in emergency situation:
When proven prophylactic, diagnostic, and therapeutic methods do not exist or have been ineffective, physicians may use new intervention as investigational drug (IND) / devices/ vaccine to provide emergency medical care to their patients in life threatening conditions. Research in such instance of medical care could be allowed in patients - When consent of person / patient/ responsible relative or custodian/ team of designated doctors for such an event is not possible. However, information about the intervention should be given to the relative/ legal guardian when available later; When the intervention has undergone testing for safety prior to its use in emergency situations and sponsor has obtained prior approval of DCGI; Only if the local IHEC reviews the protocol since institutional responsibilities of paramount importance in such instances.

6. Research on disaster management
A disaster is the sudden occurrence of a calamitous event at any time resulting in substantial material damage, affecting persons, society, community or state(s). It may be periodic, caused by both nature and humans and creates an imbalance between the capacity and resources of the society and the needs of the survivors or the people whose lives are threatened, over a given period of time. It may also be unethical sometimes not to do research in such circumstances. Disasters create vulnerable persons and groups in society, particularly so in disadvantaged communities, and therefore; the following points need to be considered when reviewing such research:
i. Research planned to be conducted after a disaster should be essential culturally sensitive and specific in nature with possible application in future disaster situations.
ii. Disaster-affected community participation before and during the research is essential and its representative or advocate must be identified.
iii. Extra care must be taken to protect the privacy and confidentiality of participants and communities.
iv. Protection must be ensured so that only minimal additional risk is imposed.
v. The research undertaken should provide direct or indirect benefits to the participants, the disaster-affected community or future disaster- affected population and a priori agreement should be reached on this, whenever possible, between the

community and the researcher.

vi. All international collaborative research in the disaster-affected area should be done with a local partner on equal partnership basis.

vii. Transfer of biological material, if any, should be as per Government rules taking care of intellectual property rights issues.

viii. Epidemiological investigations of disease outbreaks:

The investigators of ICMR-NIE may investigate any disease outbreak events brought to the knowledge of ICMR-NIE by the Public Health Systems in India with the prior approval from the Director, ICMR-NIE.

The same should be communicated in the standard template by email to the Chairperson and other Members of the IHEC through the Secretariat, IHEC. The consent and other ethical procedure should be the investigators andall study related documents (proposal consent and other documents) have to be submitted to the IHEC.

Upon completion of the outbreak investigation, the hard copy and soft copy of the report should be submitted to the Secretariat for communication to the IHEC.

The Investigator should present the findings in the next proposed full board IHEC meeting.

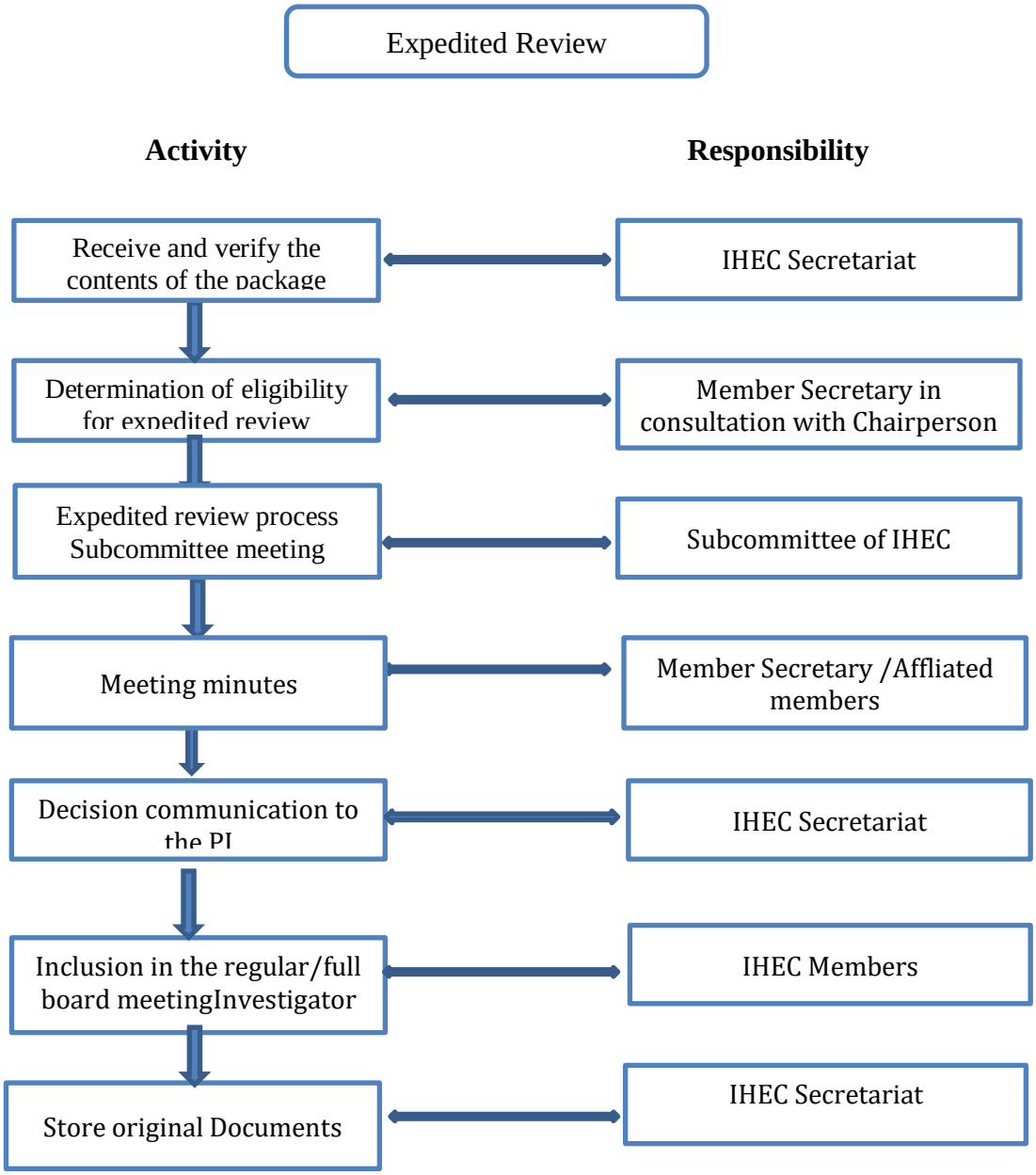
7. The expedited review procedure is not applicable:

i. When the research involves more than minimal risk to the subjects;

ii. Where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protection will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal;

iii. For studies intended to evaluate the safety and effectiveness of medical devices, including studies of cleared medical devices for new indications.

8. Flow Chart


Expedited Review
Activity
Responsibility
Receive and verify the contents of the package
IHEC Secretariat
Determination of eligibility for expedited review
Member Secretary in consultation with Chairperson
Expedited review process Subcommittee meeting
Subcommittee of IHEC
Meeting minutes
Member Secretary /Affliated members
Decision communication to the PI
IHEC Secretariat
Inclusion in the regular/full board meetingInvestigator
IHEC Members
Store original Documents
IHEC Secretariat

9. Detailed instructions:

9.1. Receive the submitted documents

Receive the application documents submitted by investigators as described in this SOP

9.2. Expedited Review

a. Member Secretary of IHEC will review the documents, which qualify for expedited review (refer section 4 & 5 of SOP or ICMR guidelines?). After deciding that the study or documents qualify for an expedited review, Member Secretary informs the Chairperson. If the Chairperson agrees that the study qualifies for the expedited review, a subcommittee comprising of the Member Secretary, the Chairperson one or two IHEC members will be formed. The external member will chair the meeting.
b. Review will be made only through formal meetings.
c. If a consensus cannot be reached or if the subcommittee decides that the proposal should be reviewed in a full board meeting, the Chairperson of the subcommittee will revert the study or the documents back to the IHEC for a full board review
d. The Member Secretary will track all research approved by expedited review and will inform at the next convened full board meeting
e. The Expedited Review process should usually be completed in no more than seven working days after it has been accepted and categorized for Expedited review by the Member Secretary and the Chairperson
f. The minutes of the expedited review subcommittee meeting should be ratified in the next regular IHEC full board meeting.
g. Full committee has the right to reverse/or modify any decision taken by the subcommittee or expedited committee

9.3. Communication between the IHEC and the investigator

The decision of the IHEC subcommittee will be communicated to the Principal Investigator after the minutes of the subcommittee are finalized. The communication should clearly state that the decision is subject to ratification by the IHEC full board. In case the full board is in disagreement with the decision of the subcommittee, amended letter will be sent to the PI.

If the project is approved / disapproved or requires resubmission after certain modifications, this will be informed to the Principal Investigator in writing. The reasons for disapproval of a project will be specified in the letter sent to the Principal Investigator.

10. References

1. National Ethical Guidelines for Biomedical and Health Research involving Human Participants provided by ICMR-2017 https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf (last accessed 25th November 2020)
2. ICMR Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006) - http://www.icmr.nic.in/ethical_guidelines.pdf (last accessed 31st Mar 2013)
3. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- http://www.ich.org/LOB/media/MEDIA482.pdf (last accessed 31st Mar 2013)
4. WHO Operational Guidelines for Ethical Review Committee that Review Biomedical Research (Geneva 2000) - www.who.int/tdr/publications/publications/(last accessed 31st Mar 2013)

Exemption from Ethical Review for Research Projects

SOP/007/03.0

Effective Date: 1st October 2021

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the category of research studies which can be exempted from review and do not require the approval from the IHEC. The Exemption Form AF 01/007/03.0 is designed to standardize the process of exemption.

2. Scope

This SOP applies to the protocols submitted for exemption from review by the IHEC. The specific points in the Exemption Form should guide the Member Secretary to determine whether the protocol qualifies for exemption from review. The decision should be taken by the Member Secretary in consultation with the Chairperson and should be informed to the members in the forthcoming IHEC meeting.

3. Responsibility

It is the responsibility of the Member Secretary to record the decision in the Exemption Form with reasons. The IHEC Secretariat is responsible for recording and filing the Exemption Form. The Member Secretary & Chairperson must sign with date in the letter conveying the decision for exemption from review.

4. Categorization of the protocols

The Member Secretary, IHEC and Secretariat shall screen the proposals for completeness and depending on the risk involved in the research proposals, they will be categorized into three, viz., Exemption from review, Expedited review and Full review. An investigator cannot categorize his/her protocol as mentioned above.

5. Exemption from review

Proposals that involve less than minimal risk fall under this category. Minimal risk

- Definition of Less than minimal risk: Probability of harm or discomfort anticipated in the research is nil or not expected. The nature of the risk may not be physical but also psychological.
- Examples of less than minimal risk:
  - Activity is limited to data analysis or health record research
  - Research on anonymous or non-identified data/samples,
  - Systematic review and meta-analysis.
  - Anonymous surveys
  - Retrospective chart/register reviews
  - Research conducted on data available in the public domain for systematic reviews or meta-analysis;
  - Observation of public behavior when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person;
  - Quality control and quality assurance audits in the institution;
  - Comparison of instructional techniques, curricula, or classroom management methods
  - Consumer acceptance studies related to taste and food quality; and

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

Research on educational practices such as effectiveness of instructional strategies or

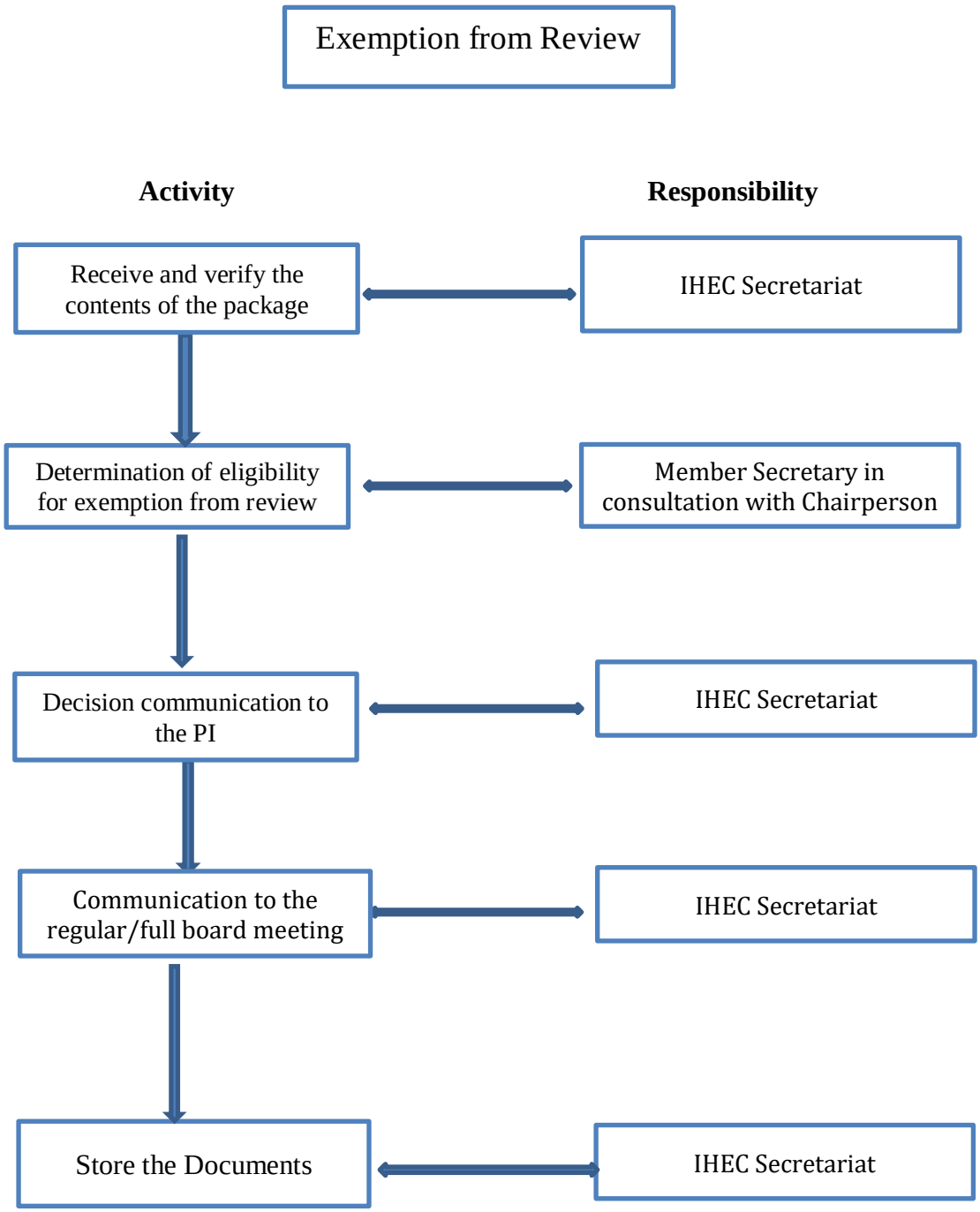
comparison among instructional techniques, curricula, or classroom management methods Exceptions:

a. When research is on use of educational tests, survey or interview procedures, or observation of public behavior which can identify the human participant directly or through identifiers, and the disclosure of information outside research could subject the participant to the risk of civil or criminal or financial liability or psychosocial harm.
b. Research in which interviews involve direct approach or access to private papers.

1. Research proposals that do not involve living human participants or data derived from them are exempt from IHEC review. For example,
    a. Audits of educational practices
    b. Research on microbes cultured in the laboratory
    c. Research on immortalized cell lines
    d. Research on cadavers or death certificates provided that such research data doesn't reveal any identification or personal data
    e. Analysis of data freely available in the public domain
2. In circumstances where research appears to meet low risk criteria may need to be reviewed by the IHEC. This might be because of requirements of:
    a. The publisher of the research
    b. An organization, which is providing funding resources, existing data, access to participants etc.

3. No research can be considered as low risk if it involves but is not restricted to the following:
    a. Invasive physical procedures or potential for physical harm
    b. Procedures that might cause mental/emotional stress or distress, moral or cultural offence
    c. Personal or sensitive issues
    d. Vulnerable groups
    e. Cross cultural research
    f. Investigation of illegal behavior (s)
    g. Invasion of privacy
    h. Collection of information that might be disadvantageous to the participant
    i. Use of information already collected that is not in the public arena, which might be disadvantageous to the participant
    j. Use of information already collected which was collected under agreement of confidentiality
    k. Participants who are unable to give informed consent
    l. Conflict of interest e.g. the researcher is also the lecturer, teacher, treatment-provider, colleague or employer of the research participants, or there is any other power relationship between the researcher and the research participants.
    m. Deception
    n. Audio or visual recording without consent
    o. Withholding benefits from "control" groups
    p. Inducements

4. Flow Chart


Exemption from Review
Activity
Responsibility
Receive and verify the contents of the package
IHEC Secretariat
Determination of eligibility for exemption from review
Member Secretary in consultation with Chairperson
Decision communication to the PI
IHEC Secretariat
Communication to the regular/full board meeting
IHEC Secretariat
Store the Documents
IHEC Secretariat

6. **Detailed instructions**

a. Receive the submitted documents
b. The Secretariat will receive the Exemption from Review Application Form AF 01/007/03.0, Protocol and other documents from the investigators.
c. Acknowledge the submitted documents
d. Hand over the received documents to the Member Secretary, IHEC.
e. Determine protocols eligibility for exemption from review
f. The IHEC-Member Secretary will determine whether a protocol qualifies for exemption from review based on criteria explained in (section 5).

Exemption Process

g. If the protocol and related documents satisfy the criteria as listed in 5, the IHEC Member Secretary in consultation with the Chairperson will review the brief summary of the project and the Exemption Form.
h. The Member Secretary will record the decision on the Exemption Form.
i. The Secretariat will communicate the decision to the investigator.
j. The Member Secretary will inform the IHEC about the decision at the next full-board meeting.
k. In case the study does not qualify for exemption from review, the Member Secretary / Chairperson will refer the study for the full board meeting.

Communication between the IHEC and the investigator

l. The decision regarding request for exemption from review, signed by the IHEC Member Secretary/Chairperson, will be forwarded by the Secretariat to the Principal Investigator within 14 days after the decision regarding the exemption is taken.
m. The Member Secretary will inform the IHEC of the decision at the forthcoming regular meeting and minute it in the meeting notes.

5. References

1. National Ethical Guidelines for Biomedical and Health Research involving Human Participants provided by ICMR-2017 https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf (last accessed 25th November 2020)
2. ICMR Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006) - http://www.icmr.nic.in/ethical_guidelines.pdf (last accessed 31st Mar 2013)
3. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- http://www.ich.org/LOB/media/MEDIA482.pdf (last accessed 31st Mar 2013)
4. WHO Operational Guidelines for Ethical Review Committee that Review Biomedical Research (Geneva 2000) - www.who.int/tdr/publications/publications/(last accessed 31st Mar 2013)

Review of amendments of protocols and related documents

SOP/008/03.0

Effective Date: 1st October 2021

1. **Purpose**
   The purpose of this procedure is to describe how protocol amendments or any other amendments are reviewed by the IHEC
2. **Scope**
   This SOP applies to amended study protocols/ documents and letters that are submitted for IHEC approval. Amendments made to protocols or any other amendments related to the study may not be implemented until reviewed and approved by the IHEC
3. **Responsibility**
   It is the responsibility of the IHEC secretariat to manage protocol amendments/documents and letters.
   Receipt of the Amendment Package
   a. The amendment /documents forwarded by the PI is received by the secretariat. The amendment /documents along with the covering letter should be accompanied by Amendment Reporting Form (AF 03/008/03.0)
   b. The secretariat will confirm that the: changes or modifications in the amended version are underlined or highlighted along with detailed summary of changes
   c. The Secretariat will check for completeness of documents and informs PI if any document/s is/are missing or incomplete and request to resubmit the same
   d. The IHEC Secretariat follows the same procedure of circulation of the received documents to the IHEC Members as in the initial review and includes the proposal for discussion in the upcoming scheduled meeting (Expedited or Full board) depending upon the nature of amendment i.e. minor or major. Amendments will be approved if "Risk and Benefit" ratio is maintained appropriately.

4. Review amended protocols/documents/letters: Review as per the guidelines provided in the SOP entitled "Full board review of study protocols"
5. **Decision**

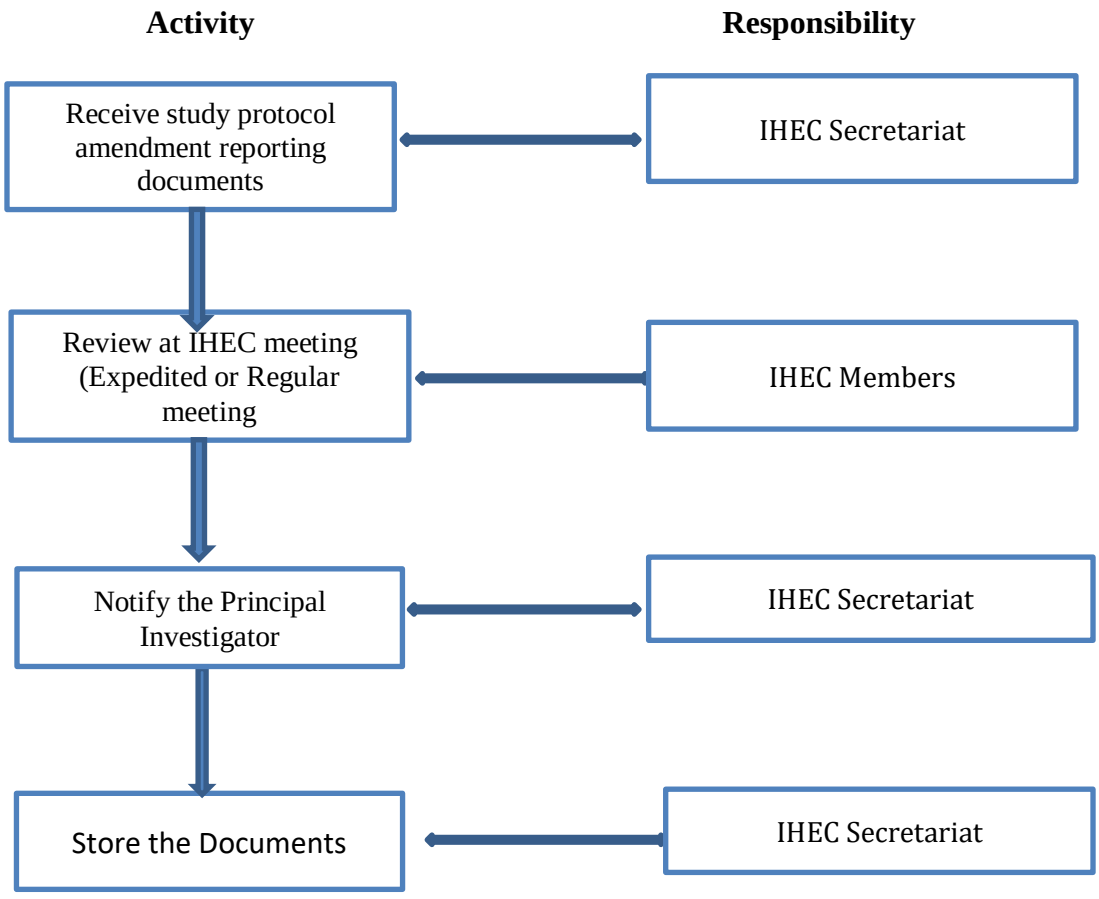
a. If the IHEC approves the amendments, the decision is communicated by the Secretariat, in writing, to the PI.

b. If the IHEC does not approve the amendments, the Secretariat should immediately notify the investigator in writing of the decision and the reason for not approving the amendment.

c. If the IHEC recommends or suggests modifications to any of the documents, or the amendments, the Secretariat sends a written communication to the investigator about the specific changes asking him or her to make the necessary changes and resubmit the documents to IHEC

6. **Storage of Documents:**
   a. File the amendments in the corresponding research protocol file, as per the SOP for documentation and archival.
7. **Minor amendments and notifications:** Minor amendments (those that do not increase the risk or decrease the potential benefit to subjects) may be approved by the expedited review subcommittee.
   Minor notifications may be noted by the Member Secretary, IHEC and not tabled in IHEC full-board meeting.
   This may include but may not restrict to:
   a. Renewed insurance policy, DCGI and DGFT approvals
   b. Administrative notes
   c. Documents of administrative nature

8. Flow Chart


Activity
Responsibility
Receive study protocol amendment reporting documents
IHEC Secretariat
Review at IHEC meeting (Expedited or Regular meeting
IHEC Members
Notify the Principal Investigator
IHEC Secretariat
Store the Documents
IHEC Secretariat

References

1. National Ethical Guidelines for Biomedical and Health Research involving Human Participants provided by ICMR-2017 https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf (last accessed 25th November 2020)
2. ICMR Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006) - http://www.icmr.nic.in/ethical_guidelines.pdf (last accessed 31st Mar 2013)
3. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- http://www.ich.org/LOB/media/MEDIA482.pdf (last accessed 31st Mar 2013)
4. WHO Operational Guidelines for Ethical Review Committee that Review Biomedical Research (Geneva 2000) - www.who.int/tdr/publications/publications/(last accessed 31st Mar 2013)

Annexure: AF 01/008/03.0

Amendment/Document Amendment Approval letter

(NIE Letterhead)

Members	Participation
1. Prof. Thangammenon Chairperson thangam56@gmail.com	☐
2. Dr. C.RamachandraBhat Pharmacologist bhatcr@gmail.com	☐
3. Ms. Swapna Sundar Legal Representative swapna@ipdome.in	☐
4. Dr. M. S. Jawahar Clinician shaheedjawahar@gmail.com	☐
5. Dr. Saradha Suresh Clinician drsaradhasuresh@gmail.com	☐
6. Dr. Rema Mathew Pediatrician remamathew@yahoo.com	☐
7. Dr. V.P. Karthik Pharmacologist dr_karthikvp@yahoo.in	☐
8. Prof. Gabriel Merigala Social Scientist/Ethicist gabrielmerigala@gmail.com	☐
9. M. Somasundaram Layperson (Community) somumeena@ymail.com	☐
10. Dr. Rajkumar Prabu Member Secretary prahar82@gmail.com	☐
11. Dr. K. Jeyashree (Affiliated) Clinician jshree@gmail.com	☐
12. Ms. P. Sharly Devi (Affiliated) Member sharlydevi@gmail.com	☐
13. Dr. Bhavani Shankara Bagepally (Affiliated) Clinician/Member secretary bshankara@gmail.com	☐

To Date:

Name and address of the PI / Co PI

Dear Dr./Mr./Ms._____,

Sub: IHEC review of research proposals.

Ref: Your letter dated dd/mm/yyyy

Type of review:	
IHEC Project ID:	
Project Title:	
Version No. & Date:	
Principal Investigator	

Thank you for submitting the Amendment reporting form which was considered at the Institutional Human Ethics Committee meeting on dd/mm/yyyy at NIE.The below mentioned documents have been reviewed and discussed.

o.
p.
q.
r.
s.
t.

The decision of the IHEC is as under:

(Approved, disapproved, major revision, minor revision)

The Committee gave the following suggestions:

1.
2.
3.

* **All projects will be reviewed annually, as part of the SOPs, and in accordance with ICMR guidelines.**

Best Wishes,

Member-Secretary Chairperson

Annexure: AF 02/008/03.0
Cover letter for submitting amendment-reporting form

Submission letter format

Letter Head of NIE

Date:

To

The Chairperson,
Institutional Human Ethics Committee,
NIE (ICMR), Chennai

Forwarded through the Director, NIE

Dear Sir / Madam,

The amendments of the study proposal with the details mentioned below is submitted for review and discussion during the NIE IHEC meeting to be held on dd/mm/yyyy at NIE.

Project ID:

Protocol Title:

Protocol Version:

Date of Initial approval:

Date (s) of continuing approval (if any)**:**

Principal investigator:

Thanking You.

Signature & Name of the Principal Investigator

Designation,

NIE, Chennai

Annexure: AF 03/008/03.0

Amendment Reporting Form

1. Protocol ID No:
2. Proposal Title:
3. Principal Investigator/ Co –investigators:
4. No. of amendment:

Ammendement No	Amendment details	Justifications

5. Have the changes/modifications in the amended versions been highlighted/ underlined? (Kindly answer Yes/No)
6. Does this amendment entail any changes in Informed Consent Form (IC) (Kindly answer Yes/No)
7. If yes, whether amended ICFs are submitted. Please specify IC Version Number, Date and its IHEC approval
8. Please mention version number and date of amended Protocol / Investigators Brochure / ICF Addendum.

Signature of the Principal Investigator & Date:

Recruiting vulnerable populations

SOP/09/03.0
Effective Date: 1st October 2021

1. **Purpose:** The purpose of this SOP is to establish policies and procedure for IHEC review of research projects undertaken by Researchers which include enrollment of vulnerable individuals

2. **Scope:** This SOP will apply to the proposals which include vulnerable individuals that are being put up for review by IHEC and will cover the review procedure to be undertaken by the IHEC for such proposals including decision making.

3. **Policy**: All research studies at ICMR-NIE that include enrollment of vulnerable individuals must meet the criteria laid down in this SOPs before the IHEC can approve such research studies.

4. **Research among vulnerable populations**

   1. Vulnerable populations have an equal right to be included in research so that benefits accruing from the research apply to them as well.
   2. If any vulnerable group is to be solely recruited then the research should answer the health needs of the group.
   3. Participants must be empowered, to the maximum extent possible, to enable them to decide by themselves whether or not to give assent/consent for participation.
   4. In vulnerable populations, when potential participants lack the ability to consent, a LAR should be involved in decision making.
   5. Special care must be taken to ensure participant's privacy and confidentiality, especially because breach of confidentiality may lead to enhancement of vulnerability.
   6. If vulnerable populations are to be included in research, all stakeholders must ensure that additional protections are in place to safeguard the dignity, rights, safety and wellbeing of these individuals.

5. **Specific vulnerable individuals may include** (Not limited to):

a. Women including pregnant or nursing women:
Pregnant or women: Pregnant or nursing women should in no circumstances be the participant of any research unless the research carries no more than minimal risk to the fetus or nursing infant and the object of the research is to obtain new knowledge about the foetus, pregnancy and lactation. As a general rule, pregnant or nursing women should not be participants of any clinical trial except such trials as are designed to protect or advance the health of pregnant or nursing women or foetuses or nursing infants, and for which women who are not pregnant or nursing would not be suitable participants.

   i. The justification of participation of these women in clinical trials would be that they should not be deprived arbitrarily of the opportunity to benefit from investigations, drugs, vaccines or other agents that promise therapeutic or preventive benefits. Example of such trials are, to test the efficacy and safety of a drug for reducing perinatal transmission of HIV infection from mother to child, trials for detecting foetal abnormalities and for conditions associated with or aggravated by pregnancy etc. Women should not be encouraged to discontinue nursing for the sake of participation in research and in case she decides to do so, harm of cessation of breast-feeding to the nursing child should be properly assessed except in those studies where breast-feeding is harmful to the infant. Compensation in terms of supplying supplementary food such as milk formula should be considered in such instances.

ii. **Research related to termination of pregnancy**: Pregnant women who desire to undergo Medical Termination of Pregnancy (MTP) could be made participants for such research as per The Medical Termination of Pregnancy Act, GOI, 1971.

iii. **Research related to pre-natal diagnostic techniques:** In pregnant women such research should be limited to detect the foetal abnormalities or genetic disorders as per the Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, GOI, 1994 and not for sex determination of the foetus.

b. Children:

Children: Research involving children, in addition, should follow the National Ethical Guidelines for Biomedical Research Involving Children, ICMR, 2017. Before undertaking trial in children, the investigator must ensure that -

a. Children will not be involved in research that could be carried out equally well with adults;
b. The purpose of the research is to obtain knowledge relevant to health needs of children. For clinical evaluation of a new drug the study in children should always be carried out after the phase III clinical trials in adults. It can be studied earlier only if the drug has a therapeutic value in a primary disease of the children;
c. A parent or legal guardian of each child has given proxy consent;
d. The assent of the child should be obtained to the extent of the child's capabilities such as in the case of mature minors from the age of seven years up to the age of 18 years.; For children less than 7 years of age, parental consent is sufficient. For children between 7 (84 months and above) and 11 years of age, oral assent must be obtained in the presence of parent/LAR. For children between 12 and 18 years of age, written assent must be obtained. If the study is of a long duration study, the researchers may have to repeat the assent process with more information, as the child grows older.
e. Research should be conducted in settings in which the child and parent can obtain adequate medical and psychological support;
f. Interventions intended to provide direct diagnostic, therapeutic or preventive benefit for the individual child participant must be justified in relation to anticipated risks involved in the study and anticipated benefits to society;
g. The child's refusal to participate in research must always be respected unless there is no medically acceptable alternative to the therapy provided/ tested, provided the consent has been obtained from parents / guardian;
h. Interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual child participant as any available alternative interventions;
i. The risk presented by interventions not intended to benefit the individual child participant is low when compared to the importance of the knowledge that is to be gained.
j. IHEC reviewing any research proposed in neonates should have an advisory member with expertise in neonatal research/care.
k. For internet-based research, The EC may allow for Internet-based consent and tele-consent (recordings to be stored) depending on the type and nature of research.
iii. From any school-based research, The researchers should submit the protocol to school authorities and obtain written approval to conduct research. A copy of the approval given by the school should be submitted to the EC.

c. Mentally incapacitated or challenged individuals:

Rights and welfare of mentally challenged and mentally differently able persons who are incapable of giving informed consent or those with behavioral disorders must be protected. Appropriate proxy consent from the legal guardian should be taken after the person is well informed about the study, need for participation, risks and benefits involved and the privacy and confidentiality procedures. The entire consent process should be properly documented;

An audio-video recording of the informed consent process in case of vulnerable subjects in clinical trials of New Chemical Entity or New Molecular Entity including procedure of providing information to the subject and his understanding on such consent, shall be maintained by the investigator for record: Provided that in case of clinical trial of anti-HIV and anti-leprosy drugs, only audio recording of the informed consent process of individual subject including the procedure of providing information to the subject and his understanding on such consent shall be maintained by the investigator for record.

d. Poor : Persons who are economically or socially disadvantaged should not be used to benefit those who are better off than them;
e. ***Other Vulnerable groups:*** Effort may be made to ensure that individuals communities invited for research be selected in such a way that the burdens and benefits of the research are equally distributed.

Adequate justification is required for the involvement of participants such as but not limited to prisoners, students, subordinates, and employees, service personnel, sexual and gender minorities, substance users, elderly, Nursing home residents or others living in institutional settings, Patients in emergency situations and etc. who have reduced autonomy as research participants, since the consent provided may be under duress or various other compelling reasons.

6. Review Process:

For review of research involving the vulnerable individuals (listed above and not limited to) the PI/Co-PI shall adhere to the applicable rules and guidelines (if any) of the respective State Government and Government of India. The PI / Co-PI should clearly state the need for and extent of involvement of the vulnerable individuals in the research and measures to safeguard their rights and safety in the submission format to the IHEC of NIE and submit the necessary supportive documents. NIE IHEC will review the submitted documents and make the final decision. Wherever needed, the IHEC may invite outside expert/s or representative of the special groups or patients to provide opinion / suggestions. However, these members will not be involved in decision-making. The other procedures provided in the SOP for NIE IHEC functioning will also be applicable to the research studies involving the vulnerable individuals. Informed consent process should be well documented and additional measures adopted if required, such as audiovisual/audio recording of assent/consent/reconsent.

7.**References**:1..National Ethical Guidelines for Biomedical and Health Research involving Human Participants provided by ICMR-2017 https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf (last accessed 25th November 2020)

2.ICMR Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006) - http://www.icmr.nic.in/ethical_guidelines.pdf (last accessed 31st Mar 2013)

3.International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- http://www.ich.org/LOB/media/MEDIA482.pdf (last accessed 31st Mar 2013)

4.WHO Operational Guidelines for Ethical Review Committee that Revie Biomedical Research (Geneva 2000) - www.who.int/tdr/publications/publications/(last accessed 31st Mar 2013)

Review of serious adverse events (SAE) reports

SOP/010/03.0
Effective Date: 1st October 2021

1. Purpose

The purpose of this SOP is to provide instructions on reporting of Serious Adverse Events (SAEs)/Adverse Events (AEs) and review of SAEs/AEs reports submitted for any active study approved by the IHEC.
Unanticipated risks are sometimes discovered during the course of studies. Information that may impact on the risk/benefit ratio should be promptly reported to and reviewed by the IHEC to ensure adequate protection of the welfare of the study participants.

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

2. Definitions

Adverse Event (AE): Any untoward medical occurrence in a patient or participant involved in a study which does not necessarily have a causal relationship with the intervention. The adverse event can therefore be any unfavorable or unintended sign or experience, whether or not related to the product under investigation

Research-related injury: Harm or loss that occurs to an individual as a result of participation in research, irrespective of the manner in which it has occurred, and includes both expected and unexpected adverse events and serious adverse events related to the intervention, whenever they occur, as well as any medical injury caused due to procedures

Serious Adverse Event (SAE): An adverse event is serious when the research outcome for the participant is death, life-threatening injury requiring hospitalization, prolongation of hospitalization, significant disability/incapacity, congenital anomaly, or requirement of intervention to prevent permanent impairment or damage.

1. Scope

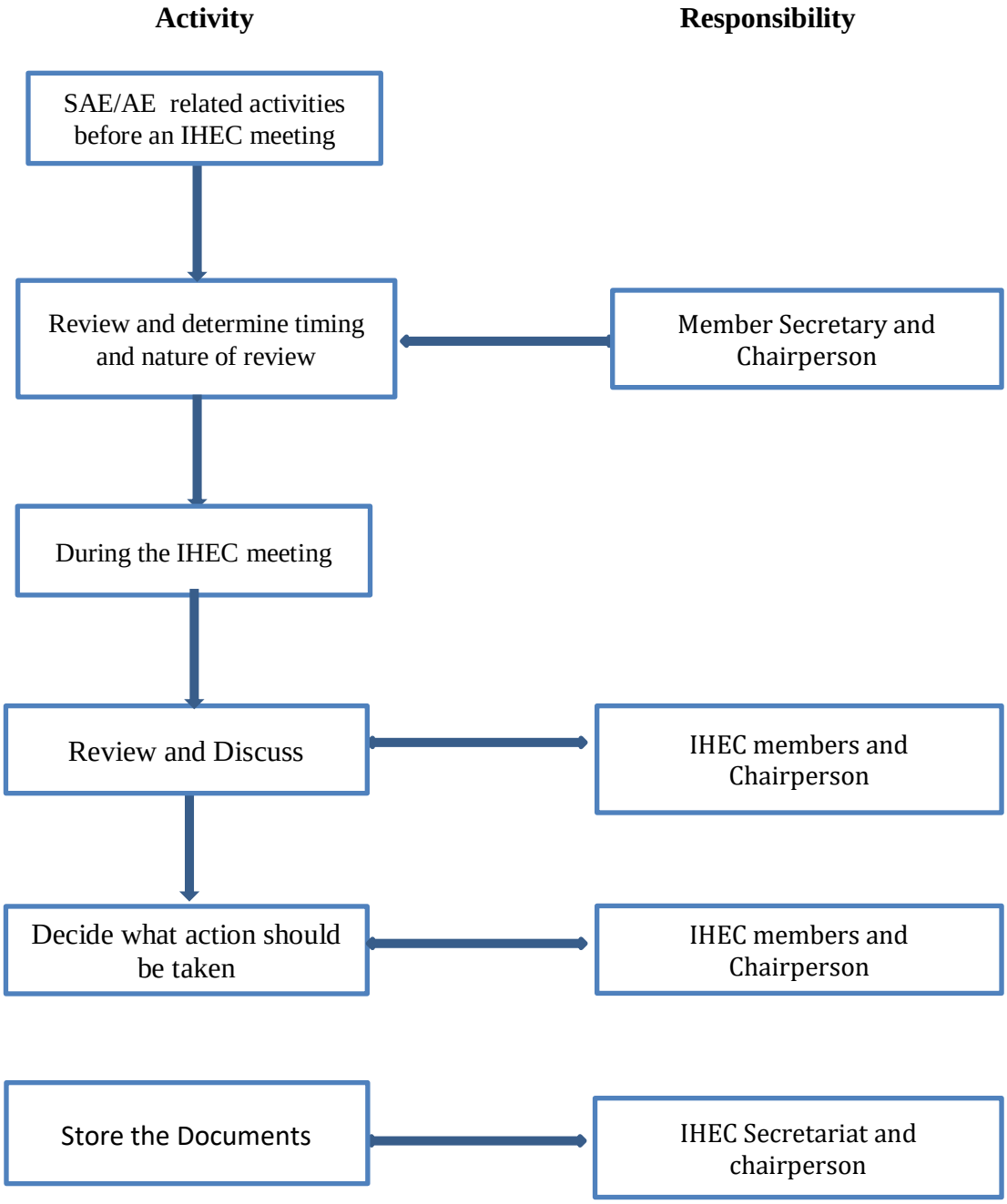
This SOP applies to the reporting of SAE/AE and review of SAE/AE reports submitted by investigators, Data Safety Monitoring Board (DSMB), sponsor, local safety monitor, IHEC/IRB members or other concerned stakeholders.

2. Responsibility

The Principal Investigator should communicate the SAE/AE to the IHEC Secretariat within 24hrs on knowing about the SAE/AE. The communication can be done through email to IHEC Secretariat.
A detailed report on the SAE in the prescribed format must be submitted by the Principal Investigator within 14 days.
Member Secretary and the Chairperson will screen the report and decide on the timing and nature of the reviewing the SAE/AE report
IHEC will review the relatedness of SAE/AE to research, management of the SAE/AE by the PI and decide on the quantum and type of assistance for the participant. The nature of the assistance can be decided based on the the type of research (interventional, observational, etc.), extent of injury (temporary/permanent, short/long term), loss of wages, etc
Post review IHEC will decide on the follow up of the SAE/AE

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

4 Flow Chart


Activity
Responsibility
SAE/AE related activities before an IHEC meeting
Review and determine timing and nature of review
Member Secretary and Chairperson
During the IHEC meeting
Review and Discuss
IHEC members and Chairperson
Decide what action should be taken
IHEC members and Chairperson
Store the Documents
IHEC Secretariat and chairperson

5. Detailed instructions:

The PI / designated person should directly inform the report of any SAE to the IHEC Chairperson with a copy to the MS within 7 working days of their occurrence. The PI should inform the sponsor about the occurrence of the SAE within 24 hours.
Onsite SAE Management:

1. On-site SAEs are those that occur at our study site.
2. Off-site SAEs are those from other study sites he end of this SOP for reference.

Appendix 1: AF 01/010/03.0
SAE reporting form

Serious Adverse Event Report
Title of study:
.....
.....
.....
.....
Principal Investigator (Name, Designation and Affiliation):
.....
.....
.....

1. Participant details:

Initials and ID	Age at the time of event	Gender
.....	.....	Male ☐ Female
.....	.....	

2. Suspected SAE diagnosis: .....
3. Date of onset of SAE: Describe the event (Duration, setting, site, signs, symptoms, severity, criteria for regarding the event serious)

Date of reporting SAE:

……

……

……

……

……

4. Details of suspected intervention causing SAE (Refers to research intervention including basic, applied and operational research or clinical research, except for investigational new drugs. If it is an academic clinical trial, mention name, indications, dosage, form and strength of the drug(s)
……
……
……
……
……
……

5. Report type: Initial Follow-up Final

If Follow-up report, state date of Initial report

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

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

.....
……

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

Hospitalization	Increased Hospital Stay Death	Congenital anomaly/ Birth defect	
Persistent of significant Disability/incapacity	Event requiring inter-vention (surgical or Medical) to prevent SAE	Event which poses threat to life	Others

.....

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

C. No permanent/significant functional/cosmetic impairment
Permanent/significant functional/cosmetic Impairment
Not Applicable

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

.....

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

.....
11. Outcome of SAE
Resolved Ongoing Death Others (specify)

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

.....

.....

.....

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

.....

.....

.....

Signature of PI: .....

Board Meeting Procedures

SOP/011/03.0
Effective Date: 1st October 2021

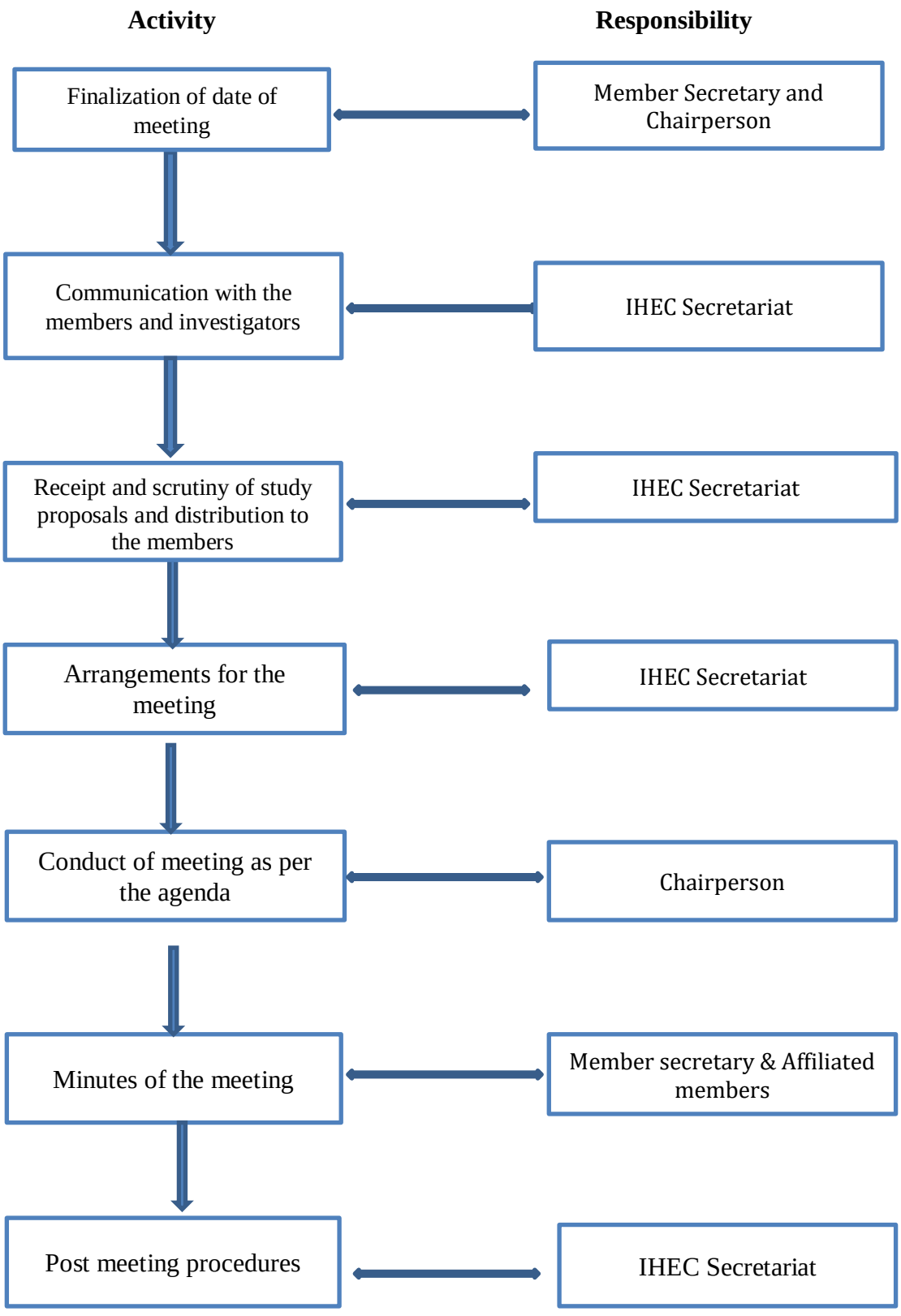
Standard Operating Procedures - Institutional Human Ethics Committee
ICMR- National Institute of Epidemiology

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

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

3. **Responsibility:**
   The Chairperson is responsible for calling for the regular meetings, which will be conducted on 3rd Wednesday of first month of every quarter. The member secretary has the responsibility of intimating all the members and investigators. Based on the necessity the ad-hoc/emergency meetings can be called for. The request for the same will come through the Director. The member secretary in consultation with the chairperson will decide on calling for the meeting.
   The expedited meeting will be conducted as per the procedures discussed in the SOP 006.

4. Flow chart:


Activity
Responsibility
Finalization of date of meeting
Member Secretary and Chairperson
Communication with the members and investigators
IHEC Secretariat
Receipt and scrutiny of study proposals and distribution to the members
IHEC Secretariat
Arrangements for the meeting
IHEC Secretariat
Conduct of meeting as per the agenda
Chairperson
Minutes of the meeting
Member secretary & Affiliated members
Post meeting procedures
IHEC Secretariat

5. Detailed instructions:

A. The member secretary will finalize the date of meeting in consultation with the Chairperson. Usually, the regular meetings to be conducted on 3rd Wednesday of first month of every quarter. The date may also be changed due to public holiday or any other reason, which will be intimated to the Chairperson, members and investigators.

B. The invitation for the meeting will be sent to the members 45 days in advance by the IHEC Secretariat. The same will be communicated to the investigators.

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

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

E. The meeting will start as per the timing mentioned in the agenda. The members will be requested to confirm the minutes of the previous board meeting. The chairperson will assess and confirm the required quorum for board meeting (50% +1). The chairperson will request the members to declare any COI with regard to the proposals to be taken for discussion. The investigator will be invited to present their research proposal and asked to provide clarifications. The primary reviewer will lead the discussion. The secondary reviewer will provide comments on ethical and consent related aspects. The investigator will be requested to leave the hall after the presentation and discussion.

F. The minutes of the meeting will be recorded by the Member secretary along with affiliated members as follows: During the discussions the member secretary will type the important discussion points and recommendations pertaining to the proposal. This will be viewed in the display screen and based on which the members will take a consensus decision about the proposal.

G. The minutes of the meeting will be finalized at the end of the meeting itself. The member secretary will seek formal approval of the Chairperson in the printed copy of the minutes.

H. The member secretary will announce the closure of the meeting followed by presenting vote of thanks.

I. The post meeting procedures like circulation of minutes, finalization of minutes, issuing suggestion letters and preparing decision letters, prepared by the Secretariat of IHEC. The IHEC will issue the decision letters to the concerned investigators .

6. Annexures:

ICMR - National Institute of Epidemiology, Chennai						
Institutional Human Ethics Committee (IHEC) Meeting						
Date:				Location:		
Time Start:				Time End:		
Called By:	Chairperson, NIE-IHEC			Rapporteur		Member Secretary
Attendees:	Chairperson & Members of IHEC, Investigators, Secretariat Coordinators					
Preparation for Meeting						
Members:	Please Read: SOP (03.0) for IHEC functioning and Project proposals			Please review: Project Proposals sent by the IHEC Secretariat		
	Open Meeting					
#	Objectives: 1. Review the Project Proposals					
1	Welcome address	The Chairperson				
1.1	Confirmation of minutes of previous meeting					
1.2	Declaration of Conflict of Interest (COI)	Members				
1.3	Announcement (if any)	Member Secretary				
2	New Project Proposals	Project ID	Principal Investigator/ Co-Investigator	Primary reviewer	Secondary reviewer	Duration
2.1						30 min
2.2						
3	Revised proposals	Project ID	Principal Investigator/ Co-Investigator	Primary reviewer	Secondary reviewer	Duration
3.1						30 min
3.2						

4	Continuing reviews (Progress reports)	Project ID	Principal Investigator/ Co-Investigator	Initial approval date	Annual review dates	Duration
4.1						10 min
4.2						
5	Continuing reviews (Amendments)	Project ID	Principal Investigator/ Co-Investigator	Initial approval date	Annual review dates	Duration
5.1						10 min
5.2						
6	Continuing reviews (SAE reports/protocol deviations/violations	Project ID	Principal Investigator/ Co-Investigator	Initial approval date	Annual review dates	Duration
6.1						10 min
6.2						
7	Continuing reviews (Final reports) (Completion/Termination/Discontinuation)	Project ID	Principal Investigator/ Co-Investigator	Initial approval date	Annual review dates	Duration
7.1						10 min
7.2						
Vote of Thanks			Member secretary			
Close of Meeting						

Minutes template

Minutes of Institutional Human Ethics Committee Meeting held on ----------

The following Members of the NIE - IHEC were present:

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

The Following members from IHEC Secretariat also attended the meeting:

1.
2.

The following NIE Investigators attended the meeting for presentation of protocols:

1.
2.
3.
4.
5.

Member Secretary Chairperson

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

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

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

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

Proposals were then taken up for consideration.

I. New proposals:

The Principal Investigator of the study presented the proposal**.**

Comments/Suggestions, clarifications:

Conflict of interest:

Decision

II. Annual review of projects/revision/clarification/amendments

The Principal Investigator of the study presented the proposal

Conflict of interest:

Decision:

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

Member Secretary Chairperson

Documentation of IHEC Activities

SOP/012/03.0
Effective Date: 1st October 2021

1. Purpose

This SOP describes the procedures for documenting the IHEC activities.

2. Scope

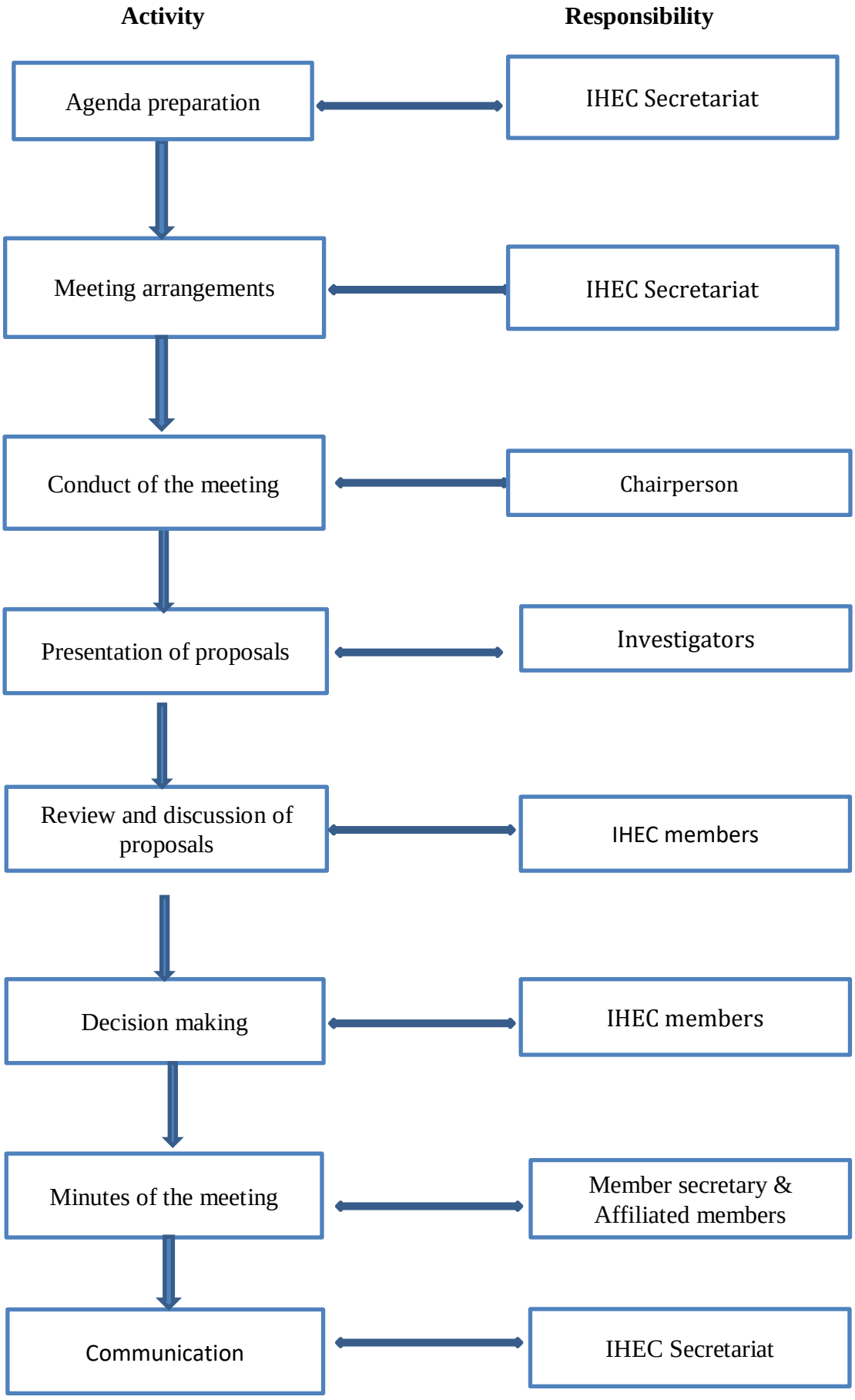
This SOP will apply to

i. Review of all research activities, irrespective of source and nature of funding.
ii. Discussions in the IHEC
iii.

3. Responsibility

It is the responsibility of the IHEC secretariat staff to maintain the IHEC files at the IHEC secretariat.

4. Flow chart for documentation of IHEC activities



5. Detailed Instructions

5.1 IHEC records will include the following

a. Appointment and Acceptance letters of each member
b. Updated Curriculum vitae
c. Training records for each IHEC member
d. Documentation of resignations/terminations
e. Confidentiality undertaking form from each IHEC Member
f. Conflict of Interest declaration form signed and dated by each IHEC Member
g. IHEC membership roster
h. IHEC attendance roster
i. IHEC meeting agenda and minutes
j. Standard Operating Procedures
k. National and International guidelines
l. Protocol files with complete history
m. Log for incoming and outgoing documents
n. Any other correspondence

5.2 Access to IHEC records

IHEC records will be made available for inspection to authorized representatives or regulatory authorities after receiving the request in writing.

6.Agenda preparation, meeting procedures and recording of minutes

a. IHEC Secretariat prepares the agenda two weeks before the actual proposed meeting and circulates to all the IHEC Members, Investigators in NIE and files the same in the unique meeting folder
b. The proposals for presentation, review and discussion are listed on first come first serve basis unless specified
c. The meeting arrangements are being supervised by the Secretariat with the help of administration and it is the responsibility of the Secretariat to ensure that all the necessary equipment are kept in good housekeeping condition
d. The meeting will always be held at the Boardroom at the 2ndfloor of the main building, if there is any modification in the venue the same will be intimated to the members and concerned investigators well in advance to prevent the inconvenience.
e. On the day of meeting the Chairperson will be requested to conduct the meeting
f. The Chairperson with the help of the Member Secretary will ensure the quorum required for reviewing the proposals listed in the agenda
g. The Chairperson will request the Members and Investigators who attend the meeting, whether they have any conflict of interest involved in the proposals listed for review. If any Member or Investigator declares any conflict of interest, the same will be recorded in the minutes and the declared person will not attend the presentation, discussion and decision-making process of the particular proposal.
h. The Chairperson will request the concerned Investigators to present the proposals as per the order listed in the agenda and the same will be taken up for discussion. The comments and discussion points will be recorded in the minutes
i. The decision-making process will be done after the presentation and discussion of each proposal. The same will be arrived at consensus and not by voting. If any Member/s has/ve any difference of opinion, the same has to be clarified in the meeting by the

Investigator. If any person has COI, the Chairperson will ensure that all persons with COI do not attend the decision-making.

j. If the Investigator is requested by the IHEC to submit addition documents/evidence, the Investigator with will submit the same in a specified time period to the Secretariat. The documents will be circulated to the IHEC and the decision will be arrived. Till then the decision is given as "Revision requested".
k. It is the responsibility of the Member Secretary to prepare the minutes and obtain the approval from the Chairperson after getting comments from all the IHEC Members. The same will be done within 2 weeks of after preparation of the draft minutes.
l. The decision letters will be prepared by the Member Secretary in the standard formats given in concerned SOPs. The same will be issued to the Investigators after obtaining acknowledgement for receipt.
m. The Meeting procedure will be completed by issuing the decision letters to the PIs.

Annex:

Log for incoming and outgoing documents

S. No.	Document name	Received from Name and designation	Date	Remarks

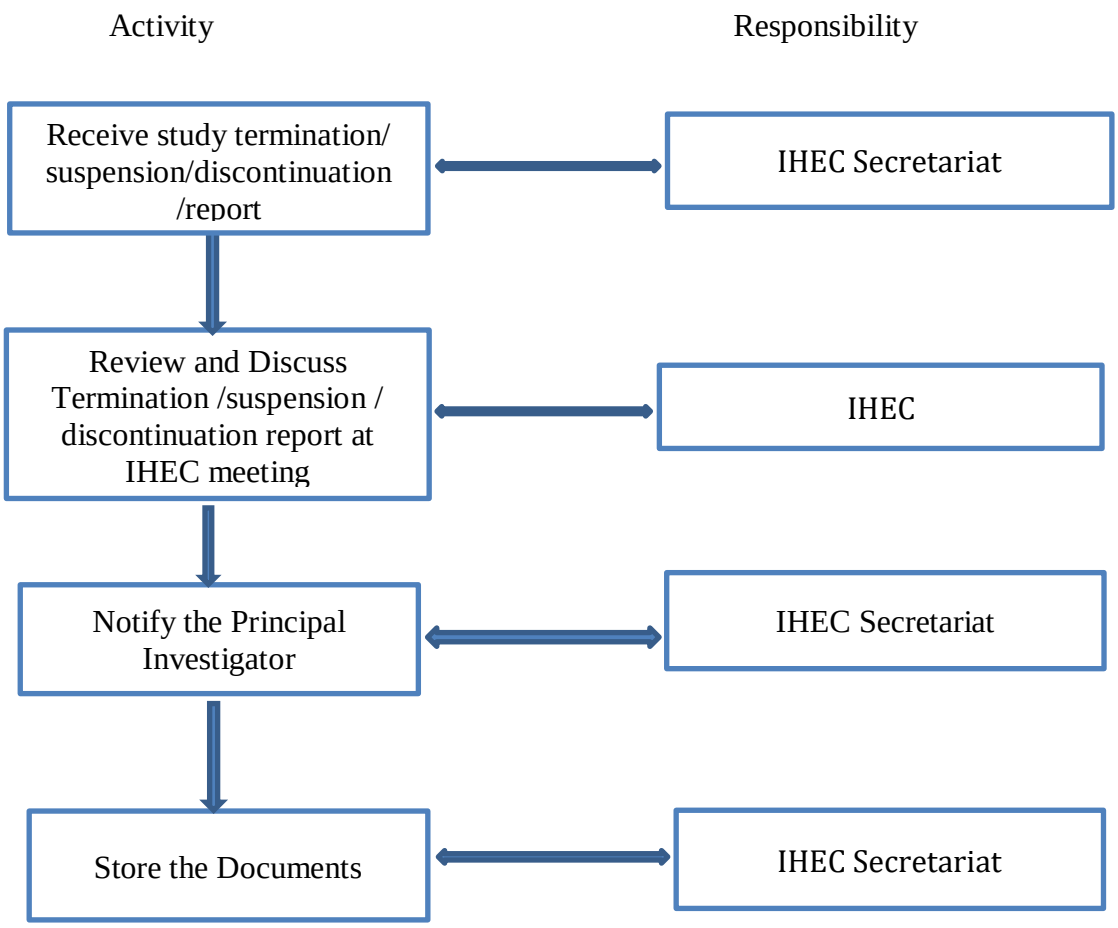
S. No.	Document name	Sent to Name and designation	Date	Remarks

Management of Premature Termination/Suspension/Discontinuation of the study

SOP/013/03.0
Effective Date: 1st October 2021

1. **Purpose**
   The purpose of this SOP is to describe the procedure for management of the premature termination/suspension/discontinuation of a research study by the IHEC. Research studies are usually terminated as per the recommendation of the IHEC, PI, sponsor or other authorized bodies wherein subject enrollment and subject follow-up are discontinued before the scheduled completion of the study.
2. **Scope**
   This SOP applies to any study approved by IHEC that is being recommended for termination/suspension/discontinuation before its scheduled completion.
3. **Responsibility**
   It is the responsibility of the IHEC to terminate any study that the IHEC has previously approved when the safety or benefit of the study participants is doubtful or at risk, also to review the termination suggested by PI, Sponsor or other authorized bodies. The secretariat is responsible for management of the premature termination/ suspension/discontinuation process.

4.Flow Chart


Activity
Responsibility
Receive study termination/ suspension/discontinuation /report
IHEC Secretariat
Review and Discuss Termination /suspension / discontinuation report at IHEC meeting
IHEC
Notify the Principal Investigator
IHEC Secretariat
Store the Documents
IHEC Secretariat

5.Detailed instructions

4.1. Receive recommendation for study termination / suspension /discontinuation

a. The secretariat will receive recommendation and comments from PI, Sponsor or other authorized bodies for premature termination of study.
b. The IHEC members/Chairperson can prematurely terminate the study if protocol non-compliance/violation is detected and IHEC decision is to terminate the study due to any reason. For e.g.- Frequency of SAEs occurring at study site may require the study to be prematurely terminated for the safety of the patients.
c. The secretariat will inform the PI to prepare and submit a protocol termination package along with Premature Termination Report (available at IHEC office)
d. The secretariat will receive the study protocol termination prepared and submitted by the PI and verify the contents of the report for inclusion of:
    a. Premature Termination Report/suspension/discontinuation (AF 01/013/03.0) signed and dated by the PI and/or other material (letter from Principal Investigator/sponsor etc)
e. The Secretariat will check the completeness of the information
f. The Secretariat will receive and acknowledge the reports.
g. in case of termination of any clinical trial, of any bioavailability or bioequivalence study the detailed reasons for such termination shall be communicated to the Central Licencing Authority within thirty working days of such termination

5.1. Review and discuss the Termination / suspension/discontinuation report

a. IHEC will review the termination report suspension/discontinuation at regular full board meeting or expedited review meeting.
b. The Secretary in the meeting will inform of the premature termination suspension/discontinuation of the project and the IHEC members will review the Premature Termination Report (AF 01/013/02.0) along with relevant SAE reports
c. If the Premature Termination Report suspension/discontinuation is unclear/more information is required from the PI, the Secretariat is instructed to send a query to the PI.
d. The Committee mentioned that if the concerned investigators do not submit necessary documents for review even after three reminders (in monthly intervals) from the Secretariat, the IHEC approvals for such studies would be terminated. The same will be ratified during the next full board meeting.

5.2 Notify the PI

a. The Secretariat will prepare a notification letter acknowledging the acceptance of termination /suspension/discontinuation or query letter to request information regarding the premature termination /suspension/discontinuation.
b. The Secretariat will send the notification letter to the PI for their records within 14days after the meeting.
c. If a query is sent to PI, on receipt of the reply letter, it is reviewed in the forthcoming full board meeting /expedited review meeting and steps in 4.2 will be performed by the secretariat.

5.3 Store the Report

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

project termination.

6 References

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, (Geneva 2000)-www.who.int/tdr/publications/publications/ (31st March 2013).
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996 http://www.ich.org/LOB/media/MEDIA482.pdf (28th March 2013)
3. National Ethical Guidelines for Biomedical and Health Research involving Human Participants provided by ICMR-2017 https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf (last accessed 25th November 2020)
4. ICMR Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006) - http://www.icmr.nic.in/ethical_guidelines.pdf (last accessed 31st Mar 2013)

Annexure: AF 01/013/03.0

Premature Termination/Suspension/Discontinuation Report

1. Protocol ID No.:
2. Protocol Title:
3. Principal Investigator:
4. Study Site:
5. Sponsor:
6. IHEC Approval Date: Date of Last Progress Report Submitted to IHEC
7. Study Start Date:
8. Termination/ suspension/discontinuation Date:
9. Study Participants
    a. Target accrual of study(entire study) _____
    b. Total participants to be recruited at the particular site (IHEC ceiling)_____
    c. Screened: _____
    d. Screen failures: _____
    e. Enrolled: _____
    f. Consent Withdrawn: _____Reason: (Attach in format below)
    g. Withdrawn by PI: _____Reason: (Attach in format below)
    h. Active (on treatment/study procedures): _____
    i. Completed (treatment/study procedures): _____
    j. Participants on Follow-up: _____
    k. Participants lost to follow up: _____
    l. Any other: _____
    m. Any Impaired participants
        i. None_____
        ii. Physically _____
        iii. Cognitively _____
        iv. Both _____
10. SAE (Total No.):
11. SAE Event:
12. Summary of Results (attach separate sheet):
13. Reason for Termination/Suspension/Discontinuation (Attach separate sheet):

PI Signature: Date:

Site Monitoring

SOP/014/03.0
Effective Date: 1st October 2021

1. **Purpose**

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

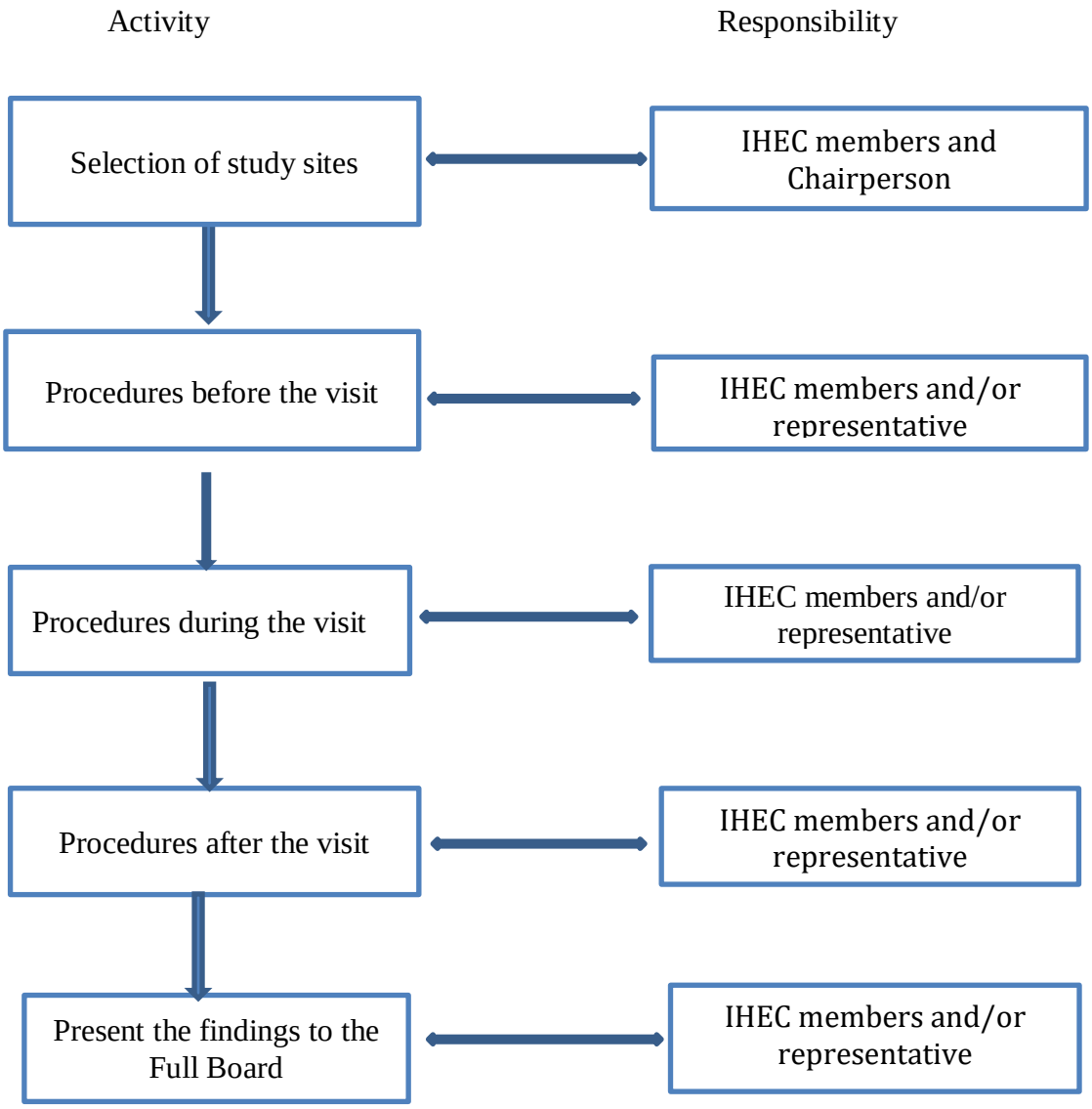
2. **Scope**

   This SOP applies to any visit and/or monitoring of any study sites as stated in the IHEC approved study protocols that identify the place(s) where the study and/or laboratory procedures are being carried out or performed.

3. **Responsibility: the IHEC may visit as an when, it is required**

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

4 Flow chart


Activity
Responsibility
Selection of study sites
IHEC members and Chairperson
Procedures before the visit
IHEC members and/or representative
Procedures during the visit
IHEC members and/or representative
Procedures after the visit
IHEC members and/or representative
Present the findings to the Full Board
IHEC members and/or representative

5. Detailed instructions

5.1 Selection of study sites

a. Review periodically the database files of the submitted/approved study protocols.

5.2 Select study sites needed to be monitored based on the following criteria:

a. New study sites
b. Reports of remarkable serious adverse events
c. Number of studies carried out at the study sites
d. Frequency of protocol submission for IHEC review
e. Non-compliance or suspicious conduct
f. Frequently fail to submit final reports
g. Failure to submit progress report

5.3 Before the visit

The IHEC representatives will

a. PI shall facilitate inspection of the required documents/records by the IHEC and any other designated person
b. PI shall facilitate inspection of the required documents/records by the IHEC and any other designated person Contact the site to notify them that they will be visiting them. At that time, the monitor and the site will coordinate a time for the site evaluation visit.
c. Make the appropriate travel arrangements.
d. Review the IHEC files for the study and site,
e. Make appropriate notes, or
f. Copy some parts of the files for comparison with the site files.

5.4 During the visit

a. Get a checklist AF 01/014/03.0
b. The IHEC representatives will
    1. Review the informed consent document to make sure that the site is using the most recent version
    2. Review randomly the participant files to ensure that participants are signing the correct informed consent
    3. Observe the informed consent process, if possible
    4. Observe laboratory and other facilities necessary for the study at the site
    5. Review the IHEC files for the study to ensure that documentation is filed appropriately.
    6. Collect views of the study participants.
    7. Debrief the visit report/comments.
    8. Get immediate feed back.

5.5 After the visit

The IHEC representative will:

a. Write a report/comment (use the form AF 01/014/03.0 see ANNEX 1) within 2 weeks describing the findings during the audit
b. Forward a copy of the site visit to the 'site monitoring' file for Full Board review.
c. Send a copy of the report to the site for their files, and
d. Place the report in the correct site files.

5.6 Present the inspection results to the Full Board

a. Consult with the IHEC secretariat.
b. Schedule the presentation in the meeting agenda.
c. Present the results of on-site inspections to the Full Board.

6. References

1. National Ethical Guidelines for Biomedical and Health Research involving Human Participants provided by ICMR-2017 https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf (last accessed 25th November 2020)
2. ICMR Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006) - http://www.icmr.nic.in/ethical_guidelines.pdf (last accessed 31st Mar 2013)
3. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- http://www.ich.org/LOB/media/MEDIA482.pdf (last accessed 31st Mar 2013)
4. WHO Operational Guidelines for Ethical Review Committee that Review Biomedical Research (Geneva 2000) - www.who.int/tdr/publications/publications/(last accessed 31st Mar 2013)

7. ANNEX

ANNEX 1 AF 01/014/0Revised Checklist of Monitoring

ANNEX 1
AF 01/014/03.0
Checklist for Monitoring Visit

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

Reporting of protocol deviation, non-compliance and violation

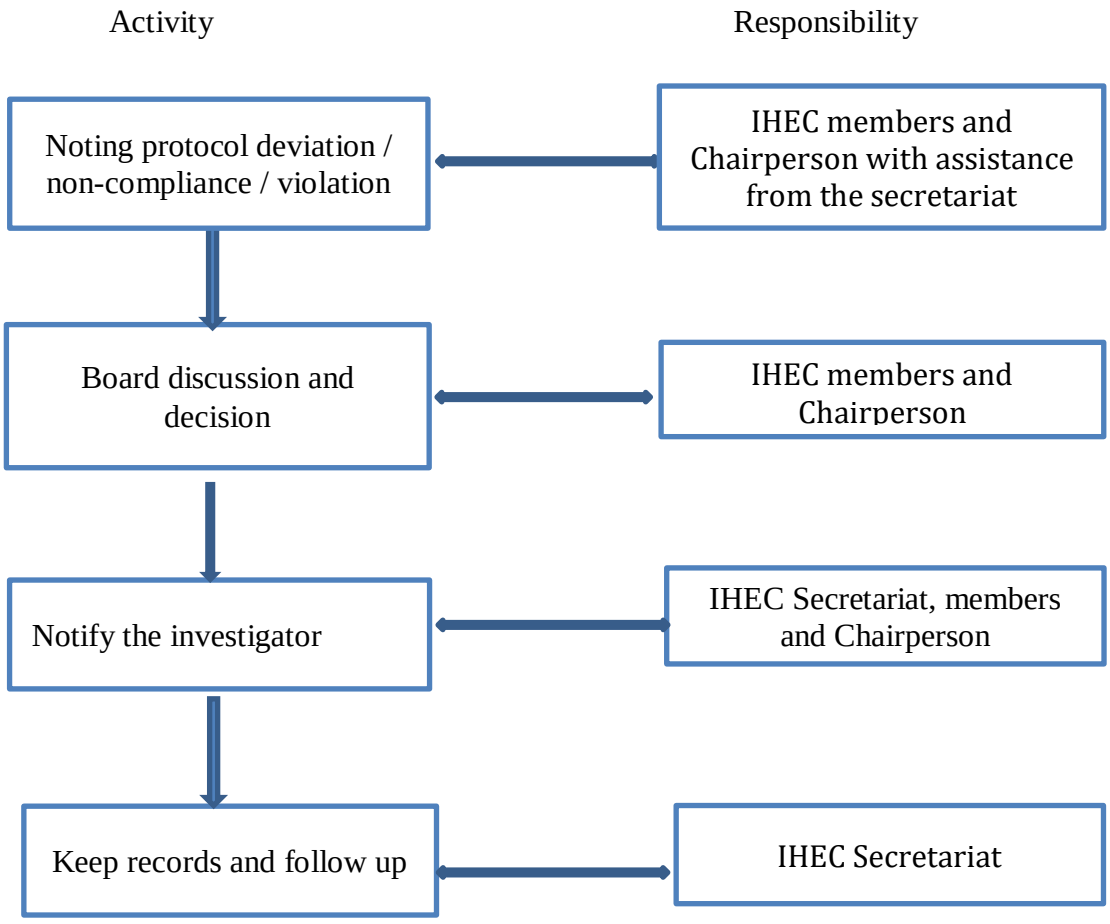
SOP/015/03.0
Effective Date: 1st October 2021

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

2. **Scope**
   This SOP applies to all IHEC approved research protocols involving human subjects, previously approved by the IHEC.

3. **Responsibility**
   The respective PI should submit the protocol deviation/violation details with appropriate justification in the prescribed formats to the IHEC for review. The IHEC secretariat will provide the information regarding SOP violation/deviation details to the Member-Secretary for presenting during the IHEC meeting The designated member of the Secretariat is responsible for collecting and recording the non-compliance list (AF/01-016/01.0).

4. Flow chart


Activity
Responsibility
Noting protocol deviation / non-compliance / violation
IHEC members and Chairperson with assistance from the secretariat
Board discussion and decision
IHEC members and Chairperson
Notify the investigator
IHEC Secretariat, members and Chairperson
Keep records and follow up
IHEC Secretariat

5. Detailed instructions

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

a. Ensure that the issues as well as the details of non-compliance involving research investigators are included in the agenda of the IHEC meeting.
b. Maintain a file that identifies investigators who are found to be non-compliant with national/international regulations or who fail to follow protocol approval stipulations or fail to respond to the IHEC's request for information/action.
c. *Note*: The Board may elect to suspend or terminate approval of current studies or refuse subsequent applications from the investigators cited. Such decisions are recorded in the minutes.
d. The clinical trials under the purview of a licensing authority must comply with all applicable regulations

5.2 The IHEC's Decision

I. The chairperson notifies the investigator of the IHEC's action in writing, when the Board

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

5.3 Notify the investigator

a. The IHEC Secretariat members record the IHEC's decision.
b. Draft a notification letter.
c. Get the Chairperson and Member-Secretary to sign and date the letter.
d. Send the original copy of the notification letter to the Director, NIE.
e. Send a copy to the relevant national authorities and institutes, if applicable.
f. Send a copy to the sponsor or the sponsor's representative of the study, if applicable.

5.4 Keep records and follow up

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

6.References

1. National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, ICMR, 2017
2 National Ethical Guidelines for Biomedical and Health Research involving Human Participants provided by ICMR-2017 https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf (last accessed 25th November 2020)
3 ICMR Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006) - http://www.icmr.nic.in/ethical_guidelines.pdf (last accessed 31st Mar 2013)
4 International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- http://www.ich.org/LOB/media/MEDIA482.pdf (last accessed 31st Mar 2013)
5 WHO Operational Guidelines for Ethical Review Committee that Review Biomedical Research (Geneva 2000) - www.who.int/tdr/publications/publications/(last accessed 31st Mar 2013)

7.ANNEX

ANNEX 1 AF/01-015/Revised Deviation/Non-Compliance/Violation Record

ANNEX 1
Form AF 01/015/03.0

Déviation / Non-Compliance / Violation Record

Protocol ID:	Date:……
Study Title:	
Investigator	Contact No.:
Institution:	Contact No.:
Sponsor:	Contact No.:

☐ Deviation from protocol ○ Major	☐ Non-Compliance ☐ Violation
Description:	
IHEC's Decision:	
Actions taken:	Outcome:

Found by…….	Reported by…….
Date…….	Date…….

Dealing participant's Request's/Complaint's

SOP/016/03.0
Effective Date: 1st October 2021

1. Purpose

The IHEC considers protection of the rights and welfare of the human subjects participating in a clinical research approved by the IHEC as its primary responsibility. Informed Consent documents reviewed by the IHEC inform the study participant that queries regarding their rights as a participant in the study may be addressed to the IHEC, Member secretary, and the IHEC address and phone number are provided.
This SOP provides guidelines for dealing with and accommodating requests by participants/patients regarding their rights as a participant or to resolve their complaints in any approved research study.

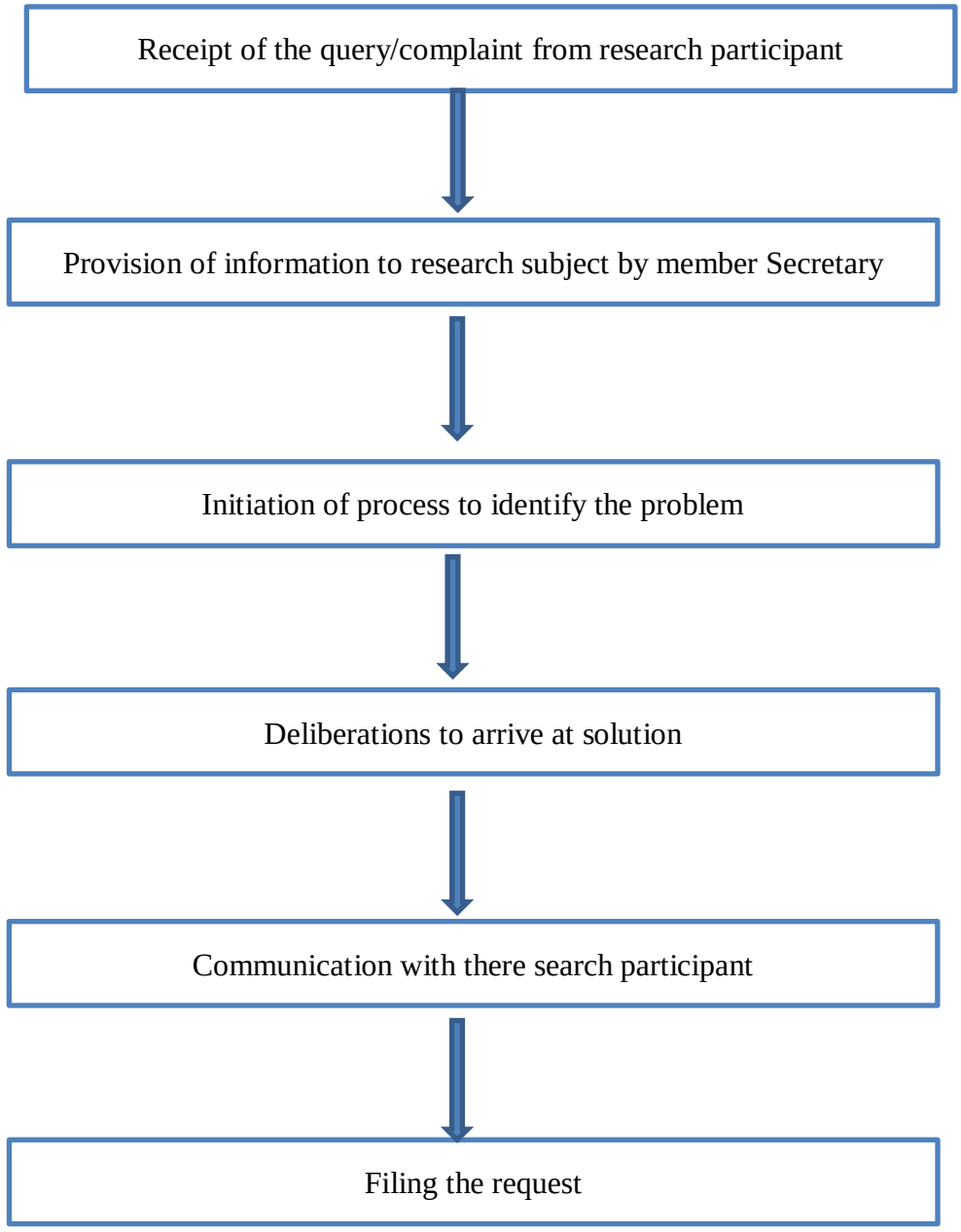
2. Scope

This SOP applies to all requests concerning the rights and well-being of the research participants participating in studies approved by the IHEC.

3. Responsibility

It is the responsibility of the IHEC Member Secretary to provide the required information to the research participants/ research participant's representatives, in case of any queries asked from them.
It is the responsibility of the Member Secretary/Chairperson to initiate the process of giving information to the participants or identifying and addressing any injustice that has occurred, if any complaints received from research participants.

Flow Chart


Receipt of the query/complaint from research participant
Provision of information to research subject by member Secretary
Initiation of process to identify the problem
Deliberations to arrive at solution
Communication with there search participant
Filing the request

4. Detailed instructions

When the IHEC member/ Secretariat staff receives an inquiry or request from research participant/ research participant's representative:

a. The request and information will be recorded in the request record form (Form AF 01/016/03.0)
b. The Member Secretary will inform the Chairperson and Director, ICMR-NIE about the query/complaint received on same day.
c. The Chairperson / Members designated by the Chairperson will provide the information required by the research participant.
d. The Chairperson will direct the Member Secretary to consider the matter with in two weeks for discussion at a full board meeting or to call an emergency meeting of 2 or more IHEC members for discussion or to appoint a subcommittee of 2 or more IHEC members for "due analysis" in order to resolve the matter.
e. The Chairperson/ Member Secretary/ designated IHEC members and Director, ICMR-NIE will assess the situation and will "facilitate" or "initiate" a dialogue between the research participant and the investigator in an attempt to resolve the matter.
f. The IHEC will insist on factual details to determine the reality between the truth and individual perception.
g. The final decision will be informed to the research participant by the Secretariat.
h. The information including any action taken or follow-up will be recorded in the form AF 01/016/03.0 and the form will be signed and dated.
i. The IHEC members will be informed about the action taken and the outcome in the forthcoming IHEC meeting.

5. Filing the request document
    a. The record form will be filed in the "response" file by the Member Secretary /Secretariat staff.
    b. A copy of the same will be kept in the study file.
    c. The file will be stored in a secure place.

Annexure: AF 01/016/03.0

Participant Request Record Form

1. Date Received:
2. Received by:
3. Request from:
- Telephone call No……
- Fax No……
- Letter / Date…… …
- E-mail / Date……
- Walk-in / Date / Time……
- Other, specify ……

4. Participant's Name:
5. Contact Address:
6. Phone:
7. Title of the Study:
8. Protocol ID No:
9. Starting date of participation:
10. Request/ Complaint :
11. Action taken:
12. Outcome:

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

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

Review of Study Completion Reports

SOP/017/03.0
Effective Date: 1st October 2021

1. Purpose

The purpose of this SOP is to provide instructions on the review of Study Completion Report for every study previously approved by the IHEC.

2. Scope

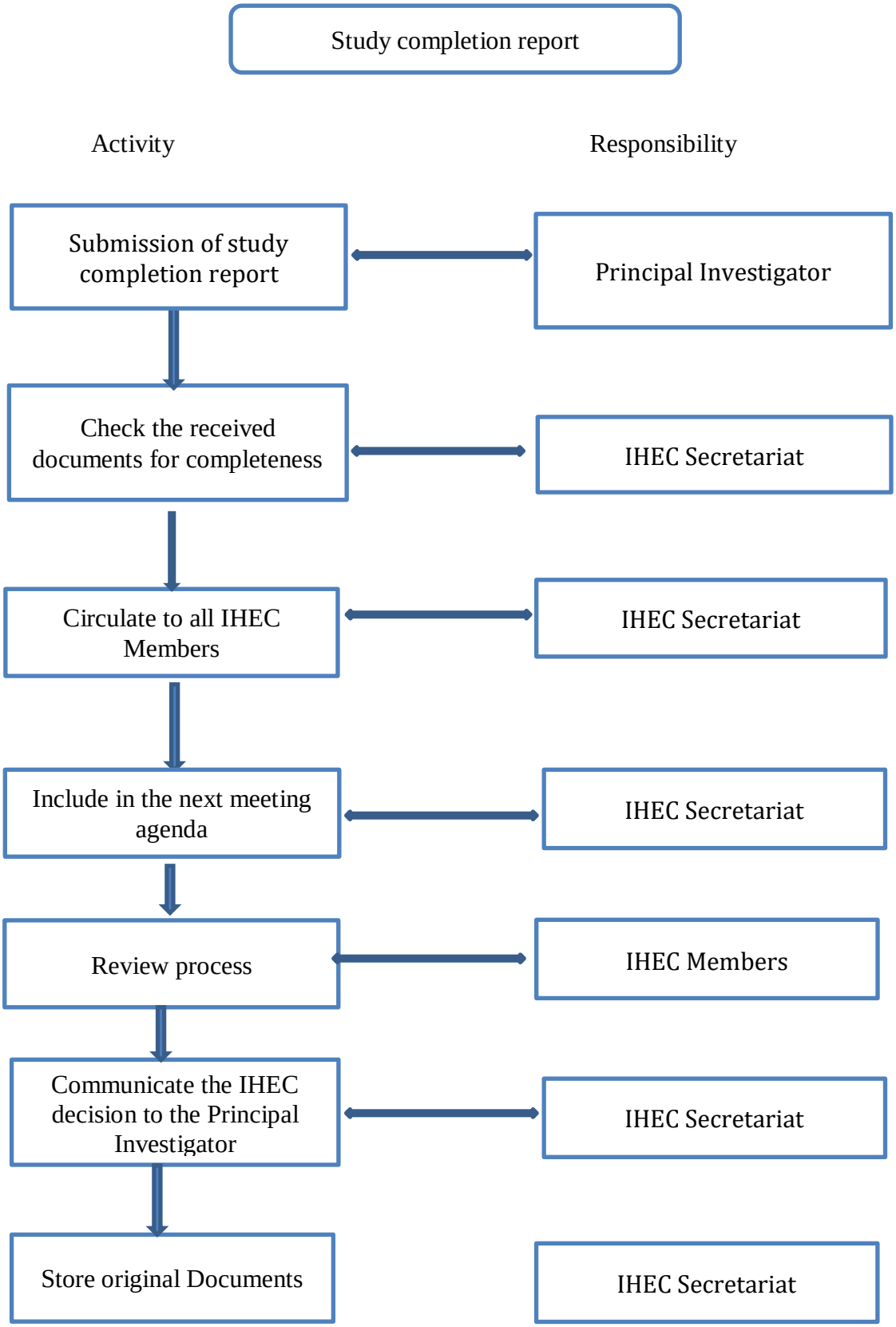
This SOP applies to the review of the Study Completion Report which is a mandatory review of each investigator's activities presented to the IHEC as a written report of study completed.

Although IHEC provides a Study Completion Report Form (AF 01/017/03.0) to the investigator, additional information (letter format, form provided by the Sponsor, etc.) may be submitted to provide adequate and sufficient information.

3. Responsibility

The study completion report should be submitted by the study PI in the prescribed formats after. It is the responsibility of the IHEC members to review the study completion report and notify it or request for further information, if necessary.

Flow Chart


Study completion report
Activity
Responsibility
Submission of study completion report
Principal Investigator
Check the received documents for completeness
IHEC Secretariat
Circulate to all IHEC Members
IHEC Secretariat
Include in the next meeting agenda
IHEC Secretariat
Review process
IHEC Members
Communicate the IHEC decision to the Principal Investigator
IHEC Secretariat
Store original Documents
IHEC Secretariat

4. Detailed instructions

4.1 Before each board meeting

a. The IHEC Secretariat will receive 14 hard copies Study Completion Reports from the PI.
b. The Secretariat will follow the guidelines given in the Management of Research study Submission (SOP/003/03.0) for receiving and checking the report documents.
c. The IHEC Secretariat will review the report for completeness before submission to the IHEC Members.
d. The Member Secretary should keep the study completion reports on the agenda for IHEC meeting.

4.2.Before and during board meeting

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

5.1 After the board meeting

a. The secretariat will note the decision in the meeting minutes and the study will be considered as closed if the document is accepted.
b. The IHEC decision is communicated to the investigator. In case, further information /action is requested; the same should be followed by the PI and communicated to the IHEC secretariat within 30 days. This update will be tabled in the full board meeting of IHEC.
c. Once the report is accepted by IHEC, the Secretariat will file the report in the study master file.
d. The IHEC secretariat will archive the entire study as per the instructions given in the SOP/017/03.0 and the report for a period of 5 years or more (as mentioned in the protocol) from the date of completion of the project, if the report is accepted.

References

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, (Geneva 2000) - www.who.int/tdr/publications/publications/
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- http://www.ich.org/LOB/media/MEDIA482.pdf
3. National Ethical Guidelines for Biomedical and Health Research involving Human Participants provided by ICMR-2017 https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf (last accessed 25th November 2020)
4. ICMR Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006) - http://www.icmr.nic.in/ethical_guidelines.pdf (last accessed 31st Mar 2013)

Annexure: AF 01/017/03.0

Study Completion Report Form

1. Project ID No.
2. Study Title:
3. Principal Investigator:
4. Sponsor
5. Objectives of the study:
6. Duration of the study
7. Study Start Date
8. Completion Date
9. Summary of Protocol participants:
10. Sample size (entire study) _____/Not applicable
11. Total patients to be recruited at each site_____/Not applicable
    a. Screened: _____
    b. Screen failures: _____
    c. Enrolled: _____
    d. Consent Withdrawn: _____Reason:
    e. Withdrawn by PI: _____Reason:
    f. Active on treatment: _____
    g. Completed treatment : _____
    h. Patients on Follow-up: _____
    i. Patients lost to follow up: _____
    j. Any other: _____
12. Any Impaired participants
    a. None_____
    b. Physical _____
    c. Cognitive _____
    d. Both _____
13. Results (brief) (use extra blank sheets, if more space is required)
14. SAEs observed (Total number and type)
    a. Whether all SAEs were intimated to the IHEC (Yes/No)
15. Protocol deviations/violations (Number and nature)
16. Conclusion
17. Presentation/publication related to the data generated in this study

Signature of PI
Date:

Maintenance of active project files, archival/disposal closed files and retrieval of documents

SOP/018/03.0
Effective Date: 1st October 2021

1. Purpose

To provide instructions for preparation and maintenance of active study files and the related documents approved by the IHEC, and storage/archival of closed files and retrieval of documents.

2. Scope

This SOP applies to all active protocol/study files, closed files and their related documents that are maintained in the IHEC Secretariat and archival site.

3. Responsibility

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

4. Active study files maintenance & archival of closed files

A Study Master File is the file comprising all essential documents and correspondence related to the study/protocol. Study master files should be established at the time of initial submission in the IHEC Secretariat.

The study files are assigned unique identifiers (serial project ID no.)

All documents related to the study file are gathered, classified and combined together appropriately.

All active files are kept in a secured file cabinet with controlled access. Only authorized individuals' i.e. IHEC Members/Secretariat will have access to the files. The study files are maintained in an easily accessible and secure place for at least 5 years after the study closure.

All closed study files are separately archived. IHEC Secretariat staff will arrange for the closed project files to be archived once the completion/status reports are reviewed by the IHEC. The completed/closed project files will be stored in archive boxes that are clearly labeled with the project number and title, Principal Investigator and disposal date. The archive boxes will be sent to a secure, dry location. The access to the files should be restricted to the IHEC and the regulatory authorities. The details of the archiving location should be recorded in a location register stored in the IHEC Secretariat. This register should record the project number and title, Principal Investigator and the disposal date. This procedure should be carried out in accordance with NIE policies.

5. **Disposal of closed files and copies of protocols and documents submitted for IHEC review**:

The study master file will be maintained in the IHEC Secretariat for a period of five years following closure of the study. After completion of the archival period the closed files will be shredded and disposed off in the shredding facility after informing the study PI. However, all the copies of the research projects and documents submitted for IHEC review will be shredded by the authorized IHEC personnel after the IHEC meeting without any notification to the Principal Investigator. If a PI proposes to get the proposal copies back, the same can be given after getting a written request. However the completed and signed reviewers form will be filed in the master study file. A logbook of disposed documents of the closed files will be maintained.

6. Accessibility / Retrieval

Master files will be made available for inspection and copying by authorized representatives of regulatory authorities after receiving the request in writing.

In case any investigator needs a copy of any document from the master file, he/she should make a written request. (AF 01/018/03.0). The IHEC staff will furnish a copy of the required document within a week with the IHEC Secretary's consent. The IHEC will issue a copy of the documents on formal written request.

Archived boxes may be retrieved from storage by the IHEC as per NIE policy.

For administrative purposes, the IHEC Secretariat can retrieve archived file(s) without requiring the Chairperson's approval. For this purpose the Member Secretary can authorize a staff member of the IHEC secretariat to physically retrieve a file.

Whenever an item is retrieved from the archives, the date, item and person retrieving the item should be documented, together with the date returned to the archives.

7. Final Disposal of Master files

The master files will be disposed off by the IHEC secretariat after the archival period of 5 years or more as mentioned in the proposal. A formal written off register (AF 02/018/03.0) will be maintained, providing details of the documents being written off / disposed off after notification to IHEC in IHEC meeting and the PI.

Annexure: AF 01/018/03.0

Document Request Form

Project ID No:
Proposal title:
Name of Principal Investigator/ Requesting Person:
Designation:
Date:
Documents requested:
Purpose of request:
Principal Investigator / Requesting person's sign & date
Permission of the Secretariat: Yes/No Signature of IHEC Secretariat:

Annexure: AF 02/018/03.0

Master register of the proposals submitted for IHEC review

S. No	Protocol title	Protocol ID	PI	Initial review	Decision	Continuing / Annual review	Decision	…..
1	XYZ	NIE/IHEC/201308/01	ABC	mm/dd/yyyy	Approved	mm/dd/yyyy	Approved	
2	ABC	NIE/IHEC/201308/02	XYZ	mm/dd/yyyy	Approved With suggestions	mm/dd/yyyy	Completed Approved	
3	PQR	NIE/IHEC/201308/03	XYZ	mm/dd/yyyy	Rejected	mm/dd/yyyy	Approved With suggestions	
4	…	…						
…								

Online Ethics Committee Meeting Procedures
SOP/019/03.0
Effective Date: 1st October 2021

1. Purpose:

This SOP is designed to describe how the IHEC meetings need to be conducted 'online' when a physical meeting is not possible certain conditions such as but not limited to pandemic situations like COVID-19. The IHEC meeting will be conducted to discuss the ethical issues in the submitted study proposals and issue decisions on the same. The term 'online' refers to a mode of meeting where the participants who are physically present in different locations meet in a common virtual internet-based platform.

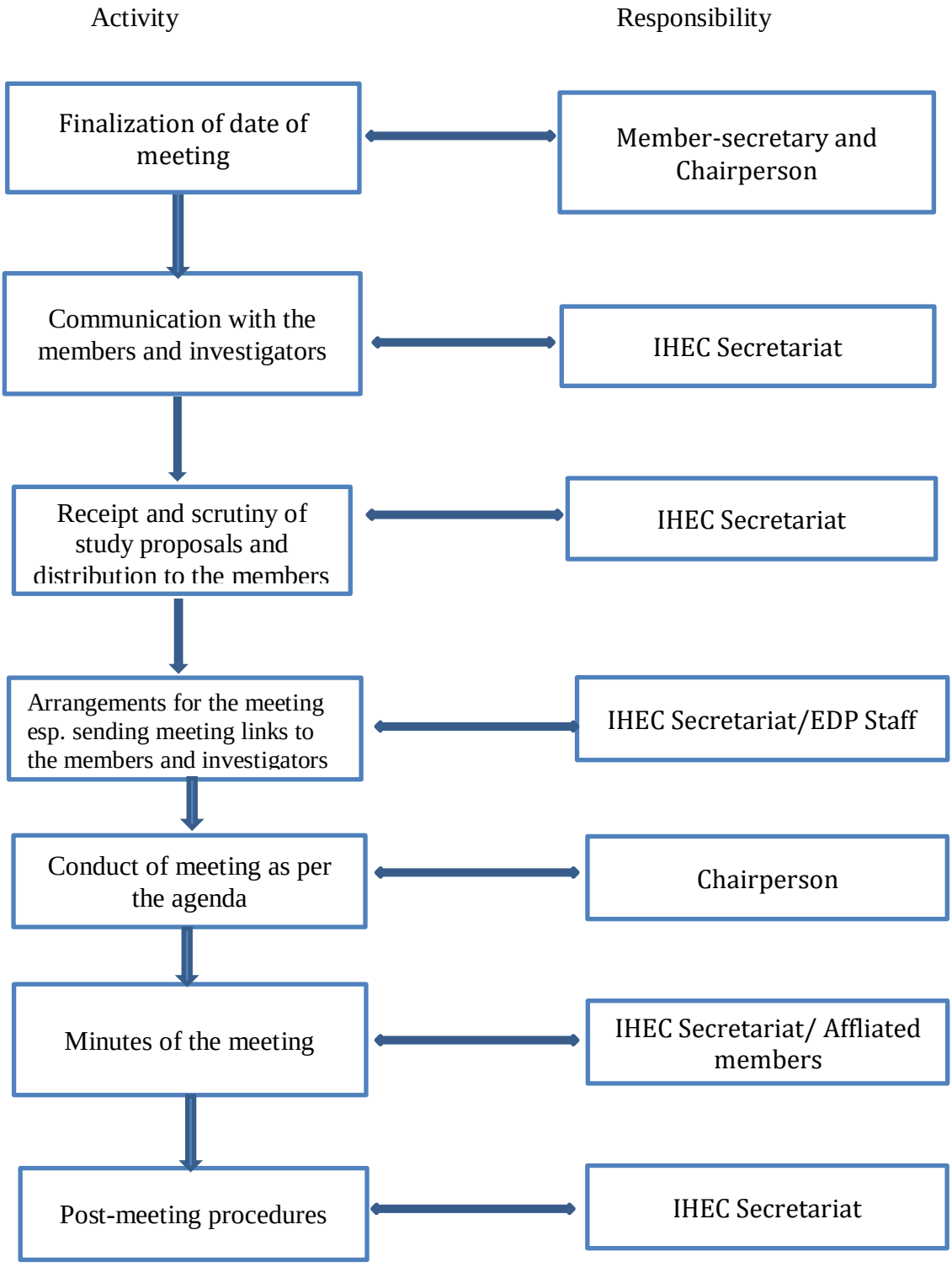
2. Scope:

The scope of this SOP is applied to the planning, communication, and organization of the regular, ad-hoc/emergency and expedited IHEC meetings in an online platform. All other SOPs applicable to a physical meeting shall also apply to the online ethics committee meeting.

3. Responsibility:

The Chairperson is responsible for calling the regular meetings, which will be conducted on the third Wednesday of the first month of every quarter. The member-secretary with the help of the technical staff (EDP section) has the responsibility of intimating all the members and investigators. Based on necessity, ad-hoc/emergency meetings can be called on the request of the Director. The member-secretary in consultation with the Chairperson will decide on calling such meetings. Expedited meeting will be conducted as per the procedures discussed in the SOP 006.

5. Flow chart:


Activity
Responsibility
Finalization of date of meeting
Member-secretary and Chairperson
Communication with the members and investigators
IHEC Secretariat
Receipt and scrutiny of study proposals and distribution to the members
IHEC Secretariat
Arrangements for the meeting esp. sending meeting links to the members and investigators
IHEC Secretariat/EDP Staff
Conduct of meeting as per the agenda
Chairperson
Minutes of the meeting
IHEC Secretariat/ Affliated members
Post-meeting procedures
IHEC Secretariat

5. Detailed instructions:

1. The member-secretary will finalize the meeting date in consultation with the Chairperson. Unless circumstances dictate otherwise, planned meetings will be conducted on the third Wednesday of the first month of every quarter. The date may be changed due to public holidays or other reasons, which will be intimated to the Chairperson, members and investigators.
2. The invitation for the meeting will be sent to the members in advance by the IHEC Secretariat. The same will be communicated to the investigators via email. The final date will be fixed by the member-secretary and Chairperson.
3. The IHEC secretariat will receive, scrutinize and distribute via email the final copies of proposals to all IHEC members. The investigators are required to submit the PowerPoint presentation along with the proposal documents. This PowerPoint file will be used to for projection at the time of the online meeting. In case the investigator wants any changes in the file, they can submit a revised file 8 days prior to the meeting.
4. The member-secretary will be available in-person at the ICMR-NIE online meeting room whereas other members will be requested to attend from their locations without the need to be physically present at the ICMR-NIE building. The Chairperson can attend in-person or from their preferred location through online platform. The Chairperson/members shall provide their electronic signatures to the member-secretary to be affixed in the appropriate documents.
5. Use of electronic signatures: The member-secretary will write an email application to the Chairperson and members requesting their electronic signatures stating the specific purpose. The Chairperson/members will provide a written consent in a reply email to the member-secretary and also provide the picture/PDF of the signature as an attachment.The same can be used as signature in those specific IHEC documents.
6. The member-secretary will contact the members and confirm their availability for the meeting. In the email communication sent to the members for confirming their availability, the member-secretary shall intimate them about the online platform that will be used, the requirements for such an online meeting (for e.g., laptop with mic and camera or specifications of the phone, software and the type of internet connection required.) and the ‘dos’ and ‘don’ts’ document specific to online meetings. The investigators shall also be intimated in a similar fashion. The members and investigators should be specifically asked to attend the meeting in a private room without interference from others and maintain professionalism at all times during the meeting. All the attendees should make themselves visible via the camera at all times to ensure their presence and identity. The selection of the online platform will be made by the member-secretary based on the resources available to the institution.

7. If any member wishes to attend the meeting in-person for any reasons, they shall apply to the member-secretary via email 8 days in advance of the scheduled meeting date. The member-secretary may decide on this request keeping in mind the space requirements and the need to maintain social distancing in the meeting room.
8. Honorarium shall be paid to the members as per the ICMR-NIE institutional meeting guidelines. Members who attend the online meetings can be reimbursed for the internet charges upon submission of a valid bill, similar to transportation allowance given for in-person attendance.
9. On the day of the meeting, an online meeting link will be setup and sent to the members. The meeting will start as per the timing mentioned in the agenda. The meeting host (Chairperson) will monitor the entry of the members into the online platform. The Chairperson will obtain verbal consent from the attendees for video recording the meeting. The Chairperson shall assess and confirm the required quorum for the meeting (as per expedited meeting norms). The members will be requested to confirm the minutes of the previous meeting. The Chairperson will request the members to declare any COI with regard to the proposals to be discussed.
10. With the help of the appropriate technical staff, the member-secretary will coordinate the sequence of the investigators who will be allowed to join the online meeting and present their proposal one-by-one. This sequence of investigators shall be prepared in advance and the investigators will be intimated just prior to the meeting so that they can be ready when their turn comes. The technical staff shall send the meeting link to the investigator upon the request of the member-secretary. The investigator will present their research proposal and asked to provide clarifications. The presentation will be managed by the technical staff. The primary reviewer will lead the discussion. The secondary reviewer will provide comments on ethical and consent related aspects. After presenting, the investigator will be exited from the online platform by the host of the meeting, before allowing the next investigator to join. The member-secretary will summarize the important discussion points and recommendations pertaining to the proposal, based on which the members will take a consensus decision about the proposal.
11. The minutes of the meeting will be recorded by the member-secretary along with assistance from affiliated members. The video recording may be sent to the members by the member-secretary after obtaining the permission of the Chairperson with the understanding that the members will not share it to anyone else outside the ethics committee.
12. In case of technical issues such as a member not being able to join the meeting, or lost in between due to internet connectivity issues, the member-secretary with the permission of the Chairperson shall take the decision so as to postpone their concerned presentation until such time that they can join the meeting. Any member who wants to leave the meeting shall do so with the permission of the Chairperson after stating appropriate reasons. The member-secretary shall monitor the quorum continuously and intimate the Chairperson if it fails the meet the minimum requirement. The meeting shall be stopped until such time the quorum is reached. The member-secretary shall update the minutes to the member(s) who lost connection in between. If the investigator faces such issues, they can be asked to rejoin after giving a fixed time limit as decided by the member-secretary. In case the investigator fails to join during that time, their presentation can be postponed to

the end. Breaks during the meeting can be give as in physical meetings. The process of quorum should be followed after every break comes to an end.

13. The post-meeting procedures like circulation and finalization of minutes, issue of suggestion and decision letters will be carried out by the Secretariat of IHEC. The IHEC will issue the decision letters to the concerned investigators after obtaining approval from the Chairperson. The member-secretary will present the vote of thanks and bring the meeting to an end. The technical staff will end the online process.

6. Annexures:

Same as in SOP 011

Review of COVID-19 research proposals
SOP/020/03.0
Effective Date: 1st October 2021

1. Purpose

The purpose of this SOP is to provide instructions on the review of COVID-19 related research study proposals.

2. Scope

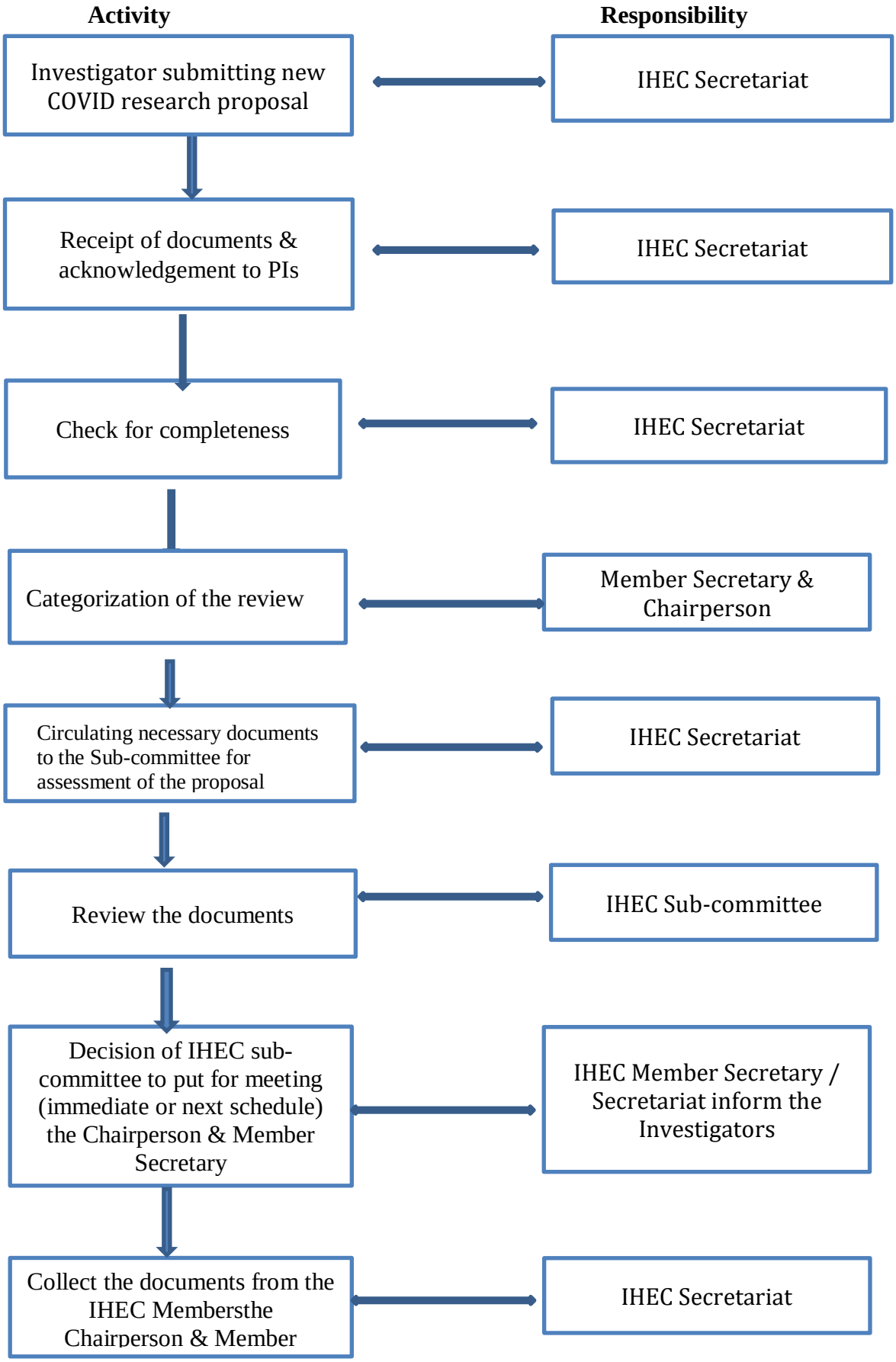
In view of the potential need for ethical review of certain studies in emergency situations/disasters/epidemics at ICMR-NIE, the Institutional Ethics Committee of ICMR-NIE is proposing the following recommendations for COVID-19 related research. However, these recommendations are subjected to change from time to time depending upon release or revision of the national and international Ethical guidelines.

3. Responsibility

- All research studies presented with more than minimal risk and which do not qualify for exemption or expedited review, or involve vulnerable populations and special groups, should be subjected to full board review. Application for a full review and the review process should be processed as described in the other SOPs.
- The PI should clearly state the nature of the study, risk of transmission of COVID-19 to the study team members (such as Sample / data collectors) and the study participants. The IHEC application form and the protocol of the study should clearly specify the means and methods adopted for protecting both researchers and participants from risk of infection and/or stigma/loss of privacy/loss of confidentiality. In case of risk of transmission, what should be the mode of management and compensation for both study participants and the researchers/study team members/field workers/laboratory technicians/data collectors, etc.,
- The EC must assess the vulnerability in the light of chance of COVID-19 transmission to the study participants and the potential complications in addition to other vulnerabilities.
- For emergency review, the PI should write to the Member Secretary (MS) of the IHEC clearly explaining the need of emergency review. The IEC Member Secretary can communicate with the Chairperson about the potentiality of the study, primary reviewer and Secondary reviewer for such studies and keep an available list of potential primary and secondary reviewers. The IHEC should try to complete the review in 48-72 hours. The IHEC reviewers may need 48-72 hours to undertake the review process thoroughly. With active engagement by researchers in terms of responses to feedback, the turnover time can be 72 hours at the very minimum. This time frame is tentative and will also depend on the complexity of the study and the number of proposals.
- The proposals should adequately describe the provision of compensation/ insurance for the study participants and/ or the field-level data collectors.

- For studies related to data sharing or biological material transfer, all existing rules from the Government of India should be followed.
- Monitored emergency use of unregistered and experimental interventions (MEURI) may be approved but must follow the guidelines provided in ICMR- National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (Clause 12.7.3, page 147)
- IHEC must ensure that the proposals which aim to handle biological sample, should ensure safety measures at all levels to protect the participants and the personnel involved in sample collection, transportation, testing, storage or repository, etc., A clear plan on adequate training of the research team members should be stated in the proposal(s).
- If written informed consent is not possible to get (If participant in isolation or quarantine), consent can be obtained orally. Electronic media like audio recording can be used to document such process. EC should evaluate the same to ensure the adequacy of the information, privacy, and confidentiality of the potential participants. Use of technology (Audio/ video/ interactive website, etc.,) can be used to provide the information about the study to the participants.
- Approval shall be granted by the IHEC, coordinated by the Member Secretary if all comments in the feedback are reasonably addressed or plausible explanations are provided for the inability to address them. This approval can be electronically transmitted if they cannot be collected in person. All such approvals and the revisions required thereof requires to be ratified in the subsequent full committee meeting of the IHEC. A complete report of outcomes of such studies should be submitted to the IHEC after the study is over. All other existing regulations regarding record keeping, follow-up of annual reviews, etc., will continue to apply as per standard IHEC SOPs by the IHEC Secretariat.

4. Flow-chart


Activity
Responsibility
Investigator submitting new COVID research proposal
IHEC Secretariat
Receipt of documents & acknowledgement to PIs
IHEC Secretariat
Check for completeness
IHEC Secretariat
Categorization of the review
Member Secretary & Chairperson
Circulating necessary documents to the Sub-committee for assessment of the proposal
IHEC Secretariat
Review the documents
IHEC Sub-committee
Decision of IHEC sub-committee to put for meeting (immediate or next schedule) the Chairperson & Member Secretary
IHEC Member Secretary / Secretariat inform the Investigators
Collect the documents from the IHEC Membersthe Chairperson & Member
IHEC Secretariat

5. Detailed instructions

(i). To take up the COVID-19 related research proposals as per the ICMR Guidelines 2020 "National Guidelines for Ethics Committees Reviewing Biomedical & Health research during COVID-19 Pandemic".

(ii). Hard copy of the study proposal needs to be shared to the Primary Reviewer in addition to soft copy. The primary reviewer should get 48 to 72 hours to go through the proposal before the scheduled meeting.

(iii). The Member Secretary will coordinate with the decisions of the IHEC to the investigators.

6. Glossary

COVID-19:

SARS-CoV-2:

Coronavirus

7. Reference

1. National Guidelines for Ethics Committees Reviewing Biomedical & Health research during COVID-19 Pandemic" Indian Council of Medical Research, April 2020
2. National Ethical Guidelines for Biomedical and Health Research involving Human participants, Indian Council of Medical Research, October 2017
3. National Ethical Guidelines for Biomedical and Health Research involving Children, Indian Council of Medical Research, October 2017.
4. National Ethical Guidelines for Biomedical and Health Research involving Human Participants provided by ICMR-2017 https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf (last accessed 25th November 2020)
5. ICMR Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006) - http://www.icmr.nic.in/ethical_guidelines.pdf (last accessed 31st Mar 2013)

8. ANNEX

Annexure: AF 01/020/03.0

Cover letter for submission

Submission letter format

Letter Head of NIE Date:

To

The Chairperson,

Institutional Human Ethics Committee,

NIE (ICMR), Chennai

Forwarded through the Director, NIE

Dear Sir / Madam,

A study proposal with the details mentioned below is submitted for review and discussion during the NIE IHEC meeting to be held on _____ at NIE.

Subject: New submission related to COVID-19 research

Project ID:

Protocol Title:

Protocol Version with date:

Principal investigator:

Thanking You.

Signature the Principal Investigator

Designation,

ICMR-NIE, Chennai

Annexure: AF 02/020/03.0

Protocol Template for submission to IHEC for review

Protocol Template for submission to IHEC for review

<Title>

Primary Investigator:

Co-Primary Investigator(s) (if any):

Co-investigator(s):

Collaborating institution(s) (if any):

Proposed funding agency:

Background Significance/Rationale Objective(s)

Methods

Inclusion /Exclusion/ Withdrawal criteria

Human participants' protection/ Ethical consideration Expected outcome

Project implementation plan Timeline

Budget outline

Role and undertaking of investigator Ref

Review of studies on Public health response to outbreaks [PHRO Review]

SOP/021/03.0

Effective Date: 1st October 2021

1. **Purpose**

Outbreaks/epidemics/clusters are public health emergencies requiring immediate attention and mitigation. Investigating an outbreak or cluster of health-related events is part of public health response through a set of procedures used to identify the cause of the disease/event, the people affected, the mode of spread of the disease, and other relevant factors involved in propagating the outbreak/event, and to take effective actions to contain and prevent the spread of the disease/health-related event.
Investigating an outbreak/epidemic is a set of procedures used to identify the cause responsible for the disease, the people affected, the circumstances and mode of spread of the disease, and other relevant factors involved in propagating the epidemic, and to take effective actions to contain and prevent the spread of the disease. Conducting an outbreak investigation requires planning and strategy to answer these key questions.

A disease outbreak/epidemic is the occurrence of cases of disease in excess of what would normally be expected in a defined community, geographical area or season.
The purpose of this SOP is to provide criteria for those research studies for public health response to outbreaks by IHEC.

2. **Scope**

This SOP applies to the review and approval of research studies for public health response to outbreaks by IHEC.

3. **Responsibility**

It is the responsibility of the Member Secretary to identify which research studies or documents are eligible for public health response to outbreaks according to the guidelines given in this SOP.

4. **Categorization of protocols**

The Member Secretary in consultation with the Chairperson, IHEC will screen the study for its completeness and depending on the risk involved in the research study categorize it into three types, viz.

d. Full committee review
e. Expedited review, including Academic reviews
f. Exemption from review

An investigator cannot categorize his/her study in to the above three types. This SOP describes emergency review for public health response to outbreaks research in detail.
An investigator may apply review for public health response to outbreaks study protocol using Request Form No. AF 01/007/Revised giving appropriate justification. However, decision to accept the request, will be made by the Member Secretary, and Chairperson or Vice-Chairperson designated member of the Committee or Subcommittee of IHEC.

5. **Review of public health response to outbreaks**

PHRO review is a procedure through which certain kinds of research proposals may be reviewed and approved by a subcommittee (refer section 6.2) without convening a meeting of the full Board.
This subcommittee should be part of the main committee and comprise Chairperson/ Vice chairperson, Member Secretary and one to two appropriate designated members. Sub-committee members should be communicated prior at least 48 hours before the

meeting about the proposals and related documents submitted for expedited review.
Constitution of Sub-committee: Sub-committee consists of four members

1. Chairperson or Vice-Chairperson
2. Member Secretary or Alternate member secretary from Affiliated memebers
3. Two designated members in which one will be a non-affiliated, non-medical member

Outbreaks/epidemics/clusters are public health emergencies requiring immediate attention and mitigation. Investigating an outbreak or cluster of health-related events is part of public health response through a set of procedures used to identify the cause of the disease/event, the people affected, the mode of spread of the disease, and other relevant factors involved in propagating the outbreak/event, and to take effective actions to contain and prevent the spread of the disease/health-related event.
Occurrence of a new or rare disease or a change in the pattern of disease in an area is more likely to prompt an investigation than occurrence of a common disease with well-established transmission patterns and control measures.

5.1. PHRO review may be conducted only if the research activities that involve only procedures listed in one or more of the following categories:

g.

- *Control or prevention of the health problem:* The most important public health reason for investigating an outbreak is to help guide disease prevention and control strategies.
- *Opportunity to learn (research opportunity):* Another important objective of many outbreak investigations is to advance research.
- Public, political, or legal concerns can be the driving force behind the decision to conduct an investigation.
- *Public health program considerations*: Sometimes the outbreak investigation is used to evaluate program effectiveness.
- *Training*: Investigating an outbreak for training the concerned team members.

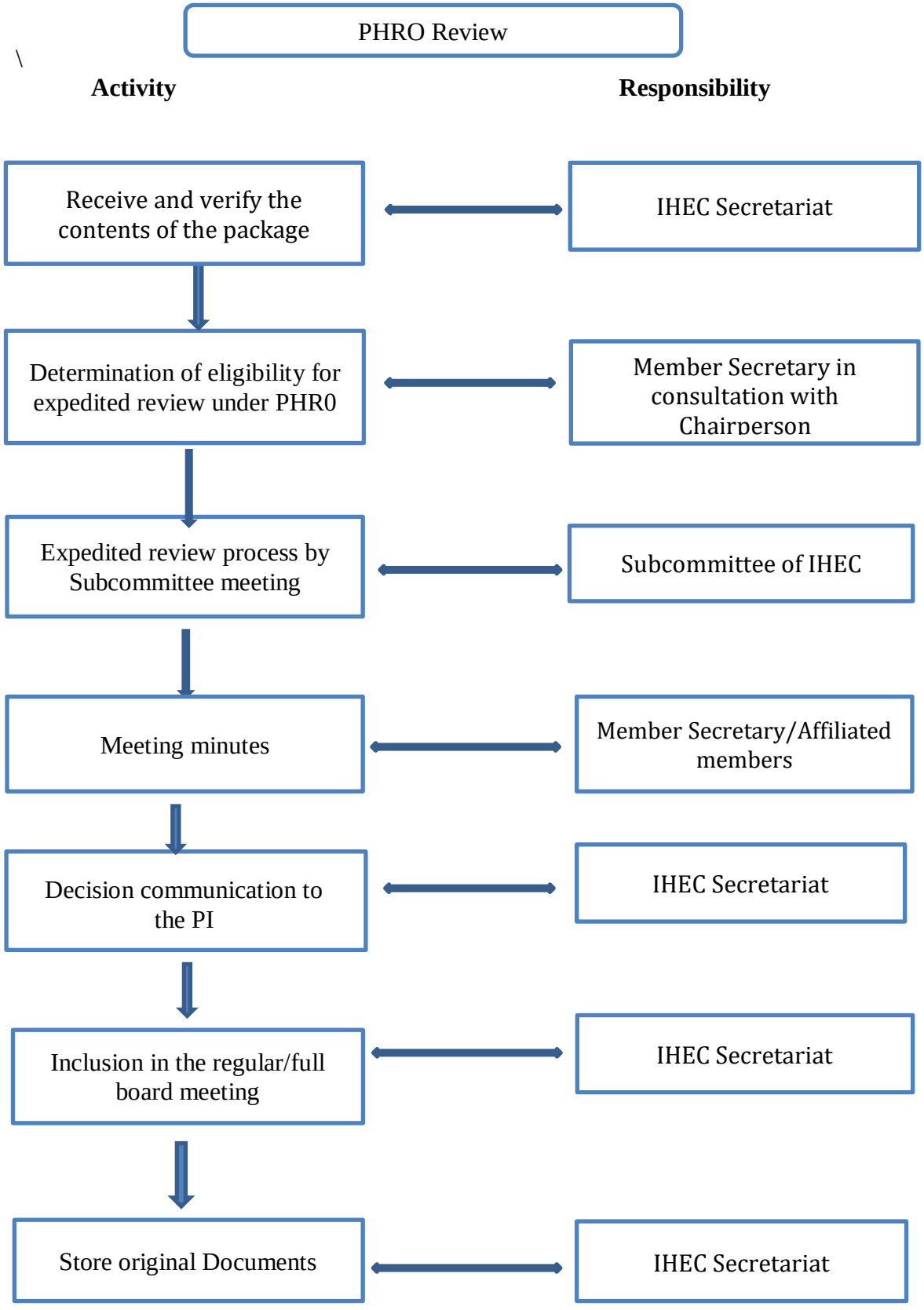
5.2. Ethics review procedures in emergency situation

Scientists and technical staff of ICMR-NIE and MPH students of ICMR School of Public Health get engaged in outbreak investigations as members of response teams set up by the public health authorities at State or Central level. Systematic approach to investigating outbreaks is part of training and practice at the ICMR-NIE (Murhekar M, Moolenaar R, Hutin Y, Broome C. Investigating outbreaks: practical guidance in the Indian scenario. Natl Med J India. 2008; 22:252–256).

Accordingly, the investigating team will be required to comply with the following procedure:

1. Submission of "Public health response to outbreaks: First Information and Plan of Investigation" to NIE-IHEC, (as per the format), prior to initiating the investigation.
2. IHEC Review of "Public health response to outbreaks: First Information and Plan of Investigation" by NIE-IHEC as per expedited review mechanism.
3. Submission of "Public health response to outbreaks: Final investigation report" to NIE-IHEC, after completion of the investigation (as per the format)

6. Flow Chart


PHRO Review
\
Activity
Responsibility
Receive and verify the contents of the package
IHEC Secretariat
Determination of eligibility for expedited review under PHR0
Member Secretary in consultation with Chairperson
Expedited review process by Subcommittee meeting
Subcommittee of IHEC
Meeting minutes
Member Secretary/Affiliated members
Decision communication to the PI
IHEC Secretariat
Inclusion in the regular/full board meeting
IHEC Secretariat
Store original Documents
IHEC Secretariat

7. Detailed instructions:

7.1. Receive the submitted documents

Receive the application documents submitted by investigators as described in this SOP

7.2. PHRO Review

h. Member Secretary of IHEC will review the documents, which qualify for PHRO review (refer section 4 & 5 of SOP or ICMR guidelines?). After deciding that the study or documents qualify for an PHRO review, Member Secretary informs the Chairperson. If the Chairperson agrees that the study qualifies for the PHRO review, a subcommittee comprising of the Member Secretary, the Chairperson one or two IHEC members will be formed. The external member will chair the meeting.

i. Review will be made only through formal meetings.

j. If a consensus cannot be reached or if the subcommittee decides that the proposal should be reviewed in a full board meeting, the Chairperson of the subcommittee will revert the study or the documents back to the IHEC for a full board review

k. The Member Secretary will track all research approved by PHRO review and will inform at the next convened full board meeting

l. The PHRO Review process should usually be completed in no more than three working days after it has been accepted and categorized for PHRO by the Member Secretary and the Chairperson

m. The minutes of the PHRO review subcommittee meeting should be ratified in the next regular IHEC full board meeting.

n. Full committee has the right to reverse/or modify any decision taken by the subcommittee or expedited committee

7.3. Communication between the IHEC and the investigator

The decision of the IHEC subcommittee will be communicated to the Principal Investigator after the minutes of the subcommittee are finalized. The communication should clearly state that the decision is subject to ratification by the IHEC full board. In case the full board is in disagreement with the decision of the subcommittee, amended letter will be sent to the PI.

If the project is approved / disapproved or requires resubmission after certain modifications, this will be informed to the Principal Investigator in writing. The reasons for disapproval of a project will be specified in the letter sent to the Principal Investigator.

8. References

5. National Ethical Guidelines for Biomedical and Health Research involving Human Participants provided by ICMR-2017 https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf (last accessed 25th November 2020)
6. ICMR Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006) - http://www.icmr.nic.in/ethical_guidelines.pdf (last accessed 31st Mar 2013)
7. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- http://www.ich.org/LOB/media/MEDIA482.pdf (last accessed 31st Mar 2013)

8. WHO Operational Guidelines for Ethical Review Committee that Review Biomedical Research (Geneva 2000) - www.who.int/tdr/publications/publications/ (last accessed 31st Mar 2013)
9. (https://www.nhp.gov.in/outbreak-investigation_pg)
10. https://www.ncdc.gov.in/WriteReadData/l892s/Check%20List%20for%20Outbreak%20Investigation%202008.pdf)

Public health response to outbreaks: *First Information and Plan of Investigation*

ICMR-National Institute of Epidemiology, Chennai

Date filed *{dd/mm/yyyy}*: _____ Version: _____

Names of investigators *{ICMR-NIE team/ MPH scholar}*

Investigator	**Name, Designation & Affiliation**
Principal Investigator	
Co-Investigators	

First Information

Subject: *{Nature of the problem (title)}*	
Location: *{State, district, Town/Village)}*	
Date of the identification of the problem by local health authorities: *{dd/mm/yyyy}*	

Description of the problem

{List the events that prompted the alert. Who is affected? Where? When? Mention possible causes and possible consequences} *<Attach separate sheet if required>*

Number of cases *(##)* **Number of deaths** *(##)*	
Person information *(Who?)*	
Place information *(Where?)*	
Time information *(When?)*	
Possible causes	
Suspected diagnosis *{Tentative diagnosis}*	

Plan of Investigation

Date of initiation of investigation *{dd/mm/yyyy}*	
Objectives of the investigation	
Outline of methods of investigation	

Signature of the PI

Date signed

Public health response to outbreaks: *Final investigation report*

ICMR-National Institute of Epidemiology, Chennai
(To be filed after completion of investigation)

Date filed *{dd/mm/yyyy}*: _____ Version: _____

Date and version of First Information and Plan of Investigation	
Final diagnosis	
Recommendations formulated based on the conclusions	
Report enclosed	Yes/ No

Signature of the PI

Formation of subcommitee

SOP/022/3.0

Effective Date: 1st October/ 2021

SOP/022/3.0

Formation for subcommittee

1. Purpose:

This Standard Operating Procedure (SOP) describes the Terms of References (TOR), which provide the framework for constitution, responsibilities, and activities of the Subcommittee.

2. Scope:

The SOP applies to all activities performed by the Subcommittee.

3.Responsibility:

It is the responsibility of the Institutional Ethics Committee members and the member secretary to read, understand, follow and respect the SOP set by the Institutional Ethics Committee.

- All research studies carried out by ICMR-NIE students (MPH/FETP/PhD) students will be qualify for the subcommitee review
- The chairperson and member secretary are responsible for appointing the Student project review Subcommittee members.
- Existing IHEC Members will be selected in their personal capacities based on their interest, ethical and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the Subcommittee work.

Membership requirement for subcommittee

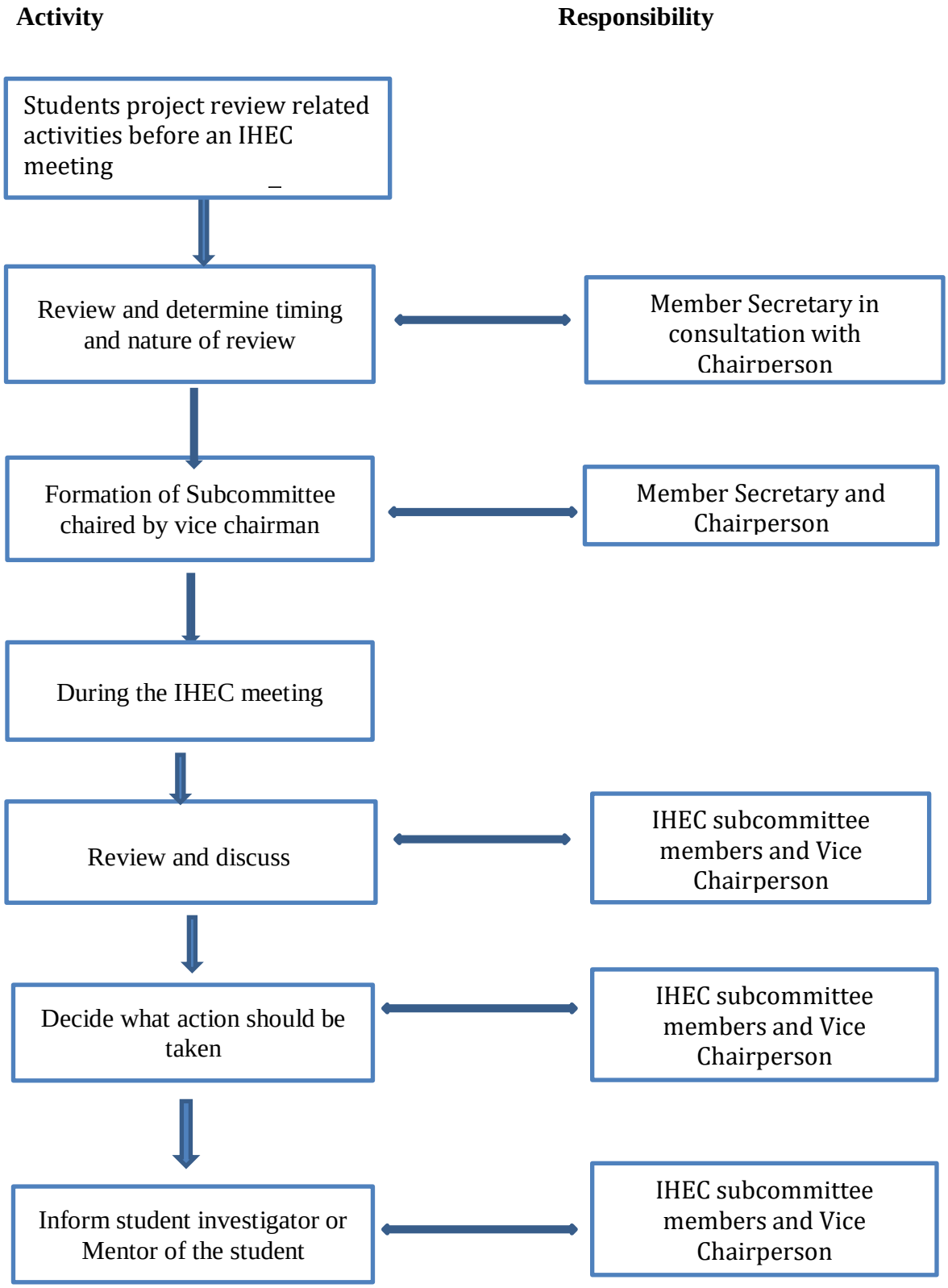
a. Clinician
b. Layperson
c. Legal expert
d. Basic medical scientist
e. Member secretary/Affliated member

- The student PI should clearly state the nature of the study, the study team members (such as Sample / data collectors) and the study participants. The IHEC application form and the protocol of the study should clearly specify the means and methods adopted for protecting both researchers and participants from risk of infection and/or stigma/loss of privacy/loss of confidentiality. In case of risk of transmission, what should be the mode of

management and compensation for both study participants and the researchers/study team members/field workers/laboratory technicians/data collectors, etc.,

- For subcommitee review , the the student researcher should write to the Member Secretary (MS) of the IHEC clearly explaining the need of review. The IEC Member Secretary can communicate with the Chairperson about the potentiality of the study.
- This subcomitte review meetings can be chaired by vice chairperson/Chairperson of IHEC.
- Any of the affliated members can act as a member secretary for handling subcomittee meetings.

4.Flow chart


Activity
Responsibility
Students project review related activities before an IHEC meeting
Review and determine timing and nature of review
Member Secretary in consultation with Chairperson
Formation of Subcommittee chaired by vice chairman
Member Secretary and Chairperson
During the IHEC meeting
Review and discuss
IHEC subcommittee members and Vice Chairperson
Decide what action should be taken
IHEC subcommittee members and Vice Chairperson
Inform student investigator or Mentor of the student
IHEC subcommittee members and Vice Chairperson

5. **Detailed instructions**:
    a. Receive the submitted documents
    b. Receive the application documents submitted by student researcher.

o. Member Secretary/ designated affliated member of IHEC will review the documents, which qualify for student research review . After deciding that the study or documents qualify for the same, Member Secretary/ designated affliated member in concurrence with the Chairperson..Member secretary/ designated affliated member will communicate to vice chairperson for scheduling of student research review meeting.
p. A subcommittee comprising of the Member Secretary/ designated affliated member, two IHEC members will be formed. The vice -chairperson will chair the meeting.
q. The Member Secretary/ designated affliated member will track all research approved by subcommitee and will inform at the next convened full board meeting
r. Full committee has the right to reverse/or modify any decision taken by the subcommittee.

Communication between the IHEC and the student researcher.

The decision of the IHEC subcommittee will be communicated to the Principal Investigator after the minutes of the subcommittee are finalized. The communication should clearly state that the decision is subject to ratification by the IHEC full board. In case the full board is in disagreement with the decision of the subcommittee, amended letter will be sent to the PI.

If the project is approved / disapproved or requires resubmission after certain modifications, this will be informed to the student researcher in writing. The reasons for disapproval of a project will be specified in the letter sent to the student researcher.

References

1. National Ethical Guidelines for Biomedical and Health Research involving Human Participants provided by ICMR-2017 https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf (last accessed 25th November 2020)
2. ICMR Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006) - http://www.icmr.nic.in/ethical_guidelines.pdf (last accessed 31st Mar 2013)
3. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- http://www.ich.org/LOB/media/MEDIA482.pdf (last accessed 31st Mar 2013)
4. WHO Operational Guidelines for Ethical Review Committee that Review Biomedical Research (Geneva 2000) - www.who.int/tdr/publications/publications/(last accessed 31st Mar 2013)

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Glossary

Active Study File	Any approved protocol, supporting documents, records containing communications and reports that correspond to each currently approved study.
Amendment	Any change in protocol and documents from that of previously IHEC approved protocol/document.
Closed Study File	Any approved protocol, supporting documents, records containing communications and reports that correspond to a study which is completed or discontinued or suspended or not initiated.
Confidentiality	Prevention of disclosure to other than authorized individuals, of information and documents related to IHEC
Deviation / Non-compliance / Violation	The IHEC monitors whether investigators do not perform the study in compliance with the approved protocol, ICH GCP, FDA regulations, Government of India notifications, ICMR ethical guidelines and/or fail to respond to the IHEC's request for information/action.
Document	Document may be in any form, e.g., paper, electronic mail (e-mail), faxes, audio or videotape, etc.
Effective date	The date of approval of the SOPs signed and dated by the Chairperson, IHEC, NIE and by Director, NIE, and subsequently the SOP is implemented from that date
Exemption from review	A research study is said to be exempt from review when it does not require the IHEC approval for its conduct
Expedited review/meeting	A review process by the IHEC subcommittee, who then report the decision to the full board in a formal meeting. An expedited review is an accelerated review for minor changes to the approved protocol, research proposal with minimal risk and documents of minor nature.
Full Board/ Regular Review	Review of initial, resubmitted, continuing review, amendments of protocols and or ICFs and any other documents, which are tabled in a formally convened meeting of the full IHEC committee for detailed discussion and decisions.
Institutional Human Ethics Committee (IHEC)	IHEC is an independent committee comprising of medical, scientific, non-medical and non scientific members, whose responsibility is to ensure the protection of the rights, safety and well being of human participants involved in bio-medical research and it shall be responsible for reviewing and approving the protocol, the suitability of the investigators, facilities, methods and adequacy of the information to be used for obtaining and

	documenting informed consent of the study participants and adequacy of confidentiality safeguards.
Independent Consultants	Professionals with advanced training and expertise in the medical or non-medical areas related to the protocol being reviewed
Initial review	The first-time review of the protocol done during the formally convened full board IHEC meeting.
IHEC members	Individuals serving as regular members of the Institutional Human Ethics Committee, NIE. This committee is constituted in accordance with the EC membership requirements set forth in ICMR ethical guidelines – 2006, Schedule Y and its respective amendments.
IHEC representatives	Many IHEC rarely find time to perform monitoring visit themselves. They may ask outside experts or the staff of Ethics Committees to perform the tasks on their behalf and later report their findings to IHEC.
Master SOP files	An official collection of the SOPs of the IHEC accessible to all staff, IHEC members, auditors and government inspectors as a paper copy with an official stamp on each page and the approval signatures. Photocopies made from these official paper versions of the SOP cannot be considered current or official.
Monitoring visit	An action that IHEC or its representatives visit study sites to assess how well the selected investigators and the institutes are conducting the research project, taking care of participants, recording data and reporting their observations, especially serious adverse events found during the studies. Normally monitoring visit will be arranged in advance with the principal investigators.
Non-Scientific member	Individual who possesses expertise and/or experience outside scientific areas and serves to represent either vulnerable populations or local cultural and community attitudes relative to the rights and welfare of human research participants.
Non-affiliated member	Individual who is a scientific or non-scientific member, is knowledgeable about clinical or scientific matters or local cultural and community attitudes, and has no association with any professional body including NIE.
Pre-clinical study	Animal and in vitro studies providing information on possible toxicities and mechanisms of action, and starting doses for human studies.
Phase I studies	Initial introduction of an investigational new drug (IND) into humans, studies designed to determine the metabolism and pharmacological actions of drugs in humans, and studies designed

	to assess the side effects associated with increasing doses.
Phase II study	A study of drug metabolism, structure-activity relationships, and mechanism of action in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes.
Phase III study	A study expands controlled and uncontrolled trials performed after preliminary evidence suggesting effectiveness of the drug has been obtained. They are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling
Phase IV study	A study that seeks to expand an approved medication's use into a new population, new indication, or new dose.
Requestors	Investigators, Sponsors, Contract Research Organizations, Regulatory authorities, Hospital administrators, and such others
Revision date	Date/year by which the SOP may be revised or reviewed
Recipients	Stakeholders who would receive a copy of SOP, viz., IHEC members, investigators, sponsors and any other concerned person
Scientific member	Individual who possesses the clinical and/or scientific knowledge and ability to effectively evaluate the research and clinical investigation.
SOP (Standard Operating Procedure)	Detailed, written instructions, in a certain format, describe all activities and action undertaken by an organization to achieve uniformity of the performance of a specific function. The aim of the SOPs and their accompanying checklists and forms is to simplify the organization and documentation of operation, whilst maintaining high standards of Good Clinical Practice.
SOP historical files	A collection of previous official versions of a SOP, table of contents, relevant information regarding changes and all preplanned deviations.

-END-