SOP Code: SOP/EC/001/05

1.1. Writing, Reviewing, Distributing and Amending Standard Operating Procedures for Institutional Ethics Committee

Revisions in the Standard Operating Procedures from version 4.0, dated 4 October 2018 to version 5.0, dated 18 May 2022

The following revisions are made in the Standard Operating Procedures from version 4.0, dated 4 October 2018 to Version 5.0, dated 18 May 2022 following the revision in the National Ethical guidelines for Biomedical and Health Research involving human participants, ICMR 2017 and NDCT Guidelines 2019.

Title of Standard Operating Procedure (SOP)	SOP Code	Revisions
Preparing Standard Operating Procedures (SOPs)		
Writing, Reviewing, Distributing and Amending Standard Operating Procedures for Institutional Ethics Committee	**SOP/EC/001/05**	3. Responsibility **"Chair, IEC and Head of the Institution -** Reviews and approves the SOPs" as per previous version. 5.6. Review and request for a revision of an existing SOP "The SOP team will review the SOPs every year" is modified as "The SOP team will review the SOPs every 5 years or as and when required"

SOP Number: SOP/EC/001	Revision Number: 05	
SOP Author: Dr G Narendran Signature	SOP Approver: Dr R Sridhar (Chair IEC) Signature	Effective Date : 18 May 2022
	Dr C Padmapriyadarsini (Director) Signature	Supersedes : (Doc. version & Date) version 4.0, dated 4 October 2018

1. PURPOSE

This Standard Operating Procedure (SOP) defines the process for writing, reviewing, distributing and amending SOPs within the National Institute for Research in Tuberculosis (NIRT) - Institutional Ethics Committee (IEC) based on the available guidelines and appropriate procedures.
The SOPs will provide clear, unambiguous instructions so that the related activities in the ethics committee are conducted in accordance with the prevailing guidelines that include National Ethical Guidelines for Biomedical and Health Research involving Human Participants - ICMR (2017), Indian GCP, New Drugs and Clinical Trial rules 2019, or their revisions / amendments as and when available.

2. SCOPE

This SOP covers the procedures of writing, reviewing, distributing and amending SOPs of NIRT- IEC.

3. RESPONSIBILITY

It is the responsibility of the Head of the Institution to appoint the SOP Team to formulate / revise the SOPs.

Secretariat/Affiliate Members of IEC

- Co-ordinates activities of writing, reviewing, distributing and amending SOPs.
- Maintains on file the current SOPs and the list of previous SOPs.

- Maintains an up-to-date distribution of list for each SOP distributed.
- Distributes the SOPs with a receipt to all users.
- Helps in uploading onto the Institute's website so that all ethics committee members and involved administrative staff have access to the SOPs.
  The IEC SOP available in the website could act as a guidance document for any other research institution..
- Ensures that the ethics committee members and involved staff are working according to current version of SOPs.

SOP team

- Proposes required SOPs.
- Selects the format and identification system.
- Drafts the SOP in consultation with affiliate ethics committee members and IEC secretariat administrative staff involved in the process.
- Assesses the request(s) for SOP revision in consultation with all IEC members, Chair and Head of the Institution.

Chair, IEC and Head of the Institution

- Reviews and approves the SOPs.
- Signs and dates upon receipt of the approved SOPs.

IEC members and Secretariat staff

- IEC members review the SOPs.
- Sign and date upon receipt of the approved SOPs.
- The prevailing SOP supersedes any previous and out-of-date SOPs

4. FLOW CHART

No.	Activity	Responsibility
1	Appoint the SOP Team (Affiliate Ethics Members)	Head of Institution
	↓	
2	List all relevant SOPs	SOP Team/IEC Members
	↓	
3	Design a format and layout and write SOPs	SOP Team/ IEC Members
	↓	
4	Review and modify SOPs	IEC Members, Chair and Head of Institution
	↓	
5	Approve a new/revised SOP	IEC Chair
	↓	

6	Approve new/revised SOP	Head of the Institution
	↓	
7	Implement, distribute and file all SOPs	IEC Secretariat
	↓	
8	Review and request for a revision of existing SOPs	IEC members / Head of the Institution
	↓	
9	Manage and archive superseded SOPs	IEC Secretariat

5. DETAILED INSTRUCTIONS

5.1. Appoint the SOP Team

Head of the Institution will appoint appropriate individuals (affiliate members) who have a thorough understanding of ethical review process as the SOP writing team.

5.2. List all relevant SOPs

The SOP team will,

- Write down step by step all IEC procedures.
- Organize, divide and name each process.
- Make a list of SOPs with identification reference.

5.3. Format and layout

The SOP team will assign a number and a title to each SOP that is self-explanatory and is easily understood.
Each SOP will also carry a unique code number.

The unique code number will have the format SOP/EC/XXX/YY followed by date. XXX will be a three-digit number assigned specifically to the SOP; *YY* will be a two-digit number identifying the version of the SOP. The number of version should be started from 01. Eg: SOP/EC/001/01.

Each annex will be given unique code number with the format *AF/EC/XXX/YY*. AF is the abbreviation for Annex Form. XXX is a three-digit number identifying the number of the annex and *YY* will be a two-digit number identifying the version of the AF, for example AF/EC/001/01 means Annex Form number 001 version 01.

Each SOP will be prepared according to the standard template. Please refer to ***Annexure code –AF/EC/001/05.***

5.4. Write and approve SOP

If an SOP supercedes a previous version, the previous SOP version and the main changes will be indicated in the SOP history page of the current version.

When the need for a new SOP has been identified and agreed on, a draft will be written by the SOP team.

The draft SOP will be reviewed by the affiliate Ethics members and the Head of the Institution.
The final version of the SOP will be passed to the Chairperson and the Head of the Institution for review and approval.

5.5. Implement, distribute and file the SOPs

- The SOPs will be effective from the date of approval.
- The approved SOPs will be distributed to the IEC members and the relevant staff by the IEC Secretariat. ***(Annexure code – AF/EC/002/05)*** via hard copy / by mail.
- When revised version is distributed, the previous version is superseded automatically as per date provided.
- One complete original set of current SOPs will be filed centrally in the SOP Master file and kept in the IEC Secretariat.

5.6. Review and request for a revision of an existing SOP

- Any member of the ethics committee, secretariat, administrative staff or Institutional staff who notices an inconsistency between two SOPs or has any suggestions on how to improve a procedure should use the form in ***Annexure code – AF/EC/003/05*** to make a request.
- If the IEC agrees with the request, it will proceed with the revision process within 15 week days of the request after deliberations with the committee.
- If the IEC does not agree, the Member Secretary (MS) will inform the person who made the request of the decision with reasons and justification.
- Revision of the SOPs will be reviewed and approved in the same manner as new SOPs (section 5.4).
- The SOP team will review the SOPs every 5 years or as and when required and record the dates of review on the SOP Master file.

5.7. Manage and archive superseded SOPs

- Superseded SOPs should be retained and clearly marked “superseded” and archived by the IEC secretariat**.**

6. ANNEXURES

Annexure code	Annexure title
AF/EC/001/05	Standard Operating Procedures Template
AF/EC/002/05	Log of SOP Recipients
AF/EC/003/05	Request for Revision of NIRT-IEC SOP

GLOSSARY

Conference	A meeting of individuals or representatives of various organizations for the purpose of discussing and/or acting on topics of common interest.
Document	Documents mean the following: - Study Protocols and related documents (such as case report forms, informed consents, diary forms, scientific documents, reports, records, expert opinions or reviews) - IEC documents (SOPs, meeting minutes, and decisions) - Correspondance (experts, study participants, etc.) of any forms, such as printed or written papers, hard copies, electronic mails (e-mail), faxes, audio or video tapes, etc.
IEC	Institutional Ethics Committee is an independent body whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection.
IEC members	Individuals serving as regular and alternate members on the institute's operational boards (i.e., IEC membership). These boards are constituted in accordance with the EC membership requirements set forth in ICMR Ethical guidelines for Biomedical research involving human participants
Master SOP files	An official collection of the institute's standard operating procedures (SOP) accessible to all staff, IEC 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.
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.
Secretariat	An office responsible for the secretarial, clerical, and administrative affairs of NIRT-IEC
SOP Team	A selected committee of the institute members and administrative staff who oversee the creation, preparation, review and periodic revision of the institute SOPs.

Annexure Code - AF/EC/001/05

Standard Operating Procedures Template

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

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.*

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

7. **RELEVANT SOPs –** *SOPs relevant to this SOP*

Annexure Code - AF/EC/002/05

Log of SOP Recipients

No.	Name of Recipient	SOP version & date	No. of Copies	Signature of recipient	Date

Annexure Code - AF/EC/003/05

Request for Revision of an NIRT-IEC SOP

SOP/EC/ XXX/YY		
Title:		
Justification for revision with details:		
Identified by:		Date (D/M/Y):
Signature of person requesting revision:		
To be filled by NIRT-IEC Member-Secretary (MS)		
Discussed with:		
SOP revision required:	☐ Yes	☐ No
If no, reason?		
Signature of MS & date:		
If SOP revision is required		
Date SOP re-finalized:		
Date SOP approved:		
Date SOP becomes effective:		
Signature of MS & date:		

Acknowledgement of awareness of this SOP

S.No	Name	Capacity	Signature	Date
1.	Dr R Sridhar	Chairperson		
2.	Dr R Arun Kumar	Vice-Chairperson		
3.	Dr G Narendran	Member Secretary		
4.	Dr K Lily Therese	Member (Non-Affiliate)		
5.	Dr S Swarnalakshmi	Member (Non-Affiliate)		
6.	Dr Shyamala Nataraj	Member (Non-Affiliate)		
7.	Mrs Rajalakshmi	Member (Non-Affiliate)		
8.	Mrs Renu Lamech	Member (Non-Affiliate)		
9.	Dr V Gowri	Member (Non-Affiliate)		
10.	Mr D Sairamkumar	Member (Non-Affiliate)		
11.	Mrs Pushkala	Member (Non-Affiliate)		
12.	Dr S Chandrasekar	Member (Non-Affiliate)		
13.	Dr P M Ramesh	Member (Non-Affiliate)		
14.	Dr Padma Srikanth	Member (Non-Affiliate)		
15.	Dr Shuba Kumar	Member (Non-Affiliate)		
16.	Dr K R Uma Devi	Member (Affiliate)		
17.	Dr Luke Elizabeth Hanna	Member (Affiliate)		
18.	Dr Bella Devaleenal	Member (Affiliate)		
19.	Dr M Muniyandi	Member (Affiliate)		
20.	Dr P K Bhavani	Member (Affiliate)		
21.	Dr R Balaji	Member (Affiliate)		

SOP Code: SOP/EC/002/05

2.1. Constituting an Institutional Ethics Committee

Revisions in the Standard Operating Procedures from version 4.0, dated 4 October 2018 to version 5.0, dated 18 May 2022

The following revisions are made in the Standard Operating Procedures from version 4.0, dated 4 October 2018 to version 5.0, dated 18 May 2022 following the revision in the National Ethical guidelines for Biomedical and Health Research involving human participants, ICMR 2017 and NDCT Guidelines 2019.

Constituting an IEC	**SOP/EC/002/05**	5.1 Ethical basis • New Drugs and Clinical Trials rules 2019 (NDCT) is included 5.11. Dissolving of the IEC / Termination of a particular member The following point has been included • Termination of a particular member will not be exercised on a member unless there is a strong justification or ardent need to do so apart from regular absence from IEC. 5.3. Membership requirements The following point has been included • Chairperson & Vice-chair will be appointed for a period of 5 years post appointment to that respective position.

SOP Number: SOP/EC/002	Revision Number: 05	
SOP Author: **Dr G Narendran** **Signature**	**SOP Approver:** **Dr R Sridhar** **(Chair IEC)** **Signature**	**Effective Date :** **18 May 2022**
	Dr C Padmapriyadarsini **(Director)** **Signature**	**Supersedes :** **(Doc. version & Date)** **version 4.0, dated 4 October 2018**

1. PURPOSE

National Institute for Research in Tuberculosis [hereinafter called the 'Institution'] Institutional Ethics Committee [hereinafter called the 'NIRT-IEC'] is the standing ethics committee of the Institution, functioning independently. It was established in order to provide independent guidance, advice, and decision (in the form of "approval / stipulation / disapproval") on health research or other specific research protocols involving human participants that ensures the protection of the rights, safety, and wellbeing of human participants in clinical, biomedical and behavioural research conducted by the Institution's Principal Investigators.

The NIRT-IEC is composed of both scientists and non-scientists. It is independent in its reflection, advice, and decision.

This SOP describes the Terms of Reference (TOR) which provide the framework for constitution, responsibilities and activities of the NIRT-IEC.

2. SCOPE

The SOP applies to all research activities of NIRT's Investigators under the NIRT-IEC.

3. RESPONSIBILITY

It is the responsibility of the IEC members and secretariat to read, understand and respect the rules set by the NIRT-IEC.

4. FLOW CHART

No.	Activity	Responsibility
1	Ethical basis / Guidelines	NIRT-IEC Members, Secretariat
	↓	
2	Composition of the IEC	Head of the Institution
	↓	
3	Membership Requirements	Head of the Institution, IEC Members and Secretariat
	↓	
4	Resignation, Disqualification, Replacement of Members	Head of the Institution, IEC Chair and Member Secretary
	↓	
5	Expert Consultants	IEC Chair and Vice-Chair through the IEC Secretariat
	↓	
6	Conditions of Appointment	Head of the Institution and IEC Secretariat
	↓	
7	Office Bearers	
8	Secretariat	Head of the Institution and IEC Member-Secretary (MS)
	↓	
9	Quorum Requirements	IEC Members, MS and Secretariat
	↓	
10	Dissolving of the IEC	Head of the Institution

5. DETAILED INSTRUCTIONS

5.1 Ethical basis

- The NIRT-IEC recognizes that the protocols it approves may also be approved by national and/or EC of Collaborating sites prior to their implementation in specific localities.
- In evaluating protocols and ethical issues, the NIRT-IEC is aware of the diversity of laws, cultures and practices governing research and medical practices in India and in various countries around the world.
- It attempts to inform itself wherever possible of the requirements and conditions of the various localities where the Institute's research is being considered.
- The NIRT-IEC also seeks to be informed, as appropriate, by national/EC of collaborating sites and researchers of the impact of the research it has approved. The NIRT-IEC is guided in its reflection, advice, and decision by the ethical principles expressed in the following guidelines whichever applicable
  - National Ethical guidelines for Biomedical and Health Research involving human participants, ICMR 2017

- Good Clinical Practice & Guidelines for Clinical Trials on Pharmaceutical products in India, CDSCO, DGHS, MoHFW, Govt of India, including Drugs and Cosmetics Acts and Rules and Amendments thereof
- Declaration of Helsinki, 2013
- International Ethical Guidelines for Biomedical Research involving human subjects, Council for International Organizations of Medical Sciences CIOMS, 2002
- International Ethical Guidelines for Epidemiological Studies, Council for International Organizations of Medical Sciences CIOMS, 2008
- Guideline for Good Clinical Practice E6 (R1), ICH Harmonised Tripartite Guideline, 1996
- National Committee for Ethics in Social Science Research in Health (NCESSRH)
- New Drugs and Clinical Trials rules 2019 (NDCT).
- the Operational Guidelines for Ethics Committees that review Biomedical Research (WHO), the WHO & ICH Guidelines for Good Clinical Practice
- Any other recognized guidelines that are not mentioned in the above guidelines

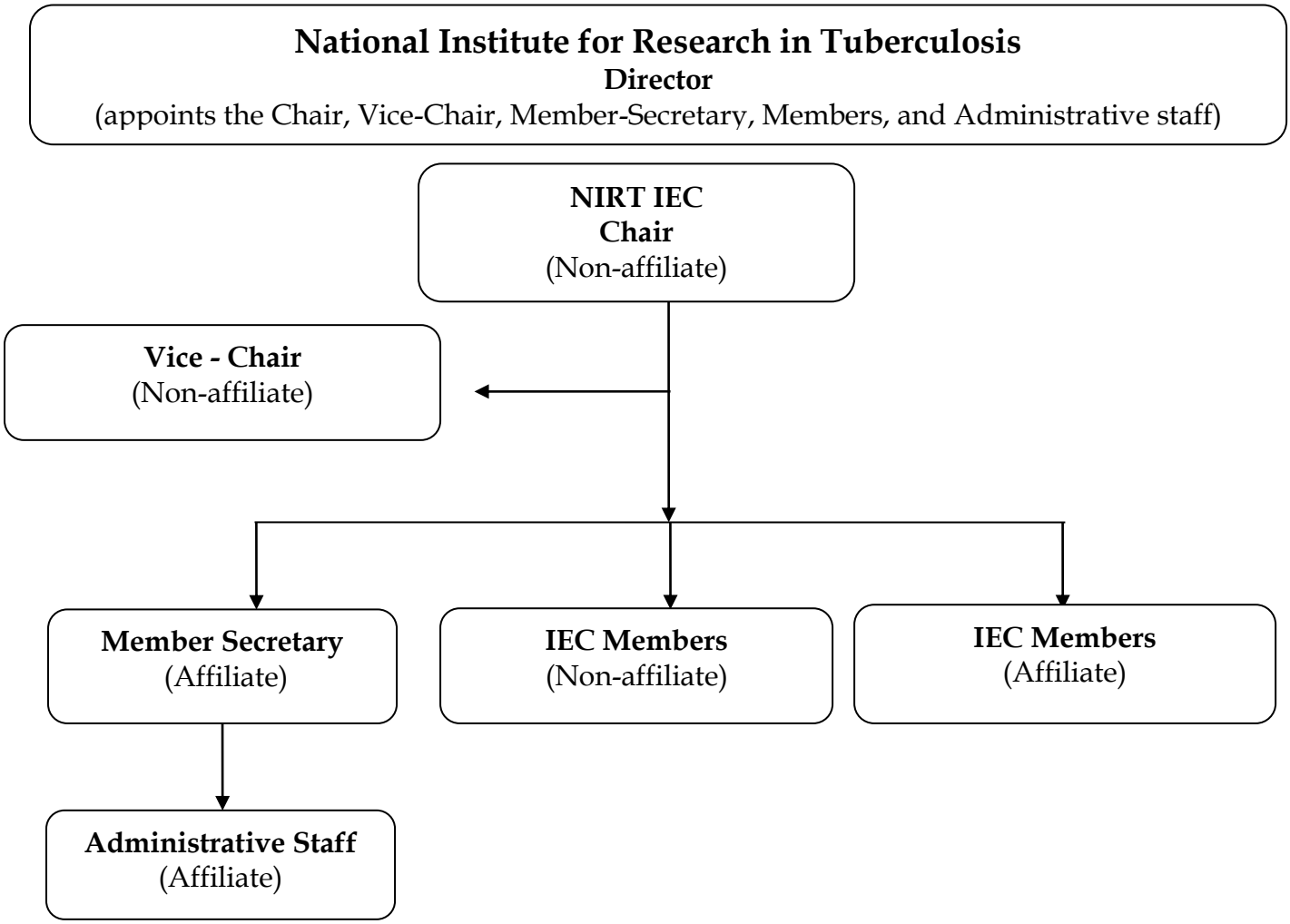
- The NIRT-IEC seeks to fulfill the requirements for national and international assurances and is established and functions to the extent in accordance with the Indian law and regulations.

5.2. Composition of the NIRT-IEC

- The NIRT-IEC will comprise of individuals with varying backgrounds with multidisciplinary and multi-sectorial members, appropriate to the nature of the projects being reviewed and relevant to the local, social, culture and customs to promote complete and adequate review of research activities conducted by the Institute. There shall be adequate representation of age, gender, and lay representative from the community in the Committee.
- The Committee shall possess adequate professional competence to review the diverse types of protocols received, and adjudicate without any bias and influence that could affect their objectivity.
- The members shall include at least one member with the primary concern of medical science, at least one member whose primary concerns is in non-medical/non-scientific areas, and at least a member from outside the institution.
- Professional qualifications may include physician, social scientist, lawyer, statistician etc.
- The NIRT-IEC ensures that there is gender balance in the IEC membership.

5.3. Membership requirements

NIRT-IEC ORGANIZATIONAL STRUCTURE



- The Head of the Institution is responsible for the appointment of committee members.
- The Chair and Vice-Chair shall be eminent persons in the society not affiliated to the Institution, in order to maintain independence of NIRT-IEC. The Head of the Institution nominates the Chair and Vice-chair on the basis of the person's suitability to the institution with appropriate competency and integrity.
- The Member Secretary (MS) will be from the Institution, and is responsible for organizing the meetings and preparing its proceedings, conduct the business of the meetings, maintain records, and communicate with concerned personnel. The MS is also responsible for preparing the minutes of the meetings, e-mailing to all the members and getting it approved by the Chair before communicating it to the researchers. The NIRT-IEC Secretariat will work under the Member Secretary.

- Members will be selected in their personal capacities, based on their expertise, interest, ethical and/or scientific knowledge, as well as on their commitment and willingness to volunteer the necessary time and effort for the IEC's work.
- The Members shall be a mix of medical / non-medical, and scientific / non-scientific persons including lay representative from the community, so as to reflect different viewpoints. The constitution of the non-affiliated members will be but not restricted to Epidemiologist, Sociologist, Legal expert, Ethicist/philosopher, Religious leader / expert, Statistician, Clinician, Basic scientist, Pharmacist / Clinical Pharmacologist, and others as relevant.
- The Members must disclose in writing any conflict of interest or involvement – financial, professional or otherwise – in a project or proposal under consideration.
- The IEC will decide the extent to which members who might have a conflict of interest may participate in bringing out an advice/decision, refer to ***SOP/EC/003/05 - Confidentiality Agreement, SOP/EC/004/05 Conflict of Interest Agreement***.
- The Members will be required to sign a confidentiality agreement at the start of their term.
- The confidentiality agreement protects the privacy and confidentiality of all parties whose information may be disclosed to the IEC in the course of its work.
- Non-affiliate Members will be appointed for a period of 3 years by a Term of Reference related to specific positions by the Head of the Institution after a Member initiate period of one year. ***(Annexure code: AF/EC/004/05- Term of reference letter from Head of the Institution (Member - Initiate), (Annexure code: AF/EC/005/05- Term of reference letter from Head of the Institution (Member)}***
- Chairperson & Vice-chair will be appointed for a period of 5 years post appointment to that respective position.
- Their appointments may be renewed by the Head of the Institution based on available expertise.

5.4. Resignation, Disqualification, Replacement of Members

- Members may resign their positions by submitting a letter of resignation to the Head of the Institution, Chair and NIRT-IEC.
- Members will be disqualified if they fail to attend three consecutive meetings.
- Members who have resigned or have been disqualified will be replaced with new members by Head of the Institution.

5.5. Expert Consultants

- The NIRT-IEC may be further supported in its reflections on specific protocols or requests for advice on specific ethical issues by Expert Consultants.
- Expert Consultants are appointed by the Chair and NIRT-IEC based on appropriate expertise.

- Their professional qualifications may be in the areas of community and/or patient representation, medicine, statistics, social science, law, ethics, religion, etc.
- Expert Consultants are appointed for the duration of the period sought ***(see SOP/EC/006/05)***

5.6. Conditions of Appointment

- Members and Expert Consultants will be appointed to the NIRT-IEC with the following conditions:
  - ✧ Willingness to publicize his/her full name, profession, and affiliation.
  - ✧ All NIRT-IEC Members and Expert Consultants must sign Confidentiality/Conflict of Interest Agreements regarding meeting deliberations, applications, information on research participants, and related matters (refer to ***SOP/EC/003/05 - Confidentiality Agreement, SOP/EC/004/05 Conflict of Interest Agreement)***.

5.7. Office Bearers

- The following officers through their respective responsibilities will contribute to the good functioning of the NIRT-IEC:

Chair	Responsible to chair the meetings and liaise directly with the Head of the Institution, report the meeting outcomes to the Head of the Institution, invite Expert consultants to provide special expertise to the IEC on proposed research protocol.
Vice-Chair	Responsible to chair the meetings in the absence of the Chair and act as Vice-chair during meetings with the Chair
Member Secretary	Responsible for the administrative aspects of the IEC (see 5.8 - below). In the absence of the MS, one of the affiliate IEC member will function as MS with the permission of the Chair

5.8. Secretariat

- The Secretariat is composed of the Member Secretary and the administrative supporting staff.
- The supporting staff are staff members of the Institution, appointed by the Head of the Institution.
- The Secretariat shall have the following functions:
  - ✯ Organizing an effective and efficient tracking procedure for each proposal received (see **SOP/EC/007/05, SOP/EC/008/05, SOP/EC/009/05, SOP/EC/010/05, SOP/EC/011/05, SOP/EC/012/05, SOP/EC /013/05**).

- ☆ Check for completeness of the submitted documents by the PI.
- ☆ Preparation, maintenance and distribution of study files.
- ☆ Organizing IEC meetings regularly (**SOP/EC/016/05, SOP/EC/017/05**).
- ☆ Preparation and maintenance of meeting agenda and minutes (**SOP/EC/016/05, SOP/EC/017/05**).
- ☆ Maintaining the IEC documentation, archiving and retrieval (See **SOP/EC/018/05**).
- ☆ Communicating with the IEC members and Principal Investigators (**SOP/EC/007/05, SOP/EC/008/05, SOP/EC/009/05, SOP/EC/010/05, SOP/EC/011/05, SOP/EC/012/05, SOP /EC/013/05**).
- ☆ Organizing training programmes for IEC members (see **SOP/EC/005/05**).
- ☆ Organizing the preparation, review, revision and distribution of SOPs and guidelines (see **SOP/EC/001/05**).
- ☆ Providing the necessary administrative support for IEC related activities to the Chairperson of the Committee (e.g. communicating a decision to the Investigator – **SOP/EC/016/05, SOP/EC/017/05**).
- ☆ Providing updates on relevant and contemporary issues related to ethics in health research, as well as relevant contemporary literature to the Committee members.

5.9. Roles and responsibilities of NIRT-IEC members

- Participate in the IEC meeting.
- Review, discuss and consider research proposals submitted for evaluation (**SOP/EC/008/05**), (**SOP/EC/009/05**), (**SOP/EC/010/05**), (**SOP/EC/011/05**), (**SOP/EC/012/05**), (**SOP/EC/013/05).**
- Monitor serious adverse event reports and recommend appropriate action(s) (**SOP/EC/015/05**).
- Review the progress reports and monitor ongoing studies as appropriate.
- Evaluate final reports and outcomes **(SOP/EC/014/05).**
- Maintain confidentiality of the documents and deliberations of IEC meetings (**SOP/EC/020/05**).
- Declare any conflict of interest.
- Participate in continuing education activities in biomedical ethics, biomedical research and GCP

5.10. Quorum Requirements

- A minimum of five IEC members must be present at a meeting in order to provide a valid advice and/or decision.
- Professional qualifications of the quorum requirements should consist of:
  - At least one member whose primary area of expertise is in a non-scientific area, one medical scientist and at least one member who is independent of the institution/research site.

- The quorum of the ethics committee approving drug trials should have at least:
    - one basic medical scientist (preferably one pharmacologist),
    - one clinician,
    - one legal expert or retired judge,
    - one social scientist/ representative of non-governmental organization/philosopher/ ethicist/ theologian or a similar person, and
    - one lay person from the community
    - one lady member

5.11. Dissolving of the IEC / Termination of a particular member

- The NIRT-IEC may also be dissolved at any time by the Head of the Institution, following written notification to each of the members and to the Chairman of the committee with appropriate justification.
- Termination of a particular member will not be exercised on a member unless there is a strong justification or ardent need to do so apart from regular absence from IEC.

5.12. Financial remuneration for IEC members

The financial remuneration for the IEC members for review of protocols as exempt/expedited/full board will be according to the Institution's policy.

5.13. Membership files

The Membership files will be maintained at the IEC Secretariat. The file will contain the following:

- Letter of invitation by the Director, NIRT to the member
- Letter of acceptance by the member
- Term of reference letter from Head of the Institution (Member – Initiate) ***Annexure code: AF/EC/004/05***
- Signed and dated CVs of IEC members
- Term of reference letter from Head of the Institution (Member) ***Annexure code: AF/EC/005/05***
- Confidentiality agreement ***Annexure code: AF/EC/007/05***
- Training records of members

6. ANNEXURE

Annexure Code	Annexure title
AF/EC/004/05	Term of reference letter from Head of the Institution (Member - Initiate)
AF/EC/005/05	Term of reference letter from Head of the Institution

	(Chairperson)
AF/EC/051/05	Term of reference letter from Head of the Institution (Vice Chair)
AF/EC/052/05	Term of reference letter from Head of the Institution (Member Secretary)
AF/EC/053/05	Term of reference letter from Head of the Institution (Member)

7. RELEVANT SOPS

SOP Code	SOP Title
SOP/EC/001/05	Writing, Reviewing, Distributing and Amending Standard Operating Procedures for Institutional Ethics Committee
SOP/EC/003/05	Confidentiality Agreement
SOP/EC/004/05	Conflict of Interest Agreement
SOP/EC/005/05	Training Ethics Committee Members
SOP/EC/006/05	Selection of Expert Consultants
SOP/EC/007/05	Management of Protocol Submissions
SOP/EC/008/05	Initial Review of Submitted Protocols
SOP/EC/009/05	Exempt Review
SOP/EC/010/05	Expedited Review
SOP/EC/011/05	Review of Resubmitted Protocols
SOP/EC/012/05	Review of Protocol Amendments
SOP/EC/013/05	Ongoing Review of Study Protocols
SOP/EC/014/05	Review of Final Reports
SOP/EC/015/05	Review of Serious Adverse Events (SAE) Reports
SOP/EC/016/05	Agenda Preparation, IEC Meeting Procedures and Minutes
SOP/EC/017/05	Unscheduled Meeting
SOP/EC/018/05	Maintenance of Active Study Files
SOP/EC/020/05	Maintaining Confidentiality of IEC Documents

GLOSSARY

Adverse Event	Any untoward medical occurrence in a patient or clinical investigation participant administered an investigational product and which does not necessarily have a causal relationship with this treatment. The adverse event can therefore be any unfavorable or unintended sign or experience associated with the use of the investigational product, whether or not related to the product.
Confidentiality	Prevention of disclosure, to other than authorized individuals, of IEC's information and documents
Confidentiality Agreement	Sometimes called Secrecy or Nondisclosure agreements An agreement designed to protect information and expertise from being misused by those who have learned about them. Most confidentiality agreements exclude certain types of information from the definition of confidential information. It is very important that the recipient include these exceptions in the confidentiality agreement. An important point that must be covered in any confidentiality agreement is the standard by which the parties will handle the confidential information. The agreement must establish a time period during which disclosures will be made and the period during which confidentiality of the information is to be maintained.
Conflict of Interest	A situation in which a person, such as a public official, an employee, or a professional, has a private or personal interest sufficient to appear to influence the objective exercise of his or her official duties. There are three key elements in this definition: financial interest; official duties; professional interest. A conflict of interest occurs when: • An individual's private interest differs from his or her professional obligations to the institute. • Professional actions or decisions occur that an independent observer might reasonably question. • A conflict depends upon situation and not on the character or actions of the individual. • Potential conflicts of interest must be disclosed and managed as per policy.
Disqualification	Excluded
Document	Documents mean the following: - Study Protocols and related documents (such as case report forms, informed consents, diary forms, scientific documents, reports, records, expert opinions or reviews) - IEC documents (SOPs, meeting minutes, and decisions) - Correspondence (experts, study participants, etc.)

	of any forms, such as printed or written papers, hard copies, electronic mails (e-mail), faxes, audio or video tapes, etc.
Exempt review	A review process only by the Chairman of the NIRT-IEC who then reports the decision to the full Board meeting. An exempt review is a *speedy one for research proposal with less than minimal risk in nature*.
Expedited review	A review process by only three NIRT-IEC members who then report the decision to the full Board meeting. An expedited review is a *speedy* one for minor *changes to the approved protocol* and for *research proposal* with *minimal risk in nature*.
Expert consultant	An expert who gives advice, comments and suggestion upon review of the study protocols with no affiliation to investigators proposing the research protocols.
Full board review	A review process by all the NIRT-IEC members in a full Board meeting for a consensus decision making
IEC	Institutional Ethics Committee is an independent body whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection.
IEC members	Individuals serving as regular and alternate members on the institute's operational boards (i.e., IEC membership). These boards are constituted in accordance with the EC membership requirements set forth in ICMR Ethical guidelines for Biomedical research involving human participants
Monitor	The act of overseeing the progress of a study, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).
Meeting agenda	A list of things to be done; a program of business at a meeting
Meeting	Deliberations between at least two (2) persons where such deliberations determine or result in the joint conduct or disposition of business.
Minutes	An official record of the business discussed and transacted at a meeting
Ongoing review	Review of IEC approved studies at periodic intervals
Principal Investigator	A person responsible for the conduct of the research study at the study site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.
Protocol amendment	A written description of a change(s) to or formal clarification of
Quorum	Number of IEC members required to act or take decision on any motion presented to the Board for action.
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.
Secretariat	An office responsible for the secretarial, clerical, and administrative affairs of NIRT-IEC
Study file	Approved and supporting and documents (protocols, protocol amendments, informed consents, advertisements, investigator and site information), records containing communications and correspondence with the investigator, and reports (including but not limited to Continuing Review Reports, IND Safety Reports, reports of injuries to subjects, scientific evaluations) that correspond to each study approved by the *NIRT-IEC*
SAE (Serious Adverse Event)	Untoward medical occurrence in a clinical trial resulting in • Death • Life threatening • In-patient hospitalisation (if the study is conducted as an out-patient) • Prolongation of existing hospitalisation (if the study is conducted as an in-patient) • Persistent or significant disability or incapacity • Congenital anomaly or birth defect
Unscheduled meeting	An NIRT-IEC meeting that is scheduled outside of a normally scheduled meeting to review/approve new studies that require full board IEC review and approval.
Well-being	The physical and mental integrity of the research participants

Annexure Code - AF/EC/004/05

Term of reference letter from Head of the Institution (Member - Initiate)

F: +91 44 2836 2525/28 T: +91 44 2836 9600/2836 9500
www.nirt.res.in Email:

தேசிய காசநோய் ஆராய்ச்சி நிறுவனம்
राष्ट्रीय यक्ष्मा अनुसंधान संस्थान
ICMR - NATIONAL INSTITUTE FOR RESEARCH IN TUBERCULOSIS
(Formerly Tuberculosis Research Centre)
Indian Council of Medical Research
Department of Health Research, Ministry of Health & Family Welfare, Government of India
#1, Sathyamoorthy Road, Chetpet, Chennai 600031

DR ---------- Dated: ***Day, month, year***
DIRECTOR

Dear Dr……..,

This letter is to confirm your appointment as an ethics committee "Member Initiate" of the National Institute for Research in Tuberculosis – Institutional Ethics Committee, effective ***Day, month, year*** for a period of one year.
You will be trained to be a member initiate for three or four scheduled meetings of NIRT-IEC, starting with the forthcoming meeting due to be held on ***Day, month, year***.
As a member initiate your responsibilities are as follows:

- Participate in the discussions during the IEC meetings.
- Maintain confidentiality of the documents and deliberations of IEC meetings
- Declare any conflict of interest.
- Participate in continuing education activities in biomedical ethics, research and GCP

As part of the IEC, your name will feature in the website of the Institution and IEC related documents. Kindly note that your absence for three consecutive meetings will be considered as your inability to continue as an IEC "Member Initiate" henceforth. You will be requested to

sign in the Conflict of Interest Declaration Agreement on appointment wherever applicable and appropriate. Your willingness to serve is well appreciated.

Thanking you,

Sincerely,

Signature of Director

Annexure Code - AF/EC/005/05

Term of reference letter from Head of the Institution (Chairperson)

F: +91 44 2836 2525/28 T: +91 44 2836 9600/2836 9500
www.nirt.res.in Email:

தேசிய காசநோய் ஆராய்ச்சி நிறுவனம்
राष्ट्रीय यक्ष्मा अनुसंधान संस्थान
ICMR - NATIONAL INSTITUTE FOR RESEARCH IN TUBERCULOSIS
(Formerly Tuberculosis Research Centre)
Indian Council of Medical Research
Department of Health Research, Ministry of Health & Family Welfare, Government of India
#1, Sathyamoorthy Road, Chetpet, Chennai 600031

DR ---------- Dated: ***Day, month, year***
DIRECTOR

Respected Dr……..,

This letter is to confirm your appointment as an ethics committee "Chair" of the National Institute for Research in Tuberculosis – Institutional Ethics Committee, effective ***Day, month, year*** for a period of five years.

As a chairperson you will be responsible to chair the meetings and liaise directly with the Head of the Institution, report the meeting outcomes to the Head of the Institution, invite Expert consultants to provide special expertise to the IEC on proposed research protocol.

As the IEC Chairperson your name will feature in the website of the Institution and IEC related documents. Kindly note that your absence for three consecutive meetings will be considered as your inability to continue as an IEC chairperson henceforth.
Your willingness to serve is well appreciated.

Thanking you,

Sincerely,

Signature of Director

Annexure Code - AF/EC/051/05

Term of reference letter from Head of the Institution (Vice Chair)

F: +91 44 2836 2525/28 T: +91 44 2836 9600/2836 9500
www.trc-chennai.org Email:

தேசிய காசநோய் ஆராய்ச்சி நிறுவனம்
राष्ट्रीय यक्ष्मा अनुसंधान संस्थान
ICMR - NATIONAL INSTITUTE FOR RESEARCH IN TUBERCULOSIS
(Formerly Tuberculosis Research Centre)
Indian Council of Medical Research
Department of Health Research, Ministry of Health & Family Welfare, Government of India
#1, Sathyamoorthy Road, Chetpet, Chennai 600031

DR ---------- Dated: ***Day, month, year***
DIRECTOR

Dear Dr……..,

This letter is to confirm your appointment as an ethics committee "Vice-Chair" of the National Institute for Research in Tuberculosis – Institutional Ethics Committee, effective ***Day, month, year*** for a period of five years.

As the Vice-Chair you will be responsible to chair the meetings in the absence of the Chair and act as Vice-chair during meetings with the Chair

As the Vice-Chair your name will feature in the website of the Institution and IEC related documents. Kindly note that your absence for three consecutive meetings will be considered as your inability to continue as an IEC Vice-Chair henceforth.
Your willingness to serve is well appreciated.

Thanking you,

Sincerely,

Signature of Director

Annexure Code - AF/EC/052/05

Term of reference letter from Head of the Institution (Member Secretary)

F: +91 44 2836 2525/28 T: +91 44 2836 9600/2836 9500
www.trc-chennai.org Email:

தேசிய காசநோய் ஆராய்ச்சி நிறுவனம்
राष्ट्रीय यक्ष्मा अनुसंधान संस्थान
ICMR - NATIONAL INSTITUTE FOR RESEARCH IN TUBERCULOSIS
(Formerly Tuberculosis Research Centre)
Indian Council of Medical Research
Department of Health Research, Ministry of Health & Family Welfare, Government of India
#1, Sathyamoorthy Road, Chetpet, Chennai 600031

DR ---------- Dated: ***Day, month, year***
DIRECTOR

Dear Dr……..,

This letter is to confirm your appointment as an ethics committee "Member Secretary" of the National Institute for Research in Tuberculosis – Institutional Ethics Committee, effective ***Day, month, year*** for a period of three years.

As the member secretary you will be coordinate and supervise the functioning of the secretariat including administrative aspects of IEC. You will also be Organizing training programmes for IEC members, communicating a decision to the Investigator and Providing updates on relevant and contemporary issues related to ethics in health research.

As the Member Secretary your name will feature in the website of the Institution and IEC related documents. Kindly note that your absence for three consecutive meetings will be considered as your inability to continue as an IEC Member Secretary henceforth. You will be requested to sign in the Conflict of Interest Declaration Agreement on appointment wherever applicable and appropriate.

Your willingness to serve is well appreciated.

Thanking you,

Sincerely,

Signature of Director

Annexure Code - AF/EC/053/05

Term of reference letter from Head of the Institution (Member)

F: +91 44 2836 2525/28 T: +91 44 2836 9600/2836 9500
www.trc-chennai.org Email:

தேசிய காசநோய் ஆராய்ச்சி நிறுவனம்
राष्ट्रीय यक्ष्मा अनुसंधान संस्थान
ICMR - NATIONAL INSTITUTE FOR RESEARCH IN TUBERCULOSIS
(Formerly Tuberculosis Research Centre)
Indian Council of Medical Research
Department of Health Research, Ministry of Health & Family Welfare, Government of India
#1, Sathyamoorthy Road, Chetpet, Chennai 600031

DR ---------- Dated: ***Day, month, year***
DIRECTOR

Dear Dr……..,

This letter is to confirm your appointment as an ethics committee "Member" of the National Institute for Research in Tuberculosis – Institutional Ethics Committee, effective ***Day, month, year*** for a period of three years.

As an IEC member your responsibilities are as follows:

- Participate in the IEC meeting.
- Review, discuss and consider research proposals submitted for evaluation.
- Monitor serious adverse event reports and recommend appropriate action (for Serious Adverse Event Review Committee members).
- Review the progress reports and monitor ongoing studies as appropriate.
- Evaluate final reports and outcomes**.**
- Maintain confidentiality of the documents and deliberations of IEC meetings.
- Declare any conflict of interest.
- Participate in continuing education activities in biomedical ethics, biomedical research and GCP.

As an IEC member, your name will feature in the website of the Institution and IEC related documents. Kindly note that your absence for three consecutive meetings will be considered as your inability to continue as an IEC member henceforth. You will be requested to sign in

the Conflict of Interest Declaration Agreement on appointment wherever applicable and appropriate.

Your willingness to serve is well appreciated.

Thanking you,

Sincerely,

Signature of Director

Acknowledgement of awareness of this SOP

S.No	Name	Capacity	Signature	Date
1.	Dr R Sridhar	Chairperson		
2.	Dr R Arun Kumar	Vice-Chairperson		
3.	Dr G Narendran	Member Secretary		
4.	Dr K Lily Therese	Member (Non-Affiliate)		
5.	Dr S Swarnalakshmi	Member (Non-Affiliate)		
6.	Dr Shyamala Nataraj	Member (Non-Affiliate)		
7.	Mrs Rajalakshmi	Member (Non-Affiliate)		
8.	Mrs Renu Lamech	Member (Non-Affiliate)		
9.	Dr V Gowri	Member (Non-Affiliate)		
10.	Mr D Sairamkumar	Member (Non-Affiliate)		
11.	Mrs Pushkala	Member (Non-Affiliate)		
12.	Dr S Chandrasekar	Member (Non-Affiliate)		
13.	Dr P M Ramesh	Member (Non-Affiliate)		
14.	Dr Padma Srikanth	Member (Non-Affiliate)		
15.	Dr Shuba Kumar	Member (Non-Affiliate)		
16.	Dr K R Uma Devi	Member (Affiliate)		
17.	Dr Luke Elizabeth Hanna	Member (Affiliate)		
18.	Dr Bella Devaleenal	Member (Affiliate)		
19.	Dr M Muniyandi	Member (Affiliate)		
20.	Dr P K Bhavani	Member (Affiliate)		
21.	Dr R Balaji	Member (Affiliate)		

SOP Code: SOP/EC/003/05

2.2. Confidentiality Agreement

SOP Number: SOP/EC/003	Revision Number: 05	
SOP Author: **Dr M Muniyandi** **Signature**	**SOP Approver:** **Dr R Sridhar** **(Chair IEC)** **Signature**	**Effective Date :** **18 May 2022**
	Dr C Padmapriyadarsini **(Director)** **Signature**	**Supersedes :** **(Doc. version & Date)** **Version 4.0, dated 04 October 2018**

1. PURPOSE

The purpose of this section is to provide a form of Confidentiality Agreement and identify who should read, understand, accept, sign and date the form. The procedures provide details when and where to sign as well as how the signed document should be kept.

2. SCOPE

This SOP covers the Agreements on Confidentiality concerning information and procedures followed by the NIRT-IEC.

3. RESPONSIBILITY

It is the responsibility of all newly-appointed NIRT-IEC member initiates / members / guest attendees / observers to read, understand, accept and sign the agreement contained in the Confidentiality form before beginning their NIRT-IEC related tasks with the Institution to protect the rights of study participants.

4. FLOW CHART

No.	Activity	Responsibility
1	Read the text carefully and thoroughly	IEC member initiates /members / guest attendees / observers
	↓	
2	Ask questions, if any	IEC member initiates / members / guest attendees / observers
	↓	
3	Sign to indicate consent	IEC member initiates /members / guest attendees / observers
	↓	
4	Documentation of the agreement.	IEC member initiates /members / guest attendees / observers

5. DETAILED INSTRUCTIONS FOR CONFIDENTIALITY AGREEMENT

5.1 Read the text carefully and thoroughly.

- Newly appointed members will obtain two copies of the Confidentiality Agreement Form ***(Annexure code: AF/EC/007/05).***
- They will read through the text of the form very carefully.
- The members will fill in their names and their addresses on the blank spaces.

5.2 Ask questions, if any.

- The members will direct questions to the MS, if any part or sentence is not clear.
- They will let the MS explain or clarify the contents of the document.

5.3 Sign with consent.

- They will sign and date both copies of the document before a member of the NIRT-IEC Secretariat.
- They will give the forms back to the Secretariat and Member Secretary to sign and date.
- A copy will be given to the members for their record.

5.4 Documentation of the Agreement.

- The MS will keep the other copy of the signed form in a Confidentiality Agreement File.
- This file will be stored in a secure cabinet with limited key holders.

6. ANNEXURE

Annexure Code	Annexure title
AF/EC/006/05	Confidentiality Agreement Form

GLOSSARY

Confidentiality	Prevention of disclosure, to other than authorized individuals, of IEC's information and documents
Confidentiality Agreement	Sometimes called Secrecy or Nondisclosure agreements An agreement designed to protect information and expertise from being misused by those who have learned about them. Most confidentiality agreements exclude certain types of information from the definition of confidential information. It is very important that the recipient include these exceptions in the confidentiality agreement. An important point that must be covered in any confidentiality agreement is the standard by which the parties will handle the confidential information. The agreement must establish a time period during which disclosures will be made and the period during which confidentiality of the information is to be maintained.
Guest attendees	One who is invited by the IEC for a full board meeting. Eg: Expert consultants, Observers like Surveyors etc.
IEC	Institutional Ethics Committee is an independent body whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection.
IEC members	Individuals serving as regular and alternate members on the institute's operational boards (i.e., IEC membership). These boards are constituted in accordance with the EC membership requirements set forth in ICMR Ethical guidelines for Biomedical research involving human participants
Member - initiate	NIRT-IEC member who is newly appointed by the Head of the Institution
Observers	One who observes the conduct of a full board IEC meeting: Eg: surveyors
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.
Secretariat	An office responsible for the secretarial, clerical, and administrative affairs of NIRT-IEC

Annexure Code - AF/EC/006/05

Confidentiality Agreement Form

Date: ___ / ___ / _____

From

To

The Chairperson
Institutional Ethics Committee
ICMR-National Institute for Research in Tuberculosis
No: 1, Sathyamoorthy Road, Chetput
Chennai – 600 031, TN, India.

Sir / Madam,

I do hereby agree not to use the National Institute for Research in TB - Institutional Ethics Committee (NIRT-IEC) related confidential and proprietary information for personal gain, nor disclose such information to third parties (other than in the course of performing my ethics committee related duties), nor copy or reproduce such information in any medium, except where I am required to do so by law, regulation, or court order. I understand that my obligation to abide by this 'confidentiality statement' shall continue indefinitely, even though my service with NIRT-IEC may end.

Thanking you.

Yours sincerely,

Signature

cc :
The Director, National Institute for Research in TB

Acknowledgement of awareness of this SOP

S.No	Name	Capacity	Signature	Date
1.	Dr R Sridhar	Chairperson		
2.	Dr R Arun Kumar	Vice-Chairperson		
3.	Dr G Narendran	Member Secretary		
4.	Dr K Lily Therese	Member (Non-Affiliate)		
5.	Dr S Swarnalakshmi	Member (Non-Affiliate)		
6.	Dr Shyamala Nataraj	Member (Non-Affiliate)		
7.	Mrs Rajalakshmi	Member (Non-Affiliate)		
8.	Mrs Renu Lamech	Member (Non-Affiliate)		
9.	Dr V Gowri	Member (Non-Affiliate)		
10.	Mr D Sairamkumar	Member (Non-Affiliate)		
11.	Mrs Pushkala	Member (Non-Affiliate)		
12.	Dr S Chandrasekar	Member (Non-Affiliate)		
13.	Dr P M Ramesh	Member (Non-Affiliate)		
14.	Dr Padma Srikanth	Member (Non-Affiliate)		
15.	Dr Shuba Kumar	Member (Non-Affiliate)		
16.	Dr K R Uma Devi	Member (Affiliate)		
17.	Dr Luke Elizabeth Hanna	Member (Affiliate)		
18.	Dr Bella Devaleenal	Member (Affiliate)		
19.	Dr M Muniyandi	Member (Affiliate)		
20.	Dr P K Bhavani	Member (Affiliate)		
21.	Dr R Balaji	Member (Affiliate)		

SOP Code: SOP/EC/004/05

2.3. Conflict of Interest Agreement

SOP Number: SOP/EC/004	Revision Number: 05	
SOP Author: **Dr Luke Elizabeth Hanna** **Signature** Luke Elizabeth Hanna	**SOP Approver:** **Dr R Sridhar** **(Chair IEC)** **Signature**	**Effective Date :** **18 May 2022**
	Dr C Padmapriyadarsini **(Director)** **Signature**	**Supersedes :** **(Doc. version & Date)** **Version 4.0, dated 04October 2018**

1. PURPOSE

The purpose of this section is to provide a Conflict of Interest (COI) declaration and identify who should read, understand, accept, keep in mind, sign and date the COI form. The procedures provide details when and where to sign as well as how the signed document should be kept.

2. SCOPE

This SOP covers the declaration of COI by NIRT-IEC members on protocols being reviewed/discussed at the NIRT-IEC meeting.

3. RESPONSIBILITY

It is the responsibility of all NIRT-IEC members to declare COI, if present, in writing during the NIRT-IEC meeting to protect the rights of study participants.

4. FLOW CHART

No.	Activity	Responsibility
1	Peruse the meeting agenda carefully	NIRT -IEC member
	↓	
2	Identify studies in which they have potential COI	NIRT-IEC member
	↓	
3	Sign the COI form mentioning the studies	NIRT-IEC member
	↓	
4	Do not take part in discussions and decision making of those studies	NIRT-IEC member

5. CONFLICT OF INTEREST AGREEMENT

It is the policy of the NIRT-IEC that no member may participate in discussion and decision making process on protocols in which he/she has a potential COI except to provide information as requested by the NIRT-IEC.

When a member has a COI, the member should notify the Chair in writing and may not participate in the NIRT-IEC approval process, except to provide information as requested by the Committee.

Examples of COI 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 bias may interfere with his or her impartial judgment.

Detailed instructions for COI agreement

5.1. Peruse the meeting agenda carefully

- Prior to the start of the NIRT-IEC meeting, the NIRT-IEC members will peruse that day's meeting agenda carefully.

5.2. Identify the studies in which the NIRT-IEC members have COI

- The NIRT-IEC members will identify studies in which they have COI.

5.3. Sign the COI form

- In case of COI, the NIRT-IEC member will obtain a copy of the COI declaration form from the IEC Secretariat (***Annexure code: AF/EC/008/05***) prior to the start of the meeting.

- They will enter their name and list the agenda item number and NIRT-IEC number for the studies in which they have COI.
- They will sign and date the document.
- They will hand over the form to the IEC Secretariat.
- A copy of the signed COI form will be kept in the COI file.
- The COI file will be stored safely with restricted access in the IEC Secretariat.

5.4. Do not take part in the decision making process

- The NIRT-IEC members who have declared COI will abstain from participating in the decision making process of the indicated protocols. They may however provide any information as requested by the IEC.
- In the absence of member secretary, or if the member secretary has declared conflict of interest, an internal member of the IEC affiliated to NIRT will assume the role of the member-secretary for that specific protocol.

6. ANNEXURE

Annexure Code	Annexure title
AF/EC/008/05	Conflict of Interest Declaration Form

GLOSSARY

Conflict of Interest	A situation in which a person, such as a public official, an employee, or a professional, has a private or personal interest sufficient to appear to influence the objective exercise of his or her official duties. There are three key elements in this definition: financial interest, official duties, professional interest. A conflict of interest occurs when: • An individual's private interest differs from his or her professional obligations to the institute. • Professional actions or decisions are taken that an independent observer might reasonably question. • A conflict depends upon the situation and not on the character or actions of the individual. • Potential conflicts of interest must be disclosed and managed as per policy.
IEC	Institutional Ethics Committee is an independent body whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a clinical trial or research study and to provide public assurance of that protection.
IEC members	Individuals serving as regular members on the institute's operational Ethics Committee (i.e., IEC membership). This Committee is constituted in accordance with the EC membership requirements set forth in the ICMR Ethical guidelines for Biomedical research involving human participants
Meeting agenda	A list of things to be done; a program of business at a meeting
Standard Operating Procedure	Detailed, written instructions, in a certain format, describing all activities and procedures followed by an organization to achieve uniformity of performance of a specific function. The aim of the SOPs and their accompanying checklists and forms is to organize and document the operation of a process, whilst maintaining high standards of Good Clinical Practice.

Annexure Code: AF/EC/008/05

Conflict of Interest declaration form

Date:

To

The Chairperson,

NIRT-IEC.

I,……. Member/Member-Secretary of the National Institute for Research in Tuberculosis-Institutional Ethics Committee (NIRT-IEC) declare conflict of interest for the following New/Amendment/Ongoing protocols to be discussed in the NIRT-IEC meeting held on----------.

AGENDA NO.	NIRT-IEC NO.

Yours sincerely,

Signature :_____

Name :_____

Date :_____

Acknowledgement of awareness of this SOP

S. No	Name	Capacity	Signature	Date
1.	Dr R Sridhar	Chairperson		
2.	Dr R Arun Kumar	Vice-Chairperson		
3.	Dr G Narendran	Member Secretary		
4.	Dr K Lily Therese	Member (Non-Affiliate)		
5.	Dr S Swarnalakshmi	Member (Non-Affiliate)		
6.	Dr Shyamala Nataraj	Member (Non-Affiliate)		
7.	Mrs Rajalakshmi	Member (Non-Affiliate)		
8.	Mrs Renu Lamech	Member (Non-Affiliate)		
9.	Dr V Gowri	Member (Non-Affiliate)		
10.	Mr D Sairamkumar	Member (Non-Affiliate)		
11.	Mrs Pushkala	Member (Non-Affiliate)		
12.	Dr S Chandrasekar	Member (Non-Affiliate)		
13.	Dr P M Ramesh	Member (Non-Affiliate)		
14.	Dr Padma Srikanth	Member (Non-Affiliate)		
15.	Dr Shuba Kumar	Member (Non-Affiliate)		
16.	Dr K R Uma Devi	Member (Affiliate)		
17.	Dr Luke Elizabeth Hanna	Member (Affiliate)		
18.	Dr Bella Devaleenal	Member (Affiliate)		
19.	Dr M Muniyandi	Member (Affiliate)		
20.	Dr P K Bhavani	Member (Affiliate)		
21.	Dr R Balaji	Member (Affiliate)		

SOP Code: SOP/EC/005/05

2.4. Training of Ethics Committee members

Revisions in the Standard Operating Procedures from version 4.0, dated 4 October 2018 to version 5.0, dated 18 May 2022

The following revisions are made in the Standard Operating Procedures from version 4.0, dated 4 October 2018 to version 5.0, dated 18 May 2022 following the revision in the National Ethical guidelines for Biomedical and Health Research involving human participants, ICMR 2017 and NDCT Guidelines 2019.

Training Ethics Committee Members	**SOP/EC/005/05**	**5.1 Topics for training** • NDCT Rules, 2019 is included. **5.2. Training modality** • "All members will be sent copies of SOPs and relevant National and International Guidelines" is changed as "All members will be sent copies of SOPs and relevant National and International Guidelines either through Hard or soft copies". • Experts in the field of Ethics would be invited to take lectures on topics of high importance and relevance for training of Ethics members is included.

SOP Number: SOP/EC/005	Revision Number: 05	
SOP Author: Dr D Bella Devaleenal Signature	SOP Approver: Dr R Sridhar (Chair IEC) Signature	Effective Date : 18 May 2022
	Dr C Padmapriyadarsini (Director) Signature	Supersedes : (Doc. version & Date) Version 4.0, dated 04 October 2018

1. PURPOSE

The purpose of this section is to inform the IEC members regarding the need for continuing training in Ethics and to encourage members to attend training in workshop and programs to up-date themselves on the prevailing guidelines and principles involving progress of technology, information and ethics.

Member-initiate period is the training period for the NIRT-IEC members.

2. SCOPE

The SOP applies to training for all NIRT-IEC members.

3. RESPONSIBILITY

It is the responsibility of the IEC members to have themselves educated and trained periodically.

4. FLOW CHART

No.	Activity	Responsibility
1	Topics for training	IEC members
	↓	
2	Training modality	IEC members , MS
	↓	
3	Keeping the training record	IEC members/ IEC Secretariat

5. DETAILED INSTRUCTIONS

5.1 Topics for training

The topics for training would be chosen in relevance but not limited to the research activity of the institute. The IEC members should maintain competence by ensuring up to date knowledge of the following but not limited to:

i. **'National Ethical Guidelines for Biomedical and Health Research involving Human Participants', Indian Council of Medical Research, India, 2017**, or its revisions as and when available
ii. Declaration of Helsinki and its revisions
iii. **Indian 'Good Clinical Practices' guidelines for clinical trials** on pharmacological products or its revisions as and when available
iv. **Standard Operating Procedures of NIRT-IEC,** or its revisions as and when available,
v. **NDCT Rules, 2019.**
vi. Developments in relevant science, technical and environmental, health and safety aspects
vii. Relevant requirements of health, safety and environmental laws and regulations and related documents
viii. Forum for Ethics Review Committees in India.

An interchange of ideas, information and experiences with other institutions and organizations related to research ethics will also be carried out as and when possible.

5.2. Training modality

- All members will be sent copies of SOPs and relevant National and International Guidelines either through Hard or soft copies.
- Member initiate period: The member-initiates will observe three to four scheduled meetings of NIRT-IEC for practical orientation on the aspects of ethical review.
- Non-Scientific member-initiates will be provided exposure to scientific and ethical principles in research by the MS and affiliate IEC members.
- The MS/Secretariat will keep the members informed of the upcoming workshops/meetings/ conferences etc related to ethics.
- The MS/Secretariat will provide Continuous Ethics Education by emailing the latest developments/publications in ethics.
- An interchange of ideas, information and experiences with other institutions and organizations related to research ethics will also be carried out as and when possible.
- Regular in-house ethics core training (initial and ongoing training) on the latest developments in Ethics will be conducted on a yearly basis. Experts in the field of

Ethics would be invited to take lectures on topics of high importance and relevance.

- Members who are delivering lectures would be hand-picked based on their expertise in relevant field.

5.3. Keeping the training records

IEC member should

- Fill in the form ***Annexure code: AF/EC/009/05*** to record the training/ workshop/ conference activities in chronological order.
- Make a copy of the form.
- Keep the original form as their record.
- Give the copy to the IEC Secretariat to keep in the IEC Member file.
- Training certificate on these sessions will be issued and Xerox copy should be filed in IEC Secretariat as a proof.

6. ANNEXURE

Annexure Code	Annexure title
AF/EC/009/05	IEC member Training Record Form

GLOSSARY

Conflict of Interest	A situation in which a person, such as a public official, an employee, or a professional, has a private or personal interest sufficient to appear to influence the objective exercise of his or her official duties. There are three key elements in this definition: financial interest; official duties; professional interest. A conflict of interest occurs when: • An individual's private interest differs from his or her professional obligations to the institute. • Professional actions or decisions occur that an independent observer might reasonably question. • A conflict depends upon situation and not on the character or actions of the individual. • Potential conflicts of interest must be disclosed and managed as per policy.
Conference	A meeting of individuals or representatives of various organizations for the purpose of discussing and/or acting on topics of common interest.
IEC	Institutional Ethics Committee is an independent body whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection.
IEC members	Individuals serving as regular and alternate members on the institute's operational boards (i.e., IEC membership). These boards are constituted in accordance with the EC membership requirements set forth in ICMR Ethical guidelines for Biomedical research involving human participants
Member - initiate	NIRT-IEC member who is newly appointed by the Head of the Institution
Meeting	Deliberations between at least two (2) persons where such deliberations determine or result in the joint conduct or disposition of business.
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.
Secretariat	An office responsible for the secretarial, clerical, and administrative affairs of NIRT-IEC
Workshop	A group of people engaged in study or work on a creative project or subject

Annexure Code: AF/EC/009/05

IEC member Training Record Form

Name of member:	
Membership since:	NIRT-IEC: Chair / Member / Member-Secretary

Ethics related Training Experience:

#	Courses / Workshops / Conferences / Meetings Attended	Organizer	Place	Duration	Source of Funding
1					
2					
3					

Signature of IEC member & date:

STANDARD OPERATING PROCEDURES
Version 5.0, dated 18 May 2022

Acknowledgement of awareness of this SOP

S. No	Name	Capacity	Signature	Date
1.	Dr R Sridhar	Chairperson		
2.	Dr R Arun Kumar	Vice-Chairperson		
3.	Dr G Narendran	Member Secretary		
4.	Dr K Lily Therese	Member (Non-Affiliate)		
5.	Dr S Swarnalakshmi	Member (Non-Affiliate)		
6.	Dr Shyamala Nataraj	Member (Non-Affiliate)		
7.	Mrs Rajalakshmi	Member (Non-Affiliate)		
8.	Mrs Renu Lamech	Member (Non-Affiliate)		
9.	Dr V Gowri	Member (Non-Affiliate)		
10.	Mr D Sairamkumar	Member (Non-Affiliate)		
11.	Mrs Pushkala	Member (Non-Affiliate)		
12.	Dr S Chandrasekar	Member (Non-Affiliate)		
13.	Dr P M Ramesh	Member (Non-Affiliate)		
14.	Dr Padma Srikanth	Member (Non-Affiliate)		
15.	Dr Shuba Kumar	Member (Non-Affiliate)		
16.	Dr K R Uma Devi	Member (Affiliate)		
17.	Dr Luke Elizabeth Hanna	Member (Affiliate)		
18.	Dr Bella Devaleenal	Member (Affiliate)		
19.	Dr M Muniyandi	Member (Affiliate)		
20.	Dr P K Bhavani	Member (Affiliate)		
21.	Dr R Balaji	Member (Affiliate)		

SOP Code: SOP/EC/006/05

2.5. Selection of Expert Consultants

Revisions in the Standard Operating Procedures from version 4.0, dated 4 October 2018 to version 5.0, dated 18 May 2022

The following revisions are made in the Standard Operating Procedures from version 4.0, dated 4 October 2018 to version 5.0, dated 18 May 2022 following the revision in the National Ethical guidelines for Biomedical and Health Research involving human participants, ICMR 2017 and NDCT Guidelines 2019.

Selection of Expert Consultants	**SOP/EC/006/05**	5.1. Selection of Expert Consultants • "Since the turnover or requirement of expert consultants has occurred in only a few occasions and the diversity inherent to selection is quite wide, it has precluded from forming a roster. Hence, as per the directions of the chair, the individual experts are requested for participation on an individual basis as per the need of the protocol" is included. • "The IEC Secretariat will contact the expert consultant by phone initially to find out their willingness and availability which is followed by sending an official email / formal letter signed by the MS" is included. The following points have been deleted: • A roster of expert consultants based on the expertise and availability will be prepared by the MS in consultation with the IEC members after a formal letter of acceptance including their latest CV. This roster would be maintained in the IEC

		secretariat after ratification of the consultants by the chair and the head of the institution. 5.2. Consultation Services • "The expert consultant may attend the IEC meeting in person" is remodified as "The expert consultant may attend the IEC meeting in person/e-platform"

SOP Number: SOP/EC/006	Revision Number: 05	
SOP Author: Dr R Balaji Signature	SOP Approver: Dr R Sridhar (Chair IEC) Signature	Effective Date : 18 May 2022
	Dr C Padmapriyadarsini (Director) Signature	Supersedes : (Doc. version & Date) Version 4.0, dated 04 October 2018

1. PURPOSE

The purpose of this SOP section is to provide procedures for engaging the expertise of a professional as an expert consultant to the IEC.

2. SCOPE

If the Chair or the IEC determines that a study will involve procedures or information that is beyond the area of expertise of the IEC members, the Chair or the IEC, in consultation with the Head of the Institution, may invite individuals with competence in these specific areas so as to assist in the review of the concerned protocols that are presented at the IEC Meeting.

3. RESPONSIBILITY

It is the responsibility of the IEC to identify and nominate the expert consultants.

4. FLOW CHART

No.	Activity	Responsibility
1	Selection of Expert Consultants ↓	Chair/Vice-chair/ IEC-Member Secretary
2	Nomination of the Expert Consultant ↓	Chair/ Head of the institution
3	Consultation Services	IEC Secretariat / Expert Consultant

5. DETAILED INSTRUCTIONS

5.1. Selection of Expert Consultants

- The MS will be informed about the requirement of an expert opinion by the chair at least 2 weeks prior to the IEC meeting.
- Since the turnover or requirement of expert consultants has occurred in only a few occasions and the diversity inherent to selection is quite wide, it has precluded from forming a roster. Hence, as per the directions of the chair, the individual experts are requested for participation on an individual basis as per the need of the protocol.
- The IEC Secretariat will contact the expert consultant by phone initially to find out their willingness and availability which is followed by sending an official email / formal letter signed by the MS
    - A signed Confidentiality Agreement ***(Annexure code: AF/EC/006/05)*** *and declaration of conflict of Interest* ***(Annexure code: AF/EC/007/05)*** *would be obtained when either the expert consultant appears in person or the documents mailed to him as appropriate.*
- If the Expert Consultant declares a COI if any, then
  An alternate Expert Consultant will be selected by the Chair / MS in consultation with the Head of the Institution.

5.2. Consultation Services

- IEC secretariat provides study protocol documents to the expert consultant for review after assurance of confidentiality.
- The expert consultant will submit the report and the protocol assessment form to be reviewed by the IEC at the time the study is reviewed.
- The expert consultant may attend the IEC meeting in person/e-platform to, present the report and participate in the discussion or email their comments to chair and MS however, *they will not be part of the decision making process*.
- The report becomes a permanent part of the study file.

The financial remuneration for the expert consultant will be according to the Institution's policy.

6. ANNEXURE

Annexure Code	Annexure title
AF/EC/006/05	Confidentiality Agreement Form
AF/EC/007/05	Declaration of Conflict of Interest

GLOSSARY

Conflict of Interest	A situation in which a person, such as a public official, an employee, or a professional, has a private or personal interest sufficient to appear to influence the objective exercise of his or her official duties. There are three key elements in this definition: financial interest; official duties; professional interest. A conflict of interest occurs when: • An individual's private interest differs from his or her professional obligations to the institute. • Professional actions or decisions occur that an independent observer might reasonably question. • A conflict depends upon situation and not on the character or actions of the individual. • Potential conflicts of interest must be disclosed and managed as per policy.
Expert consultant	An expert who gives advice, comments and suggestion upon review of the study protocols with no affiliation to investigators proposing the research protocols.
IEC	Institutional Ethics Committee is an independent body whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection.
IEC members	Individuals serving as regular and alternate members on the institute's operational boards (i.e., IEC membership). These boards are constituted in accordance with the EC membership requirements set forth in ICMR Ethical guidelines for Biomedical research involving human participants
Ratification	Formal approval/ sanction of a decision
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.
Secretariat	An office responsible for the secretarial, clerical, and administrative affairs of NIRT-IEC
Study file	Approved and supporting documents (protocols, protocol amendments, informed consents, advertisements, investigator and site information), records containing communications and correspondence with the investigator, and reports (including but not limited to Continuing Review Reports, Investigational New Drug Safety Reports, reports of injuries to subjects, scientific evaluations) that correspond to each study approved by the *NIRT-IEC*

Annexure Code - AF/EC/006/05

Confidentiality Agreement Form

Date: ___ / ___ / _____

From

To

The Chairperson
National Institute for Research in Tuberculosis Institutional Ethics Committee
No: 1, Sathyamoorthy Road, Chetpet
Chennai – 600 031, TN, India.

Sir / Madam,

I do hereby agree not to use the National Institute for Research in TB - Institutional Ethics Committee (NIRT-IEC) related confidential and proprietary information for personal gain, nor disclose such information to third parties (other than in the course of performing my ethics committee related duties), nor copy or reproduce such information in any medium, except where I am required to do so by law, regulation, or court order. I understand that my obligation to abide by this 'confidentiality statement' shall continue indefinitely, even though my service with NIRT-IEC may end.

Thanking you.

Yours truly,

Signature

Cc :

The Director, National Institute for Research in TB

Annexure Code : AF/EC/007/05

Undertaking for declaration of Conflict of Interest

Date:

To
The Chairperson,
NIRT-IEC.

I,……. solemnly, declare that, I am not involved in multiple interests, financial or otherwise that could possibly influence my motivation or decision-making in the capacity of Expert Consultant for the National Institute for Research in Tuberculosis – Institutional Ethics Committee (NIRT-IEC) .

Yours sincerely,

Signature :_____
Name :_____
Date :_____

Acknowledgement of awareness of this SOP

S.No	Name	Capacity	Signature	Date
1.	Dr R Sridhar	Chairperson		
2.	Dr R Arun Kumar	Vice-Chairperson		
3.	Dr G Narendran	Member Secretary		
4.	Dr K Lily Therese	Member (Non-Affiliate)		
5.	Dr S Swarnalakshmi	Member (Non-Affiliate)		
6.	Dr Shyamala Nataraj	Member (Non-Affiliate)		
7.	Mrs Rajalakshmi	Member (Non-Affiliate)		
8.	Mrs Renu Lamech	Member (Non-Affiliate)		
9.	Dr V Gowri	Member (Non-Affiliate)		
10.	Mr D Sairamkumar	Member (Non-Affiliate)		
11.	Mrs Pushkala	Member (Non-Affiliate)		
12.	Dr S Chandrasekar	Member (Non-Affiliate)		
13.	Dr P M Ramesh	Member (Non-Affiliate)		
14.	Dr Padma Srikanth	Member (Non-Affiliate)		
15.	Dr Shuba Kumar	Member (Non-Affiliate)		
16.	Dr K R Uma Devi	Member (Affiliate)		
17.	Dr Luke Elizabeth Hanna	Member (Affiliate)		
18.	Dr Bella Devaleenal	Member (Affiliate)		
19.	Dr M Muniyandi	Member (Affiliate)		
20.	Dr P K Bhavani	Member (Affiliate)		
21.	Dr R Balaji	Member (Affiliate)		

SOP Code: SOP/EC/007/05

3.1. Management of protocol submissions

Revisions in the Standard Operating Procedures from version 4.0, dated 4 October 2018 to version 5.0, dated 18 May 2022

The following revisions are made in the Standard Operating Procedures from version 4.0, dated 4 October 2018 to version 5.0, dated 18 May 2022 following the revision in the National Ethical guidelines for Biomedical and Health Research involving human participants, ICMR 2017 and NDCT Guidelines 2019.

Management of Protocol Submissions	**SOP/EC/007/05**	The term hard copies have been modified as hard/ soft copies at the appropriate places and the term receipt and dispatch by post is modified as by post/by email at the appropriate places of the SOP. 4.1. Submission of study documents by PI to IEC Secretariat • "The PI will submit the required number of copies of new protocols or resubmit Protocols with Correction and other associated documents for Initial IEC Review" is modified as **"**The PI will submit the final copy of the new/resubmitted protocol with the required number of copies either as hard or soft copies along with associated documents for Ethical clearance" • "The secretariat will dispatch the submitted documents 2 to 3 weeks prior to the meeting" is modified as "The secretariat will dispatch/email the submitted documents 2 weeks prior to the meeting in usual circumstances" • "The scheduled IEC meetings will be held on the 2nd Saturday of even months starting

		February" is modified as "The scheduled IEC meetings will be held on the 2nd /3rd Saturday" 4.3 Review of documents and segregation The following point has been included: • In case of study protocols related to vulnerable population, the Member Secretary and affiliate members of IEC will consider the proposal for full board review/ full committee and ensure that initial and continuing review of such proposals is done as per Chapter VI, table 6.1 (Vulnerable population group) of ICMR National Ethical Guidelines 2017. 4.4. Submission process for Full board / Expedited review/Exempt review • "The IEC Secretariat will receive the total set of study documents from the PI and check for completeness. The IEC Secretariat will dispatch the package by speed post appropriately for full board / Expedited review / Exempt review" is modified as "The IEC Secretariat will receive the total set of study documents from the PI (Soft copies) and check for completeness. The IEC Secretariat will send the submitted protocols/ amendments/ ongoing/completed/yet to be initiated documents by email

		communication for full board / Expedited review / Exempt review appropriately" • "For full board review the following will be dispatched 2 to 3 weeks prior to the meeting" is modified as "For full board review the following will be circulated via email communication at least 2 weeks prior to the meeting" and annexure code: **AF/EC/012A/05** is added for email communication of protocols. • "With the advent of Covid-19, only soft copies are sent to IEC and loaded in the tablets to conserve paper as a green environment approach. Hard copies to members/ chair is given based on their request" is included. **4.5. Store the received packages** • "The IEC Secretariat will store the document package in the respective study file" is modified as "The IEC Secretariat will store the document package in the respective study file and soft copies will be appropriately saved in designated folders"

SOP Number: SOP/EC/007	Revision Number: 05	
SOP Author: Dr D Bella Devaleenal Signature	SOP Approver: Dr R Sridhar (Chair IEC) Signature	Effective Date : 18 May 2022
	Dr C Padmapriyadarsini (Director) Signature	Supersedes : (Doc. version & Date) Version 4.0, dated 4 October 2018

1. PURPOSE

This standard operating procedure is designed to describe how the Secretariat of the NIRT-IEC manages protocol submissions to the IEC.

2. SCOPE

Protocol submissions include:

- Submission for Initial Review
- Resubmission of Protocols with Corrections
- Protocol Amendment
- Ongoing Review of Approved Protocols
- Review of final report
- Protocol Termination

3. RESPONSIBILITY

It is the responsibility of the NIRT-IEC secretariat to receive, record and distribute the submission packages for review and approval by the IEC, as well as to deliver the review results to the Investigators.

4. FLOW CHART

No.	Activity	Responsibility
1	Submission of study documents by PI to IEC Secretariat	Study PI
	↓	
2	Review the documents and segregate for full board/ expedited review/exempt review	MS, Affiliate IEC member, IEC Secretariat
	↓	
3	Verify the submission items as per checklist for completeness	IEC Secretariat
	↓	
4	Complete the submission process for Full board / Expedited review/Exempt review	IEC Secretariat/Members/Chair /Vice-Chair
	↓	
5	Dispatch of submitted packages to IEC members appropriately	IEC Secretariat
	↓	
6	Store the received packages	IEC Secretariat

4. DETAILED INSTRUCTIONS

4.1. Submission of study documents by PI to IEC Secretariat

- The PI will submit the final copy of the new/resubmitted protocol with the required number of copies either as hard or soft copies along with associated documents for **Initial review submission / Resubmission for Ethical clearance *(Annexure code: AF/EC/010/05) and* Checklist for documents submitted by PI to NIRT-IEC *(Annexure code: AF/EC/042/05).***
- The Protocol Amendment, Ongoing Review of Approved Protocol and Protocol Termination have to be accompanied by the Amendment Submission form preferably soft copies (Annexure Code : SOP/EC/012/05), **Ongoing/Completed/Terminated protocol review submission form (*Annexure code: AF/EC/011/05*) *and* Checklist for documents submitted by PI to NIRT-IEC *(Annexure code: AF/EC/042/05).***
- The timelines for PI submission and subsequent procedures is as follows:
- The scheduled IEC meetings will be held on the 2nd/3rd Saturday of even months starting February.
- The PIs will submit the study documents 1 month prior to the meeting date.
- The secretariat will dispatch/email the submitted documents 2 weeks prior to the meeting in usual circumstances.

4.2. Verify the submission items as per checklist

- The IEC Secretariat will verify if the documents are submitted according to the **Checklist for documents submitted by PI to NIRT-IEC *(Annexure code: AF/EC/042/05).***
- The Secretariat will fill-in the receipt of documents section of the checklist.
- The Secretariat will inform the PI to submit the pending documents, receive, and add them to the list.

4.3. Review of documents and segregation

- The MS and affiliate members of IEC will review all new protocols to be submitted for initial full board IEC review.
- In case of study protocols related to vulnerable population, the Member Secretary and affiliate members of IEC will consider the proposal for full board review/ full committee and ensure that initial and continuing review of such proposals is done as per Chapter VI, table 6.1 (Vulnerable population group) of ICMR National Ethical Guidelines 2017.
- The MS and at least one affiliate IEC member will decide on protocol amendment review as exempt, expedite or full board.
- The MS and/or the affiliate members will review ongoing protocol submissions, protocol terminations and final study reports for completion to be submitted to full board.

4.4. Submission process for Full board / Expedited review/Exempt review

- The IEC Secretariat will receive the total set of study documents from the PI (Soft copies) and check for correctness and completeness. The IEC Secretariat will send the submitted protocols/amendments/ongoing/completed/yet to be initiated documents by email communication for full board / Expedited review / Exempt review appropriately.
- The IEC Secretariat will ensure that soft /hard copies of Lead Discussant Assessment form ***(Annexure code: AF/EC/043/05)*** are sent to the Lead Discussants for initial full board review and Protocol Assessment form alone for initial expedited review.
- For dispatch for expedited review refer to **SOP/EC/010/05**
- For dispatch for exempt review refer to **SOP/EC/009/05**
- For full board review the following will be circulated via email communication at least 2 weeks prior to the meeting.
  - Email communication from member-secretary/IEC Secretariat indicating the date, time and venue of the NIRT-IEC meeting ***(Annexure code: AF/EC/012/05) & (*Annexure Code: AF/EC/012A/05)**
  - List of protocols due for new/ ongoing review with S.No, NIRT-IEC No., Title of the protocol, Name of the Principal Investigator, month and year of IEC approval
  - Protocol and its related documents

- Lead Discussant Assessment form ***(Annexure code: AF/EC/043/05)*** to the Lead Discussants
- With the advent of Covid-19, only soft copies are sent to IEC and loaded in the tablets to conserve paper as a green environment approach. Hard copies to members/ chair is given based on their request.

4.5. Store the received packages

The IEC Secretariat will store the document package in the respective study file and soft copies will be appropriately saved in designated folders.

5. ANNEXURE

Annexure Code	Annexure title
AF/EC/010/05	Initial review submission / Resubmission form for Ethical clearance
AF/EC/011/05	Ongoing/Completed/Terminated protocol review submission form
AF/EC/012/05	IEC meeting intimation letter to members
AF/EC/042/05	Checklist for documents submitted by PI to NIRT-IEC
AF/EC/043/05	Lead Discussant Assessment form

6. RELEVANT SOPs

SOP Code	SOP Title
SOP/EC/009/05	Exempt Review
SOP/EC/010/05	Expedited Review
SOP/EC/011/05	Review of Resubmitted Protocols
SOP/EC/012/05	Review of Protocol Amendments
SOP/EC/013/05	Ongoing Review of Study Protocols
SOP/EC/014/05	Review of Final Reports

GLOSSARY

Exempt review	A review process only by the Chairman of the NIRT-IEC who then reports the decision to the full Board meeting. An exempt review is a *speedy one for research proposal with less than minimal risk in nature*.
Expedited review	A review process by only three NIRT-IEC members who then report the decision to the full Board meeting. An expedited review is a *speedy* one for minor *changes to the approved protocol* and for *research proposal* with *minimal risk in nature*.
Full board review	A review process by all the NIRT-IEC members in a full Board meeting for a consensus decision making
IEC	Institutional Ethics Committee is an independent body whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection.
IEC members	Individuals serving as regular and alternate members on the institute's operational boards (i.e., IEC membership). These boards are constituted in accordance with the EC membership requirements set forth in ICMR Ethical guidelines for Biomedical research involving human participants
Ongoing review	Review of IEC approved studies at periodic intervals
Protocol	A document that describes the objective (s), design, methodology, statistical considerations, and organization of the study
Protocol amendment	A written description of a change(s) to or formal clarification of
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.
Secretariat	An office responsible for the secretarial, clerical, and administrative affairs of NIRT-IEC

Annexure Code: AF/EC/010/05

Initial review submission / Resubmission form for Ethical clearance

S No	Title	Particulars
1	Title of the research proposal	
2	NIRT-IEC No.	
3	Name of the Principal Investigator (PI) with Qualification, Designation, name of Section / Department	
4	Name of the Co-PI, Co-Investigator(s)(Co-I) with Qualification, Designation, name of Section / Department	
5	Source of funding & financial allocation for the project / trial	
6	Type of research (Please circle)	Clinical / Epidemiological / Operational / Laboratory (Bacteriology/Immunology/Biochemistry) / Socio-behavioural / Others
7	Expected duration of the project	----------years
8	Name of the Institution(s) where research is to be conducted	
9	Is the research proposal approved by the Scientific Advisory Committee of NIRT? If yes, month and year of approval	Yes / No
10	Is approval by ICMR Central Ethics Committee required for this project?	Yes / No
11	Will the research proposal be submitted to the Health Ministry Screening Committee (HMSC) for International Collaboration?	Yes / No
12	List of documents enclosed for ethical review (with version number & date)	
13	Research Proposal: Precise, yet relevant background information	
14	Research Proposal: Main objectives	
15	Study design	

16	Sample size	
17	Usefulness of the project / trial	
18	Expected 'benefits' to volunteer / community	
19	Explain all anticipated 'risks' (adverse events, injury, discomfort…) of the project	
20	Efforts taken to minimize the 'risks'	
21	Explain the plans to maintain confidentiality of records / data	
22	Whether compensation for travel and incidental expenses to the research participants be provided?	Yes / No If yes, details:
23	Research Participant Information sheet	
24	Describe the Informed Consent Process Mention : Written / Oral / Audio-visual	
25	Disclose Conflict of Interest, if any	
26	Specific ethical issues, as identified by the investigating team (eg) Vulnerability Storage of Biological samples	
27	Declaration of adherence to regulatory guidelines (please √ as appropriate)	□ National Ethical Guidelines for Biomedical and Health Research involving Human participants, ICMR, 2017 □ Good Clinical Practice & Guidelines for Clinical Trials on Pharmaceutical products in India, CDSCO, DGHS, MoHFW, Govt of India, including Schedule Y 2005 and its revisions □ Others If Others, specify _____ _____ _____
28	Signature of the Principal Investigator with date	

Annexure Code: AF/EC/011/05

Ongoing / Completed / Terminated protocol review submission form

S No	Title	Particulars
1	NIRT-IEC Protocol Number	
2	Title of the research proposal	
3	Name of the Principal Investigator (PI) with Qualification and Designation	
4	Name of the Co-PI and Co-Investigator(s) with Qualification and Designation	
5	Duration of the project / trial (yrs)	
6	Source of funding & financial allocation for the project / trial	
7	Name of the Institute where research is being conducted	
8	Month / Year of IEC approval	
9	Number of ongoing review (Not applicable for 'Yet to be initiated' studies)	
10	What are the study objectives ?	
11	What is the sample size required?	
12	Has the project implementation begun?	Yes / No Date
13	Has study participant recruitment begun?	Yes / No Date
14	If study participant recruitment has not begun, give reasons and proceed to S No: 23	
15	How many study participants have been screened?	
16	How many study participants have been recruited?	
17	Is study participant recruitment continuing? If no, give reason	Yes / No / Not applicable
18	Are there any 'drop outs'? If yes, give details.	Yes / No / Not applicable
19	Are study participants still receiving active intervention? If no, give reasons.	Yes / No / Not applicable
20	Have there been any **adverse events**? If yes, give details.	Yes / No / Not applicable
21	Have there been any other **unexpected adverse events**? If yes, give details.	Yes / No / Not applicable
22	Have there been any **unanticipated study-related problems**? If yes, give details.	Yes / No / Not applicable
23	Is there any **new risk or benefit** information?	Yes / No

	If yes, give details	
24	Are there any interim changes to the protocol or consent form? If yes, give details, including submission of revised protocol and consent form for approval. a) State/describe the amendment as annexure	Yes / No
	b) Give reason for the amendment	
	c) Any untoward effects to original protocol (ie. Study objective, design, outcome)	
	d) Expected risks to participants due to the amendment	
25	Does the scientific literature indicate changes in knowledge relevant to the conduct of the study? If yes, give details	
26	Is the study Yet to be initiated/ ongoing/ completed / terminated? If completed please provide the date and provide the Study summary (Participant recruitment completed & analysis ongoing) / Final report (Analysis completed) If terminated, please provide the date and details on the management of the enrolled participants (active and follow-up), if applicable	Yet to be initiated/ Ongoing / completed / terminated
27	Presentations / Publications, if any If yes, provide details	Yes / No
28	Do you require extension of the study period? If yes, please provide justification and summary of study findings as annexure	Yes / No
29	List of attachments for review, if any	
30	Remarks, if any	
31	Signature of the Principal Investigator with date	

Annexure Code: AF/EC/012/05

IEC meeting intimation letter to members

ICMR - National Institute for Research in Tuberculosis

INSTITUTIONAL ETHICS COMMITTEE

(SIDCER Recognized Ethics Committee in the Asian and Western Pacific Region)

No: 1, Mayor Sathyamoorthy Road, Chetput, Chennai – 600 031, Tamil Nadu, India

Dr
Member Secretary

e-mail:

No: ……./NIRT-IEC/20…. Date: ……

To
.....
.....
.....

Dear NIRT-IEC Member,

Please find enclosed new proposals (……Nos.) and ongoing review forms (……Nos.) for the forthcoming NIRT IEC meeting to be held on …….. Kindly review the proposals and make it convenient to attend the meeting on ……at ……..am. The venue is in ……, National Institute for Research in Tuberculosis, Chetpet, Chennai – 600 031.

With regards,

Yours truly,

Member Secretary

Cc to:
Director, NIRT

Annexure Code: AF/EC/012A/04

IEC meeting intimation E-mail to members

Respected All,

Greetings from NIRT!

This is to inform you that the next NIRT IEC meeting is scheduled to be held **on (date…….) at (time …..)**. The meeting will be conducted **in person at (venue…….)**

We have (…….No.) New Protocols and (No…..) Protocol Amendment for the forthcoming IEC meeting.

We are herewith sending the PDF of the 4 new submissions and 1 Amendment protocol for your kind review.

The lead discussants for the new submissions are as follows:

New Submission

1) Protocol Name …….. [NIRT IEC NO:…….].
PI Name:……, Designation(……)

Lead Discussants 1: (Name ……)
Lead Discussant 2: (Name …….
Subject Expert(if any): ……..

2) Protocol Name …….. [NIRT IEC NO:…….].
PI Name:……, Designation(……)

Lead Discussants 1: (Name ……)
Lead Discussant 2: (Name …….
Subject Expert(if any): ……..

The lead discussant forms will be sent in a separate email to the concerned.

All are requested to kindly make it convenient to attend the meeting.

Thanking you,

Yours sincerely,
NIRT IEC Secretariat

Cc to:

Director, NIRT

Annexure code AF/EC/042/05

Checklist for documents submitted by PI to NIRT-IEC (To be filled by PI)

NIRT-IEC No:		**Submitted date:**	
Type of Submission:	☐ Initial Review ☐ Resubmission for re-review ☐ Protocol Amendments	☐ Ongoing review ☐ Study completed ☐ Protocol Termination	
Protocol Title:			
Name of Principal Investigator: **Designation:** **Department:**			
Institute:			

☐ **Initial Review Submitted Package for full board**

- Initial Review Submission / re-submission Form
- NIRT- SAC approval
- Response to SAC comments
- Protocol with version no. & date and to include section on Ethical Consideration
- Protocol-Related Documents with version no. & date
  - ☐ Participant Information sheet (English)
  - ☐ Informed consent form (English)
  - ☐ Participant Information sheet (Local vernacular)
  - ☐ Informed consent form (Local vernacular)
  - ☐ Data collection forms
  - ☐ Others……
    - ☐ Site specific document
    - ☐ Assent Form (English)
    - ☐ Assent Form (Local vernacular)
    - ☐ Investigator's Brochure
    - ☐ Approvals from collaborating institutes
    - ☐ Insurance

- ☐ CTRI registration
- ☐ DCGI approval
- ☐ HMSC approval

☐ **Initial Review Submitted Package for Exempt / Expedited Review**

- ❑ Initial Review Submission / re-submission Form
- ❑ NIRT- SAC approval / Letter from the Director
- ❑ Response to SAC comments
- ❑ Protocol with version no. & date and to include section on Ethical Consideration
- ❑ Protocol-Related Documents with version no. & date
  - ☐ Data collection forms

☐ **Resubmission for Re-review Submitted Package**

Full Board / Expedited Review

- ❑ IEC Initial Review decision letter
- ❑ Initial Review Submission / re-submission Form
- ❑ IEC comments and responses
- ❑ Revised Protocol with version no. & date
- ❑ Protocol history page listing the changes made to the documents
- ❑ Protocol-Related Documents with version no. & date
  - ☐ Participant Information sheet (English)
  - ☐ Informed consent form (English)
  - ☐ Participant Information sheet (Local vernacular)
  - ☐ Informed consent form (Local vernacular)
  - ☐ Data collection forms
  - ☐ Others……
    - ☐ Site specific document
    - ☐ Assent Form (English)
    - ☐ Assent Form (Local vernacular)
    - ☐ Investigator's Brochure
    - ☐ Approvals from collaborating institutes
    - ☐ Insurance
    - ☐ CTRI registration
    - ☐ DCGI approval
    - ☐ HMSC approval

☐ **Protocol Amendment Submitted Package**
- ❑ Ongoing / completed / terminated protocol Review Submission Form
- ❑ Document listing the changes made to the protocol / associated documents
- ❑ Protocol with version no. & date
- ❑ Amended Documents with version no. & date
  - ☐ Participant Information sheet (English)
  - ☐ Informed consent form (English)
  - ☐ Participant Information sheet (Local vernacular)
  - ☐ Informed consent form (Local vernacular)
  - ☐ Data collection forms
  - ☐ Others……
    - ☐ Site specific document
    - ☐ Assent Form (English)
    - ☐ Assent Form (Local vernacular)
    - ☐ Investigator's Brochure
    - ☐ Approvals from collaborating institutes
    - ☐ Insurance
    - ☐ CTRI registration
    - ☐ DCGI approval
    - ☐ HMSC approval

☐ **Ongoing Review Package**
- ❑ Ongoing / completed / terminated protocol Review Submission Form
- ❑ Protocol amendment if any
- ❑ Study completed / terminated, if applicable

☐ **Study completed Package**
- ❑ Ongoing / completed / terminated protocol Review Submission Form
- ❑ Final report

☐ **Protocol Termination Package**
- ❑ Ongoing / completed / terminated protocol Review Submission Form
- ❑ Reasons for termination
- ❑ Minutes of other committee meetings that were held if any
- ❑ Final report if available

☐ **Protocol Suspension Package**
- ❑ Ongoing / completed / terminated protocol Review Submission Form
- ❑ Reasons for Suspension
- ❑ Minutes of other committee meetings that were held if any

☐ **Serious Adverse Events**
- ❑ SAE form for Clinical Trials
- ❑ SAE form for non-pharmacological Intervention
  - ☐ Initial ☐ Follow-up

☐ **Protocol Deviation / Violation**

- Protocol Deviation / Violation notification to IEC by PI

☐ **Notification**

- Specify documents to be notified
  - ☐

Signature of the Principal Investigator & date	

Receipt of documents from PI (To be filled by NIRT-IEC Secretariat)

NIRT-IEC No:		
Type of Submission:	☐ Initial Review ☐ Resubmission for re-review ☐ Protocol Amendments	☐ Ongoing review ☐ Study completed ☐ Protocol Termination
Protocol Title:		
Received by:		**Date received:**
Pending documents : Nil / Yes, If yes, details: ☐ Patient Information sheet ☐ Case report forms (CRF) ☐ Data collection forms ☐ Investigator's Brochure, if applicable ☐ Informed consent form (English) ☐ Informed consent form (Local vernacular) ☐ others……		
Received by:		**Date received:**

Annexure Code: AF/EC/043/05

LEAD DISCUSSANT ASSESSMENT FORM

Part – 1

Protocol Assessment form

NIRT-IEC No:		**Date (D/M/Y):**			
Protocol title:					
Protocol version no. & date:					
NIRT-IEC Member name:					
1. Is SAC approval available : Yes ☐ No ☐					
2. Need for the study (Check Background & Justification sections of protocol)					
		Yes	**No**	**NA**	**Comment:**
1	Background and justification - sufficient?				
2	Literature review – adequate?				
3	Need for human participants justified?				
4	Does the study contribute to development of local capacity for Research / Treatment?				
3. Scientific value (Check Methods section of protocol)					
5	Methodology – clear and well-described?				
6	Study Design - appropriate?				
7	Is the use of placebo justified?				
8	Inclusion Criteria - appropriate				
9	Exclusion Criteria - appropriate				
10	Laboratory methods – clear, well defined and feasible?				

11	Follow-up procedures well defined?				
12	Are study end points well defined?				
13	Are unbiased assessments used?				
14	Sample size adequate?				
15	Statistical methods proposed - appropriate				
16	Is there a provision for interim analysis in interventional studies				
4. Fair subject selection (Check Methods section of protocol)					
17	Inclusion Criteria - appropriate				
18	Exclusion Criteria - appropriate				
19	Is the recruitment of participants voluntary, non-coercive				
20	Is there an Inducement for participation?				
21	Is participant deception avoided?				
5. Favourable risk-benefit ratio					
22	Risks and benefits assessment – acceptable?				
23	Are predictable risks minimized?				
24	Tests and procedures that are more than minimal risk cautiously used				
25	Provision for Medical/Psychosocial Support				
26	Is participant discontinuation and withdrawal criteria appropriate?				
27	Provision for treatment of Study-Related Injuries				
28	Provision for compensation (where applicable)				
29	Does the study benefit the individual?				
30	Does the study benefit the local community?				

6. Informed consent					
31	Are procedures for obtaining informed consent appropriate (written/verbal)?				
32	Content of the information sheet and consent form clear and contain necessary details?				
33	Translations of all forms consistent?				
34	Contact details of PI given in both information sheet & consent forms?				
7. Respect for human subjects					
35	Privacy and confidentiality ensured				
36	Are vulnerable populations involved?				
	26.1 If yes, is it justifiable to conduct the study in that population?				
37	Are blood/ tissue samples sent abroad?				
	27.1 If samples are sent, is it mentioned in the ICF?				
38	Is the fate of the samples once study is over mentioned?				
39	Is appropriate consent included for storage of biological samples?				
8. Others					
40	Are facilities and infrastructure of Participating Sites appropriate?				
41	Is community Consultation addressed if required?				
42	Is disclosure or Declaration of potential Conflicts of Interest addressed?				
43	Is the PI adequately qualified to do the study?				
44	Are qualification and experience of the Participating Investigators appropriate?				

Comments :

Decision*: Approved /Minor modification s/ Major modifications /rejected*

Part – 2 (to be filled in case of full board review)

INFORMED CONSENT REVIEW FORM
(Participant Information sheet and Informed Consent Form Checklist)

Participant Information sheet date and Version:

Informed Consent Form Date and Version:

Are the following items included in the Participant Information sheet?

A statement that the trial / study involves research	**Y**	**N**		
Purpose of the trial/ study	**Y**	**N**		
Trial// study treatments and the probability of random assignment	**Y**	**N**	**NA**	
Trial / study procedures to be followed, including all invasive procedures			**Y**	**N**
Those aspects of the trial /study that are experimental			**Y**	**N**
Expected duration of subject's participation			**Y**	**N**

Approximate number of subjects involved in the trial/study		**Y**	**N**
Reasonably foreseeable risks or inconveniences to the subject		**Y**	**N**
Expected benefits to the subject (or no intended clinical benefit)		**Y**	**N**
Alternative procedures or treatments, and their potential benefits/risks		**Y**	**N**
Subject's responsibilities		**Y**	**N**
Compensation and / or treatment in the event of trial-related injury	**Y**	**N**	**NA**
Dissemination of new information in a timely manner		**Y**	**N**
Foreseeable circumstances/ reasons for termination of subject's participation		**Y**	**N**
Contact(s) for further information or in the event of trial/study-related injury		**Y**	**N**
Participation in the trial/study is voluntary. Refusal to participate, or withdrawal from the trial, at any time, is without penalty or loss of benefits to which the subject is otherwise entitled		**Y**	**N**
The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation		**Y**	**N**
The investigator will inform the subject's primary physician about the subject's participation in the study if the subject agrees		**Y**	**N**
Anticipated prorated payment, if any	**Y**	**N**	**NA**
Anticipated prorated expenses, if any	**Y**	**N**	**NA**
Monitor, auditor, EC and regulatory authority are granted direct access to personal medical records without violating the confidentiality of the subject		**Y**	**N**
Confidentiality: personal information will not be made publicly available, including if study results are published		**Y**	**N**

Are the following items included in the Informed Consent Form (signature sheet) ?

Consent Statement	**Y**	**N**

Reference made to voluntariness, confidentiality, compensation, rights	**Y**	**N**
Consent for Storage of biological samples (if applicable**)**	**Y**	**N**
A space for subject's name / signature / date	**Y**	**N**
A space for witness name / signature / date	**Y**	**N**
A space for investigator's name / signature / date	**Y**	**N**

Other

Investigator's name, protocol #, version date, and page # of #	**Y**	**N**
Was the language used as non-technical as practical, and was it understandable to the subject ?	**Y**	**N**

Comments:

Decision*: Approved /Minor modifications/ Major modifications /rejected*

Signature of the reviewer:

Date of review (DD/MM/YY):

Acknowledgement of awareness of this SOP

S. No	Name	Capacity	Signature	Date
1.	Dr R Sridhar	Chairperson		
2.	Dr R Arun Kumar	Vice-Chairperson		
3.	Dr G Narendran	Member Secretary		
4.	Dr K Lily Therese	Member (Non-Affiliate)		
5.	Dr S Swarnalakshmi	Member (Non-Affiliate)		
6.	Dr Shyamala Nataraj	Member (Non-Affiliate)		
7.	Mrs Rajalakshmi	Member (Non-Affiliate)		
8.	Mrs Renu Lamech	Member (Non-Affiliate)		
9.	Dr V Gowri	Member (Non-Affiliate)		
10.	Mr D Sairamkumar	Member (Non-Affiliate)		
11.	Mrs Pushkala	Member (Non-Affiliate)		
12.	Dr S Chandrasekar	Member (Non-Affiliate)		
13.	Dr P M Ramesh	Member (Non-Affiliate)		
14.	Dr Padma Srikanth	Member (Non-Affiliate)		
15.	Dr Shuba Kumar	Member (Non-Affiliate)		
16.	Dr K R Uma Devi	Member (Affiliate)		
17.	Dr Luke Elizabeth Hanna	Member (Affiliate)		
18.	Dr Bella Devaleenal	Member (Affiliate)		
19.	Dr M Muniyandi	Member (Affiliate)		
20.	Dr P K Bhavani	Member (Affiliate)		
21.	Dr R Balaji	Member (Affiliate)		

SOP Code: SOP/EC/008/05

3.3. Initial review of submitted protocols

Revisions in the Standard Operating Procedures from version 4.0, dated 4 October 2018 to Version 5.0, dated 18 May 2022

The following revisions are made in the Standard Operating Procedures from version 4.0, dated 4 October 2018 to version 5.0, dated 18 May 2022 following the revision in the National Ethical guidelines for Biomedical and Health Research involving human participants, ICMR 2017 and NDCT Guidelines 2019.

Initial Review of Submitted Protocols	**SOP/EC/008/05**	**3. RESPONSIBILITY** "The secretariat should create a study specific file, distribute the protocol and associated documents and get them reviewed by the NIRT-IEC" is modified as "the secretariat should create a study specific file as hard and soft copies, distribute the protocol and associated documents and get them reviewed by the NIRT-IEC" **5.1. Receive the protocol packages** • "The NIRT-IEC member will receive the protocol packages 2-3 weeks in advance of the IEC meeting date" is modified as "The NIRT-IEC member will receive the protocol packages as soft/hard copies 2 weeks in advance of the IEC meeting date" 5.3. Review the Protocol and related documents "NIRT –IEC member will ensure that all the cardinal principles of research ethics viz. Beneficence, Non-maleficence, Respect for individuals, and Justice are addressed in the proposed research project. They will look into the

		aspects of informed consent process, assess the risks and benefits to human participants, and requirements for appropriate compensations" is modified as "NIRT –IEC member will ensure that all the cardinal principles as outlined in ICMR Ethical Guidelines 2017 are addressed in the proposed research project. They will look into the aspects of informed consent process, assess the risks benefit ratio to human participants, and requirements for appropriate compensations for trial related injury" • Possibility of AE/ SAE during specimen collection and PI responsibilities will be discussed" is modified as "AE/ SAE management will be discussed" 5.5. Decision making • "The opinion of the members who are absent if available will be considered for discussion" is modified as "The opinion of the members who are absent but communicated to IEC will be considered for discussion" 5.6. Communication of the decision to PI • "The NIRT –IEC secretariat will send a written communication regarding the decision of the IEC to the PI" is modified as "The NIRT –IEC secretariat will send a written communication (hard/soft copy) regarding the decision of the IEC to the PI" • "If the study has to be re-submitted

		or disapproved, IEC review decision letter***(Annexure code: AF/EC/014/05)*** with appropriate reasons will be communicated to the PI" is modified as "If the study has to be re-submitted or disapproved, IEC review decision letter ***(Annexure code: AF/EC/014/05)*** with appropriate reasons will be communicated to the PI with a copy to Head of the Institution"

SOP Number: SOP/EC/008	**Revision Number: 05**	
SOP Author: **Dr D Bella Devaleenal** **Signature**	**SOP Approver:** **Dr R Sridhar** **(Chair IEC)** **Signature**	**Effective Date :** **18 May 2022**
	Dr C Padmapriyadarsini **(Director)** **Signature**	**Supersedes :** **(Doc. version & Date)** **Version 4.0, dated 04 October**

1. PURPOSE

This standard operating procedure describes how the NIRT-IEC manages to review an initially submitted protocol.

2. SCOPE

This SOP applies to the review process of the study protocol submitted for the first time.

3. RESPONSIBILITY

It is the responsibility of the NIRT-IEC members to review the study protocols delivered to them, give their suggestions, comments and decision during the NIRT-IEC meeting

The NIRT-IEC Secretariat is responsible for receiving, verifying and managing the contents of both the hard copies /electronic version of the received protocol. In addition, the secretariat should create a study specific file as hard and soft copies, distribute the protocol and associated documents and get them reviewed by the NIRT-IEC and deliver the review results to the PI.

4. FLOW CHART

No.	Activity	Responsibility
1	Receive the protocol package	NIRT-IEC Members
	↓	
2	Verify the contents of the package	NIRT-IEC Members
	↓	
3	Review the protocol and related documents	NIRT-IEC Members
	↓	
4	Discuss in the NIRT-IEC meeting	NIRT-IEC Members
	↓	
5	Decision making	NIRT-IEC Members
	↓	
6	Communication of the decision to PI	NIRT-IEC MS
	↓	
7	Storage of the Documents	NIRT-IEC Secretariat

5. DETAILED INSTRUCTIONS

5.1. Receive the protocol packages

- ✧ The NIRT-IEC member will receive the protocol packages as soft/hard copies 2 weeks in advance of the IEC meeting date.

5.2. Verify the contents of the package

- The NIRT-IEC member will check the package for completeness of the documents.
- The NIRT –IEC member will check the meeting date to see if he/she is available to attend the meeting. He/She will notify the NIRT-IEC Secretariat if there are

documents missing, or if unable to attend the meeting on the specified date and if possible send their comments on the protocol as email or hard copy to the MS.

5.3. Review the Protocol and related documents

NIRT –IEC member will ensure that all the cardinal principles as outlined in ICMR Ethical Guidelines 2017 are addressed in the proposed research project. They will look into the aspects of informed consent process, assess the risks benefit ratio to human participants, and requirements for appropriate compensations for trial related injury.

The Lead Discussants will fill the Lead Discussant Assessment form ***(Annexure code AF/EC/043/05)*** while reviewing the protocol and associated documents. **(SOP/ EC/021/05)**

5.4. Discuss in the NIRT-IEC meeting

- ✧ The PI will make a brief presentation of the study.
- ✧ The IEC members will discuss each document under consideration (e.g., protocol, informed consent, investigator's brochure, site qualifications, advertisements, agreements/contracts if any, etc) based on the observations made by the Lead Discussants in the Lead Discussant Assessment form ***(Annexure code AF/EC/043/05)***
- ✧ The Lead Discussants will initiate the discussions.
- ✧ Technical issues which include stronger rationale, culture, immunology issues, laboratories to be used, site qualifications, randomization, analysis will be discussed in depth
- ✧ Ethical Issues which include risks and benefits to patients will be deliberated.
- ✧ The language, comprehension, voluntariness, full disclosure, vernacular translation of Informed consent form will be discussed in detail.
- ✧ The issue of vulnerability of patients to be enrolled in the study and how it should be addressed will be reviewed.
- ✧ Referral/access to care to patients during screening will be discussed
- ✧ AE/ SAE management will be discussed in detail, if applicable.
- ✧ The PI will be given a chance to clarify the issues related to the study raised by the NIRT-IEC members.
- ✧ The Members will take down the minutes of the meeting.

5.5. Decision making

- ✧ A final decision of approval/re-submission with minor modifications/ re-submission with major modifications/disapproval will be taken on the basis of Consensus by the IEC.
- ✧ The opinion of the members who are absent but communicated to IEC will be considered for discussion.

- ✧ If the study is approved, the Committee determines the frequency of ongoing Review.
- ✧ If the study is to be re-submitted, the committee will decide whether the re-submitted study will be reviewed either by expedited process (minor modifications) or full board review (major modifications).
- ✧ If the study is disapproved, appropriate reasons for disapproval will be recorded

5.6. Communication of the decision to PI

- The NIRT –IEC secretariat will send a written communication (hard/soft copy) regarding the decision of the IEC to the PI with a copy to the Head of the Institution within 2 weeks of the IEC meeting.
- If the study is approved, Certificate of Institutional Ethics Committee Full board approval ***(Annexure code: AF/EC/013/05)*** will be issued to the PI.
- If the study has to be re-submitted or disapproved, IEC review decision letter ***(Annexure code: AF/EC/014/05)*** with appropriate reasons will be communicated to the PI with a copy to Head of the Institution.
- All the communications to the PI pertaining to the IEC decisions will be signed by the MS.
- If the MS has COI, an affiliate IEC member will sign the communications.

5.7. Storage of the Documents

- The NIRT –IEC secretariat will keep a copy of decision letter sent to the PI in the respective study file.

6. ANNEXURE

Annexure Code	Annexure title
AF/EC/013/05	Certificate of Institutional Ethics Committee Full Board approval
AF/EC/014/05	IEC review decision letter
AF/EC/043/05	Lead Discussant Assessment form

7. RELEVANT SOP

SOP Code	SOP title
SOP/ EC/021/05	Protocol review with Assessment forms

GLOSSARY

Advertisements	Communication materials to persuade / encourage potential study participants to enroll to the study
Adverse Event	Any untoward medical occurrence in a patient or clinical investigation participant administered an investigational product and which does not necessarily have a causal relationship with this treatment. The adverse event can therefore be any unfavorable or unintended sign or experience associated with the use of the investigational product, whether or not related to the product.
Beneficence	Do good
Consensus	Group decision with consent of all members
Document	Documents mean the following: - Study Protocols and related documents (such as case report forms, informed consents, diary forms, scientific documents, reports, records, expert opinions or reviews) - IEC documents (SOPs, meeting minutes, and decisions) - Correspondence (experts, study participants, etc.) of any forms, such as printed or written papers, hard copies, electronic mails (e-mail), faxes, audio or video tapes, etc.
IEC	Institutional Ethics Committee is an independent body whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection.
Justice	Distributive justice, equitable distribution of risks and benefits
Investigator's brochure	Investigator's brochure is a compilation of the clinical and nonclinical data on the investigational product(s) that are relevant to the study of the product(s) in human subjects..
Meeting	Deliberations between at least two (2) persons where such deliberations determine or result in the joint conduct or disposition of business.
Non-maleficene	Do no harm
Protocol	A document that describes the objective (s), design, methodology, statistical considerations, and organization of the study
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.
Secretariat	An office responsible for the secretarial, clerical, and administrative affairs of NIRT-IEC
Study file	Approved and supporting and documents (protocols, protocol amendments, informed consents, advertisements, investigator and site information), records containing communications and correspondence with the

	investigator, and reports (including but not limited to Continuing Review Reports, IND Safety Reports, reports of injuries to subjects, scientific evaluations) that correspond to each study approved by the *NIRT-IEC*
SAE (Serious Adverse Event)	Untoward medical occurrence in a clinical trial resulting in • Death • Life threatening • In-patient hospitalisation (if the study is conducted as an out-patient) • Prolongation of existing hospitalisation (if the study is conducted as an in-patient) • Persistent or significant disability or incapacity • Congenital anomaly or birth defect

Annexure Code: AF/EC/013/05

Certificate of Institutional Ethics Committee Full Board Initial approval

ICMR - National Institute for Research in Tuberculosis

INSTITUTIONAL ETHICS COMMITTEE

(SIDCER Recognized Ethics Committee in the Asian and Western Pacific Region)

No: 1, Mayor Sathyamoorthy Road, Chetput, Chennai – 600 031, Tamil Nadu, India

Dr.
Chairperson

Dr.
Vice Chair

Members (Non Affiliated)

Dr.
Member-Secretary

No: 000/NIRT-IEC/YEAR Date:

Certificate of Institutional Ethics Committee Approval

Members (Affiliated)

The Institutional Ethics Committee met on …….

under the Chairmanship of ……and reviewed the project titled

"……

…….....

NIRT-IEC No: …….., which was presented

by ……., NIRT.

The following Institutional Ethics Committee members were attended the meeting held in the …… Room, National Institute for Research in Tuberculosis, Chennai.

Name	**Capacity**

Conflict of Interest:

The Committee reviewed the following documents –

After deliberations, following a consensus opinion, the protocol and all the associated documents, **----------** with the following **recommendations addressed:**

Ongoing project review will be conducted:

Note to PI:

1. The study is approved for the study duration of …….. years. Kindly apply for extension of IEC approval if extension of study duration is required along with appropriate justification and summary of study findings.
2. Please submit the ongoing review details of the study at the frequency mentioned.
3. Please report Serious Adverse Events (SAE) within 24 hrs of knowledge and detailed report within 10 days.
4. Please inform the IEC about any protocol deviation and explanation for the same.
5. Please obtain the IEC approval prior to implementing any change/amendment in study procedures/protocol..
6. Please note that the IEC has the right to monitor the study with prior intimation.

Member Secretary

To: Principal Investigator,
Designation
National Institute for Research in Tuberculosis

cc to:
Director, National Institute for Research in Tuberculosis

Annexure Code: AF/EC/014/05

Letter to PI - IEC Initial review decision

ICMR - National Institute for Research in Tuberculosis

INSTITUTIONAL ETHICS COMMITTEE

(SIDCER Recognized Ethics Committee in the Asian and Western Pacific Region)

No: 1, Mayor Sathyamoorthy Road, Chetput, Chennai – 600 031, Tamil Nadu, India

Dr.
Vice Chair

Dr.
Chairperson

Members (Non Affiliated)

Dr.
Member-Secretary

Members (Affiliated)

No: 000/NIRT-IEC/YEAR Date:

To: Principal Investigator,
Designation
National Institute for Research in Tuberculosis

The Institutional Ethics Committee met on …….

under the Chairmanship of ---------- and reviewed the project titled

"…….....

.NIRT-IEC No: …….., which was presented by

……., NIRT

The Committee reviewed the following documents –

- and following a consensus decision, the project requires to be re-submitted with the following recommendations addressed

OR

- and after deliberations, disapproves the project for the following reasons

Member Secretary

cc to:

Director, National Institute for Research in Tuberculosis

Annexure Code: AF/EC/043/05

LEAD DISCUSSANT ASSESSMENT FORM

Part – 1

Protocol Assessment form

NIRT-IEC No:			**Date (D/M/Y):**		
Protocol title:					
Protocol version no. & date:					
NIRT-IEC Member name:					
1. Is SAC approval available : Yes ☐ No ☐					
2. Need for the study (Check Background & Justification sections of protocol)					
		Yes	**No**	**NA**	**Comment:**
1	Background and justification - sufficient?				
2	Literature review – adequate?				
3	Need for human participants justified ?				
4	Does the study contribute to development of local capacity for Research / Treatment?				
3. Scientific value (Check Methods section of protocol)					
5	Methodology – clear and well-described?				
6	Study Design - appropriate?				
7	Is the use of placebo justified?				
8	Inclusion Criteria - appropriate				
9	Exclusion Criteria - appropriate				
10	Laboratory methods – clear, well defined and feasible?				

11	Follow-up procedures well defined?				
12	Are study end points well defined?				
13	Are unbiased assessments used?				
14	Sample size adequate?				
15	Statistical methods proposed - appropriate				
16	Is there a provision for interim analysis in interventional studies				
4. Fair subject selection (Check Methods section of protocol)					
17	Inclusion Criteria - appropriate				
18	Exclusion Criteria - appropriate				
19	Is the recruitment of participants voluntary, non-coercive				
20	Is there an Inducement for participation?				
21	Is participant deception avoided?				
5. Favourable risk-benefit ratio					
22	Risks and benefits assessment – acceptable ?				
23	Are predictable risks minimized?				
24	Tests and procedures that are more than minimal risk cautiously used				
25	Provision for Medical/Psychosocial Support				
26	Is participant discontinuation and withdrawal criteria appropriate?				
27	Provision for treatment of Study-Related Injuries				
28	Provision for compensation (where applicable)				
29	Does the study benefit the individual?				
30	Does the study benefit the local community?				

6.	**Informed consent**				
31	Are procedures for obtaining informed consent appropriate (written/verbal)?				
32	Content of the information sheet and consent form clear and contain necessary details?				
33	Translations of all forms consistent?				
34	Contact details of PI given in both information sheet & consent forms?				
7.	**Respect for human subjects**				
35	Privacy and confidentiality ensured				
36	Are vulnerable populations involved?				
	26.1 If yes, is it justifiable to conduct the study in that population?				
37	Are blood/ tissue samples sent abroad?				
	27.1 If samples are sent, is it mentioned in the ICF?				
38	Is the fate of the samples once study is over mentioned?				
39	Is appropriate consent included for storage of biological samples?				
8.	**Others**				
40	Are facilities and infrastructure of Participating Sites appropriate?				
41	Is community Consultation addressed if required?				
42	Is disclosure or Declaration of potential Conflicts of Interest addressed?				
43	Is the PI adequately qualified to do the study?				
44	Are qualification and experience of the Participating Investigators appropriate?				

Comments :

Decision*: Approved /Minor modification s/ Major modifications /rejected*

Part – 2 (to be filled in case of full board review)

INFORMED CONSENT REVIEW FORM

(Participant Information sheet and Informed Consent Form Checklist)

Participant Information sheet date and Version:

Informed Consent Form Date and Version:

Are the following items included in the Participant Information sheet?

A statement that the trial / study involves research	**Y**	**N**		
Purpose of the trial/ study	**Y**	**N**		
Trial// study treatments and the probability of random assignment	**Y**	**N**	**NA**	
Trial / study procedures to be followed, including all invasive procedures			**Y**	**N**
Those aspects of the trial /study that are experimental			**Y**	**N**
Expected duration of subject's participation			**Y**	**N**
Approximate number of subjects involved in the trial/study			**Y**	**N**

Reasonably foreseeable risks or inconveniences to the subject	**Y**	**N**	
Expected benefits to the subject (or no intended clinical benefit)	**Y**	**N**	
Alternative procedures or treatments, and their potential benefits/risks	**Y**	**N**	
Subject's responsibilities	**Y**	**N**	
Compensation and / or treatment in the event of trial-related injury	**Y**	**N**	**NA**
Dissemination of new information in a timely manner	**Y**	**N**	
Foreseeable circumstances/ reasons for termination of subject's participation	**Y**	**N**	
Contact(s) for further information or in the event of trial/study-related injury	**Y**	**N**	
Participation in the trial/study is voluntary. Refusal to participate, or withdrawal from the trial, at any time, is without penalty or loss of benefits to which the subject is otherwise entitled	**Y**	**N**	
The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation	**Y**	**N**	
The investigator will inform the subject's primary physician about the subject's participation in the study if the subject agrees	**Y**	**N**	
Anticipated prorated payment, if any	**Y**	**N**	**NA**
Anticipated prorated expenses, if any	**Y**	**N**	**NA**
Monitor, auditor, EC and regulatory authority are granted direct access to personal medical records without violating the confidentiality of the subject	**Y**	**N**	
Confidentiality: personal information will not be made publicly available, including if study results are published	**Y**	**N**	

Are the following items included in the Informed Consent Form (signature sheet) ?

Consent Statement	**Y**	**N**
Reference made to voluntariness, confidentiality , compensation, rights	**Y**	**N**

Consent for Storage of biological samples (if applicable**)**	**Y**	**N**
A space for subject's name / signature / date	**Y**	**N**
A space for witness name / signature / date	**Y**	**N**
A space for investigator's name / signature / date	**Y**	**N**

Other

Investigator's name, protocol #, version date, and page # of #	**Y**	**N**
Was the language used as non-technical as practical, and was it understandable to the subject ?	**Y**	**N**

Comments:

Decision*: Approved /Minor modifications/ Major modifications /rejected*

Signature of the reviewer:

Date of review (DD/MM/YY):

Acknowledgement of awareness of this SOP

S.No	Name	Capacity	Signature	Date
1.	Dr R Sridhar	Chairperson		
2.	Dr R Arun Kumar	Vice-Chairperson		
3.	Dr G Narendran	Member Secretary		
4.	Dr K Lily Therese	Member (Non-Affiliate)		
5.	Dr S Swarnalakshmi	Member (Non-Affiliate)		
6.	Dr Shyamala Nataraj	Member (Non-Affiliate)		
7.	Mrs Rajalakshmi	Member (Non-Affiliate)		
8.	Mrs Renu Lamech	Member (Non-Affiliate)		
9.	Dr V Gowri	Member (Non-Affiliate)		
10.	Mr D Sairamkumar	Member (Non-Affiliate)		
11.	Mrs Pushkala	Member (Non-Affiliate)		
12.	Dr S Chandrasekar	Member (Non-Affiliate)		
13.	Dr P M Ramesh	Member (Non-Affiliate)		
14.	Dr Padma Srikanth	Member (Non-Affiliate)		
15.	Dr Shuba Kumar	Member (Non-Affiliate)		
16.	Dr K R Uma Devi	Member (Affiliate)		
17.	Dr Luke Elizabeth Hanna	Member (Affiliate)		
18.	Dr Bella Devaleenal	Member (Affiliate)		
19.	Dr M Muniyandi	Member (Affiliate)		
20.	Dr P K Bhavani	Member (Affiliate)		
21.	Dr R Balaji	Member (Affiliate)		

SOP Code: SOP/EC/009/05

3.4. Exempt review

Revisions in the Standard Operating Procedures from version 4.0, dated 4 October 2018 to version 5.0, dated 18 May 2022

The following revisions are made in the Standard Operating Procedures from version 4.0, dated 4 October 2018 to version 5.0, dated 18 May 2022 following the revision in the National Ethical guidelines for Biomedical and Health Research involving human participants, ICMR 2017 and NDCT Guidelines 2019.

Exempt Review	**SOP/EC/009/005**	5.2. Determine protocols for exempt review • "NIRT-IEC MS and one affiliate member of the NIRT-IEC will determine whether a study is qualified for exempt review" is modified as "NIRT-IEC MS and at least one affiliate member of the NIRT-IEC will determine whether a study is qualified for exempt review upon email circulation"

SOP Number: SOP/EC/009	**Revision Number: 05**	
SOP Author: **Dr P K Bhavani** **Signature**	**SOP Approver:** **Dr R Sridhar** **(Chair IEC)** **Signature**	**Effective Date :** **18 May 2022**
	Dr C Padmapriyadarsini **(Director)** **Signature**	**Supersedes :** **(Doc. version & Date)** **Version 4.0, dated 04 October 2018**

1. PURPOSE

The purpose of this Standard Operating Procedure is to provide criteria for determination of which study protocols can be eligible for exempt review process as well as instructions on management, review and decision of the **exempt** review.

2. SCOPE

This SOP applies to the review and approval of study protocols with less than minimum risk to study participants.

3. RESPONSIBILITY

It is the responsibility of the NIRT-IEC members to define which study protocols should be reviewed and approved through exempt channel, if the Member Secretary feels that.

4. FLOW CHART

No.	Activity	Responsibility
1	Receive the submitted documents	NIRT-IEC Secretariat
	↓	
2	Determine protocols for exempt review	NIRT-IEC MS and one affiliate NIRT-IEC member
	↓	
3	Exempt review process	NIRT-IEC Chair
	↓	
4	Communicate to the NIRT – IEC and PI	NIRT-IEC MS and Secretariat

5. DETAILED INSTRUCTIONS

5.1 Receive the submitted documents

- ❖ IEC Secretariat will receive the application documents submitted by investigators.
- ❖ IEC Secretariat will check the contents of submitted package with reference to **SOP/EC/007/05** (Management of Protocol Submissions)
- ❖ Hand over the received documents to the NIRT-IEC MS.

5.2. Determine protocols for exempt review

- ❖ NIRT-IEC MS and at least one affiliate member of the NIRT-IEC will determine whether a study is qualified for exempt review according to the following criteria:

5.2.1. Proposals which present less than minimal risk where there are no linked identifiers fall under this category as may be seen in following situations:

- research conducted on data available in the public domain for systematic reviews or meta-analysis
- observation of public behaviour when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person
- quality control and quality assurance audits in the institution
- comparison of instructional techniques, curricula, or classroom management methods
- consumer acceptance studies related to taste and food quality
- 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).

❖ If the protocol satisfied the criteria for **exempt** review, the NIRT-IEC secretariat will send the protocol for exempt review and approval.

5.3. Exempt Review Process

❖ NIRT-IEC secretariat will prepare a packet to be sent to the NIRT-IEC Chair. The packet will contain
  ✓ a Covering letter to NIRT-IEC Chair for exempt review ***(Annexure Code: AF/EC/015/05)*** from the member-secretary with details of the documents submitted for exempt review
  ✓ the documents for exempt review
  ✓ an exempt review decision report ***(Annexure Co/de: AF/EC/016/05)*** template
  ✓ a return envelope
❖ The Chair will review the documents and decide if it qualifies for exempt review/expedited/ full board review.
❖ The Chair will indicate in writing/communicate the decision to the NIRT-IEC Secretariat.

5.4. Communication with the investigator and the NIRT-IEC

❖ The MS will issue the Certificate of Institutional Ethics Committee Exempt Review ***(Annexure code: AF/EC/017/05)*** to the PI.
❖ If the study is not approved, the decision will be communicated to the PI by the MS by an IEC Exempt review decision letter ***(Annexure code: AF/EC/018/05).***
❖ The MS will inform the NIRT-IEC of the proposals approved/not approved by exempt review at the subsequent meeting for full board notification and ratification.

6. ANNEXURE

Annexure Code	Annexure title
AF/EC/015/05	Covering letter to Chairperson for exempt review
AF/EC/016/05	IEC Chairperson exempt review decision report
AF/EC/017/05	Certificate of Institutional Ethics Committee Exempt review
AF/EC/018/05	Letter to PI - IEC Exempt review decision

7. RELEVANT SOPs

SOP Code	SOP Title
SOP/EC/007/05	Management of Protocol Submissions

GLOSSARY

Document	Documents mean the following: - Study Protocols and related documents (such as case report forms, informed consents, diary forms, scientific documents, reports, records, expert opinions or reviews) - IEC documents (SOPs, meeting minutes, and decisions) - Correspondence (experts, study participants, etc.) of any forms, such as printed or written papers, hard copies, electronic mails (e-mail), faxes, audio or video tapes, etc.
Exempt review	A review process only by the Chairman of the NIRT-IEC who then reports the decision to the full Board meeting. An exempt review is a *speedy one for research proposal with less than minimal risk in nature*.
IEC	Institutional Ethics Committee is an independent body whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection.
Minimum risk	Risk equivalent to that encountered in day to day activities of a living human being.
Protocol	A document that describes the objective (s), design, methodology, statistical considerations, and organization of the study
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.
Secretariat	An office responsible for the secretarial, clerical, and administrative affairs of NIRT-IEC

Annexure Code: AF/EC/015/05

Covering letter to Chairperson for exempt review

ICMR - National Institute for Research in Tuberculosis

INSTITUTIONAL ETHICS COMMITTEE

(SIDCER Recognized Ethics Committee in the Asian and Western Pacific Region)

No: 1, Mayor Sathyamoorthy Road, Chetput, Chennai – 600 031, Tamil Nadu, India

Dr
Member-Secretary

Ref No: ……../NIRT-IEC/20….. Date:
……
To

Sir /Madam,
Please find enclosed a project submission requesting for *exempt review*: (the exempt review decision form is enclosed)

Project Title: ……
List of Documents: ……
……

Please review the submission and kindly sign the exempt review form appropriately and return to the undersigned in the enclosed envelope. Thanking you in anticipation.

Member Secretary

Encl:
As above
cc to:
Director, NIRT

Annexure Code: AF/EC/016/05

IEC Chairperson exempt review decision report

ICMR - National Institute for Research in Tuberculosis

INSTITUTIONAL ETHICS COMMITTEE

(SIDCER Recognized Ethics Committee in the Asian and Western Pacific Region)

No: 1, Mayor Sathyamoorthy Road, Chetput, Chennai – 600 031, Tamil Nadu, India

Exempt Review Decision Report

Date: _____ / _____ / _____

Project Title :

Name of the Reviewer : Chair – Dr

Risk-Benefit Ratio :

Recommendations :

Decision : Approved for exempt review ☐

To re-submit for expedited / full board review ☐

Signature

Annexure Code: AF/EC/017/05

Certificate of Institutional Ethics Committee Exempt Review

ICMR - National Institute for Research in Tuberculosis

INSTITUTIONAL ETHICS COMMITTEE

(SIDCER Recognized Ethics Committee in the Asian and Western Pacific Region)

No: 1, Mayor Sathyamoorthy Road, Chetput, Chennai – 600 031, Tamil Nadu, India

Members (Non Affiliated)

Dr.
Vice Chair

Dr.
Chairperson

Dr.
Member-Secretary

Members (Affiliated)

No: ……../NIRT-IEC/20….. Date: ……

Certificate of Institutional Ethics Committee Exempt Review

NIRT-IEC ID: ……..

"Title of the project: ……..".

Receipt of the amendment to the above referenced protocol is acknowledged. This submission includes the following documents: ……

The submission was reviewed by the Chair and the Member Secretary of the committee. As the submission involves research on -- ---------- and as it has less than minimal risk to humans, the submission is exempt from review.

Member Secretary

To: Principal Investigator

cc to:
The Director, National Institute for Research in Tuberculosis

Annexure Code: AF/EC/018/05

Letter to PI - IEC Exempt review decision

ICMR - National Institute for Research in Tuberculosis

INSTITUTIONAL ETHICS COMMITTEE

(SIDCER Recognized Ethics Committee in the Asian and Western Pacific Region)

No: 1, Mayor Sathyamoorthy Road, Chetput, Chennai – 600 031, Tamil Nadu, India

No: ……../NIRT-IEC/20….. Date:

To

Sir / Madam,

Sub: NIRT-IEC ID:

Ref: (i) Your Letter dated

Receipt of the above referenced protocol is acknowledged.

This submission includes:

The submission was reviewed by the Chair and the Member Secretary of the committee. As the submission involves research on ---------- ---------- and as it has more than minimal risk to humans, the submission has to undergo a full board / expedited review.

(Member Secretary)

cc to:

Director, NIRT

Acknowledgement of awareness of this SOP

S.No	Name	Capacity	Signature	Date
1.	Dr R Sridhar	Chairperson		
2.	Dr R Arun Kumar	Vice-Chairperson		
3.	Dr G Narendran	Member Secretary		
4.	Dr K Lily Therese	Member (Non-Affiliate)		
5.	Dr S Swarnalakshmi	Member (Non-Affiliate)		
6.	Dr Shyamala Nataraj	Member (Non-Affiliate)		
7.	Mrs Rajalakshmi	Member (Non-Affiliate)		
8.	Mrs Renu Lamech	Member (Non-Affiliate)		
9.	Dr V Gowri	Member (Non-Affiliate)		
10.	Mr D Sairamkumar	Member (Non-Affiliate)		
11.	Mrs Pushkala	Member (Non-Affiliate)		
12.	Dr S Chandrasekar	Member (Non-Affiliate)		
13.	Dr P M Ramesh	Member (Non-Affiliate)		
14.	Dr Padma Srikanth	Member (Non-Affiliate)		
15.	Dr Shuba Kumar	Member (Non-Affiliate)		
16.	Dr Luke Elizabeth Hanna	Member (Affiliate)		
17.	Dr Bella Devaleenal	Member (Affiliate)		
18.	Dr M Muniyandi	Member (Affiliate)		
19.	Dr P K Bhavani	Member (Affiliate)		
20.	Dr R Balaji	Member (Affiliate)		
21.	Dr R Sridhar	Chairperson		

SOP Code: SOP/EC/010/05

3.5. Expedited review

Revisions in the Standard Operating Procedures from version 4.0, dated 4 October 2018 to version 5.0, dated 18 May 2022

The following revisions are made in the Standard Operating Procedures from version 4.0, dated 4 October 2018 to version 5.0, dated 18 May 2022 following the revision in the National Ethical guidelines for Biomedical and Health Research involving human participants, ICMR 2017 and NDCT Guidelines 2019.

Expedited Review	**SOP/EC/010/05**	5.3. Expedited Review Process The following points are included: • All communications from concerned IEC Members will be received either through hard copy or email. • The protocol approved expeditedly will be reviewed annually or earlier, as per the duration of the study. • "Unanimous agreement among the reviewers will be taken as approved" is modified as "A Consensus opinion from the majority of reviewers will be taken and approved".

SOP Number: SOP/EC/010	Revision Number: 05	
SOP Author: **Dr P K Bhavani** **Signature**	**SOP Approver:** **Dr R Sridhar** **(Chair IEC)** **Signature**	**Effective Date :** **18 May 2022**
	Dr C Padmapriyadarsini **(Director)** **Signature**	**Supersedes :** **(Doc. version & Date)** **Version 4.0, dated 04 October 2018**

1. PURPOSE

The purpose of this SOP is to provide criteria for determination of which study protocols can be reviewed through expedited process as well as instructions on management, review and approval of the **expedited** review.

2. SCOPE

This SOP applies to the review and approval of study proposals with minimal risk, resubmission of protocols with minor modifications, protocol amendments or informed consent changes of currently approved studies with minimum risk to participants.

3. RESPONSIBILITY

It is the responsibility of the NIRT-IEC members to define which study protocols should be reviewed and approved through expedited channel.

4. FLOW CHART

No.	Activity	Responsibility
1	Receive the submitted documents	NIRT-IEC Secretariat
	↓	
2	Determine protocols for expedited review	NIRT-IEC MS and atleast one affiliate NIRT-IEC member
	↓	
3	Expedited review process	NIRT-IEC Chair / Vice-Chair / atleast one Non-affiliate member who is a
	↓	

		subject expert
4	Communicate with the NIRT-IEC and the Investigator	NIRT-IEC MS and Secretariat

5. DETAILED INSTRUCTIONS

5.1 **Receive the submitted documents**

- IEC Secretariat will receive the study documents submitted by investigators.
- IEC Secretariat will check the contents of submitted package with reference to **SOP/EC/012/05** (Review of Protocol Amendments) or **SOP/EC/007/05** (Management of Protocol Submissions).
- Inform the NIRT-IEC MS.

5.2. **Determine protocols for expedited review**

- NIRT-IEC Member – Secretary and at least one affiliate member of the NIRT-IEC will determine whether a study qualifies for expedited review according to the following criteria:

5.2.1Protocols with no more than minimal risk:

- research involving de-identified specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples
- research involving clinical documentation materials that are de-identified / anonymised (data, documents, records)
- Research during emergency and disasters as describe in the *Indian Council of Medical Research –National Ethical guidelines for Biomedical and Health Research involving human participants (2017)* under expedited review.

5.2.2 Modification / amendment of protocol

- Resubmission of protocol with minor modifications as per the initial review decision letter
- Minor protocol amendments which does not adversely affect risk/ benefit ratio of the study, rights, safety and welfare of the participants e.g. change in study procedure/ visits, quantity of blood drawn, number of questions in the questionnaire which do not compromise the integrity of study and do not lead to additional risk to participants
- *Administrative revisions,* such as correction of typo errors and grammar
- Revision of protocol in which activity is limited to data analysis
- Change in PI sent through proper channel.
- Change /Addition of Co-Investigators

If the protocol satisfied any of the criteria for **expedited** review, the NIRT-IEC secretariat will send the protocol for expedited review and approval.

5.3. Expedited Review Process

- The protocol with minimal risk will be sent to the Chair, Vice-Chair and atleast one non-affiliate member for review
- The re-submitted protocol with minor modifications will be sent to the original lead discussants, Vice-Chair and Chair for review
- NIRT-IEC secretariat will prepare a packet/ folder (e-copy) to be sent to the expedited reviewers. The packet will contain
  - ✓ a Covering letter to reviewers for expedited review ***(Annexure code: AF/EC/019/05)*** from the MS with details of the documents submitted for expedited review
  - ✓ the documents for expedited review
  - ✓ a IEC member expedited review decision letter***(Annexure code: AF/EC/020/05)*** template
  - ✓ Protocol Assessment form ***(Annexure code: AF/EC/043/05- Part I)*** for initial expedited review

  All communications from concerned IEC Members will be received either through hard copy or email.

- The reviewers will communicate the decision independently to the NIRT-IEC Secretariat along with Protocol Assessment form ***(Annexure code: AF/EC/043/05- Part I)*** for initial expedited review.
- A Consensus opinion from the majority of reviewers will be taken and approved.
- In case of disagreement among the reviewers, the protocol will be sent for full board review.
- In case of non availability of Chair/Vice-Chair, the protocol will be sent to one other IEC member in consultation 7with the Chair / Vice-Chair. The protocol approved expeditedly will be reviewed annually or earlier, as per the duration of the study.

5.4. Communication with the investigator and the NIRT-IEC

- If the study is approved, the MS will issue the Certificate of Institutional Ethics Committee Expedited approval –Initial Review ***(Annexure code: AF/EC/021/05)*** or Letter to PI - Protocol Amendments Expedited approval ***(Annexure code: AF/EC/022/05)*** to the PI.
- If the study is not approved, the decision will be communicated to the PI ***(Annexure code: AF/EC/023/05***, and that the study will be reviewed at the forthcoming full board***).***
- The MS will inform the NIRT-IEC of the proposals approved / not approved by expedited review at its subsequent meetings for full board notification and ratification.

6. ANNEXURE

Annexure Code	Annexure title
AF/EC/019/05	Covering letter to IEC member for expedited review
AF/EC/020/05	IEC member expedited review decision letter
AF/EC/021/05	Certificate of Institutional Ethics Committee Expedited Review approval - Initial Review
AF/EC/022/05	Letter to PI - Protocol Amendments Expedited Review and Approval
AF/EC/023/05	IEC Expedited review decision letter
AF/EC/043/05	Lead Discussant Form

7. Relevant SOPs

SOP Code	SOP Title
SOP/EC/007/05	Management of Protocol Submissions
SOP/EC/012/05	Review of Protocol Amendments

GLOSSARY

Document	Documents mean the following: - Study Protocols and related documents (such as case report forms, informed consents, diary forms, scientific documents, reports, records, expert opinions or reviews) - IEC documents (SOPs, meeting minutes, and decisions) - Correspondence (experts, study participants, etc.) of any forms, such as printed or written papers, hard copies, electronic mails (e-mail), faxes, audio or video tapes, etc.
Expedited review	A review process by only three NIRT-IEC members who then report the decision to the full Board meeting. An expedited review is a *speedy* one for minor *changes to the approved protocol* and for *research proposal* with *minimal risk in nature*.
IEC	Institutional Ethics Committee is an independent body whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection.
IEC members	Individuals serving as regular and alternate members on the institute's operational boards (i.e., IEC membership). These boards are constituted in accordance with the EC membership requirements set forth in ICMR Ethical guidelines for Biomedical research involving human participants
Informed Consent Document	Informed Consent Document is a written, signed and dated paper confirming participant's willingness to voluntarily participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the participant's decision to participate.
Minimum risk	Risk equivalent to that encountered in day to day activities of a living human being.
Protocol	A document that describes the objective (s), design, methodology, statistical considerations, and organization of the study
Protocol amendment	A written description of a change(s) to or formal clarification of
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.
Secretariat	An office responsible for the secretarial, clerical, and administrative affairs of NIRT-IEC

Annexure Code: AF/EC/019/05

Covering letter to IEC member for expedited review

F: +91 44 2836 2525/28 T: +91 44 2836 9600/2836 9500
www.nirt.res.in Email:

தேசிய காசநோய் ஆராய்ச்சி நிறுவனம்
राष्ट्रीय यक्ष्मा अनुसंधान संस्थान
ICMR - NATIONAL INSTITUTE FOR RESEARCH IN TUBERCULOSIS
(Formerly Tuberculosis Research Centre)
Indian Council of Medical Research
Department of Health Research, Ministry of Health & Family Welfare,
Government of India
#1, Sathyamoorthy Road, Chetpet, Chennai 600031

Dr
Member-Secretary

Ref No: ……../NIRT-IEC/20….. Date:
……
To

Sir /Madam,
Please find enclosed a project submission requesting for *expedited review*: (the expedited review decision form is enclosed)

Project Title: ……
List of Documents: ……
……

Please review the submission and kindly fill and sign the protocol assessment form and the expedited review form appropriately and return to the undersigned in the enclosed envelope. Thanking you in anticipation.

Member Secretary

Encl:
As above
cc to:
Director, NIRT

Annexure Code: AF/EC/020/05

IEC member expedited review decision report

F: +91 44 2836 2525/28 T: +91 44 2836 9600/2836 9500
www.nirt.res.in Email:

தேசிய காசநோய் ஆராய்ச்சி நிறுவனம்
राष्ट्रीय यक्ष्मा अनुसंधान संस्थान
ICMR - NATIONAL INSTITUTE FOR RESEARCH IN TUBERCULOSIS
(Formerly Tuberculosis Research Centre)
Indian Council of Medical Research
Department of Health Research, Ministry of Health & Family Welfare,
Government of India
#1, Sathyamoorthy Road, Chetpet, Chennai 600031

Expedited Review Decision Report

Date: _____ / _____ / _____

Project Title: ……

……

Name of the Reviewer	:	Chair / Vice Chair / IEC member
Risk-Benefit Ratio	:	
Recommendations	:	
Waiver of Consent to be given	:	Yes / No / Not Applicable
Decision	:	Approved / For full board review

Signature

Annexure Code: AF/EC/021/05

Certificate of Institutional Ethics Committee Expedited review and approval (Initial review)

ICMR - National Institute for Research in Tuberculosis (ICMR)
(Formerly Tuberculosis Research Centre)

INSTITUTIONAL ETHICS COMMITTEE

No: 1, Mayor Sathyamoorthy Road, Chetput, Chennai – 600 031, Tamil Nadu, India

Members (Non Affiliated)

Dr.
Vice Chair

Dr.
Chairperson

Dr.
Member-Secretary

Members (Affiliated)

No: ……../NIRT-IEC/20….. Date: ……

Certificate of Institutional Ethics Committee Approval

NIRT-IEC ID: ……..
"Title of the project: ……..".

Receipt of the above referenced protocol is acknowledged. This submission includes the following documents:
……

The protocol and the associated documents were reviewed and approved through expedited process.

Member Secretary

To: Principal Investigator

cc to:
The Director, National Institute for Research in Tuberculosis

Annexure Code: AF/EC/022/05

Letter to PI - Protocol Amendments Expedited review and approval

ICMR - National Institute for Research in Tuberculosis (ICMR)
(Formerly Tuberculosis Research Centre)

INSTITUTIONAL ETHICS COMMITTEE

No: 1, Mayor Sathyamoorthy Road, Chetput, Chennai – 600 031, Tamil Nadu, India

Members (Non Affiliated)

Dr.
Vice Chair

Dr.
Chairperson

Dr.
Member-Secretary

Members (Affiliated)

No: ……/NIRT-IEC/2013
Date: …….

To
.....
.....
.....

Sir / Madam,

Sub: NIRT-IEC ID: ……..
"Title: ……..." – reg.

Ref: (i) Your Letter dated ……
(ii) NIRT IEC Letter No: …… dated ……

Receipt of the amendment to the above referenced protocol is acknowledged. This submission includes the following documents:
……
……..

The amended protocol and the associated documents were reviewed and approved through expedited process.

The approved protocol

Member Secretary

cc to: The Director, National Institute for Research in Tuberculosis

Annexure Code: AF/EC/023/05

Letter to PI- IEC Expedited review decision

ICMR - National Institute for Research in Tuberculosis (ICMR)
(Formerly Tuberculosis Research Centre)

INSTITUTIONAL ETHICS COMMITTEE

No: 1, Mayor Sathyamoorthy Road, Chetput, Chennai – 600 031, Tamil Nadu, India

No: ……/NIRT-IEC/2013 Date: …….

To

.....
.....
.....

Sir / Madam,

Sub: NIRT-IEC ID: ……..
"Title: ……...." – reg.

Ref: (i) Your Letter dated ……
(ii) NIRT IEC Letter No: …… dated …….

Receipt of the above referenced protocol / Receipt of the amendment to the above referenced protocol is acknowledged. This submission includes the following documents:

……

The protocol / amended protocol was reviewed through expedited process.
In view of the following reasons,

the study protocol / amendments were not approved and needs to undergo a full board review.

Member Secretary

cc to:
The Director, National Institute for Research in Tuberculosis

Annexure Code: AF/EC/043/05

LEAD DISCUSSANT ASSESSMENT FORM

Part – 1

Protocol Assessment form

NIRT-IEC No:		**Date (D/M/Y):**			
Protocol title:					
Protocol version no. & date:					
NIRT-IEC Member name:					
1. Is SAC approval available : Yes ☐ No ☐					
2. Need for the study (Check Background & Justification sections of protocol)					
		Yes	**No**	**NA**	**Comment:**
1	Background and justification - sufficient?				
2	Literature review – adequate?				
3	Need for human participants justified ?				
4	Does the study contribute to development of local capacity for Research / Treatment?				
3. Scientific value (Check Methods section of protocol)					
5	Methodology – clear and well-described?				
6	Study Design - appropriate?				
7	Is the use of placebo justified?				
8	Inclusion Criteria - appropriate				
9	Exclusion Criteria - appropriate				
10	Laboratory methods – clear, well defined and feasible?				

11	Follow-up procedures well defined?				
12	Are study end points well defined?				
13	Are unbiased assessments used?				
14	Sample size adequate?				
15	Statistical methods proposed - appropriate				
16	Is there a provision for interim analysis in interventional studies				
4. Fair subject selection (Check Methods section of protocol)					
17	Inclusion Criteria - appropriate				
18	Exclusion Criteria - appropriate				
19	Is the recruitment of participants voluntary, non-coercive				
20	Is there an Inducement for participation?				
21	Is participant deception avoided?				
5. Favourable risk-benefit ratio					
22	Risks and benefits assessment – acceptable ?				
23	Are predictable risks minimized?				
24	Tests and procedures that are more than minimal risk cautiously used				
25	Provision for Medical/Psychosocial Support				
26	Is participant discontinuation and withdrawal criteria appropriate?				
27	Provision for treatment of Study-Related Injuries				
28	Provision for compensation (where applicable)				
29	Does the study benefit the individual?				
30	Does the study benefit the local community?				

6.	**Informed consent**				
31	Are procedures for obtaining informed consent appropriate (written/verbal)?				
32	Content of the information sheet and consent form clear and contain necessary details?				
33	Translations of all forms consistent?				
34	Contact details of PI given in both information sheet & consent forms?				
7.	**Respect for human subjects**				
35	Privacy and confidentiality ensured				
36	Are vulnerable populations involved?				
	26.1 If yes, is it justifiable to conduct the study in that population?				
37	Are blood/ tissue samples sent abroad?				
	27.1 If samples are sent, is it mentioned in the ICF?				
38	Is the fate of the samples once study is over mentioned?				
39	Is appropriate consent included for storage of biological samples?				
8.	**Others**				
40	Are facilities and infrastructure of Participating Sites appropriate?				
41	Is community Consultation addressed if required?				
42	Is disclosure or Declaration of potential Conflicts of Interest addressed?				
43	Is the PI adequately qualified to do the study?				
44	Are qualification and experience of the Participating Investigators appropriate?				

Comments :

Decision*: Approved /Minor modification s/ Major modifications /rejected*

Part – 2 (to be filled in case of full board review)

INFORMED CONSENT REVIEW FORM

(Participant Information sheet and Informed Consent Form Checklist)

Participant Information sheet date and Version:

Informed Consent Form Date and Version:

Are the following items included in the Participant Information sheet?

A statement that the trial / study involves research	**Y**	**N**		
Purpose of the trial/ study	**Y**	**N**		
Trial// study treatments and the probability of random assignment	**Y**	**N**	**NA**	
Trial / study procedures to be followed, including all invasive procedures			**Y**	**N**
Those aspects of the trial /study that are experimental			**Y**	**N**
Expected duration of subject's participation			**Y**	**N**

Approximate number of subjects involved in the trial/study		**Y**	**N**
Reasonably foreseeable risks or inconveniences to the subject		**Y**	**N**
Expected benefits to the subject (or no intended clinical benefit)		**Y**	**N**
Alternative procedures or treatments, and their potential benefits/risks		**Y**	**N**
Subject's responsibilities		**Y**	**N**
Compensation and / or treatment in the event of trial-related injury	**Y**	**N**	**NA**
Dissemination of new information in a timely manner		**Y**	**N**
Foreseeable circumstances/ reasons for termination of subject's participation		**Y**	**N**
Contact(s) for further information or in the event of trial/study-related injury		**Y**	**N**
Participation in the trial/study is voluntary. Refusal to participate, or withdrawal from the trial, at any time, is without penalty or loss of benefits to which the subject is otherwise entitled		**Y**	**N**
The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation		**Y**	**N**
The investigator will inform the subject's primary physician about the subject's participation in the study if the subject agrees		**Y**	**N**
Anticipated prorated payment, if any	**Y**	**N**	**NA**
Anticipated prorated expenses, if any	**Y**	**N**	**NA**
Monitor, auditor, EC and regulatory authority are granted direct access to personal medical records without violating the confidentiality of the subject		**Y**	**N**
Confidentiality: personal information will not be made publicly available, including if study results are published		**Y**	**N**

Are the following items included in the Informed Consent Form (signature sheet) ?

Consent Statement	**Y**	**N**
Reference made to voluntariness, confidentiality , compensation, rights	**Y**	**N**

Consent for Storage of biological samples (if applicable**)**	**Y**	**N**
A space for subject's name / signature / date	**Y**	**N**
A space for witness name / signature / date	**Y**	**N**
A space for investigator's name / signature / date	**Y**	**N**

Other

Investigator's name, protocol #, version date, and page # of #	**Y**	**N**
Was the language used as non-technical as practical, and was it understandable to the subject ?	**Y**	**N**

Comments:

Decision*: Approved /Minor modifications/ Major modifications /rejected*

Signature of the reviewer:

Date of review (DD/MM/YY):

Acknowledgement of awareness of this SOP

S.No	Name	Capacity	Signature	Date
1.	Dr R Sridhar	Chairperson		
2.	Dr R Arun Kumar	Vice-Chairperson		
3.	Dr G Narendran	Member Secretary		
4.	Dr K Lily Therese	Member (Non-Affiliate)		
5.	Dr S Swarnalakshmi	Member (Non-Affiliate)		
6.	Dr Shyamala Nataraj	Member (Non-Affiliate)		
7.	Mrs Rajalakshmi	Member (Non-Affiliate)		
8.	Mrs Renu Lamech	Member (Non-Affiliate)		
9.	Dr V Gowri	Member (Non-Affiliate)		
10.	Mr D Sairamkumar	Member (Non-Affiliate)		
11.	Mrs Pushkala	Member (Non-Affiliate)		
12.	Dr S Chandrasekar	Member (Non-Affiliate)		
13.	Dr P M Ramesh	Member (Non-Affiliate)		
14.	Dr Padma Srikanth	Member (Non-Affiliate)		
15.	Dr Shuba Kumar	Member (Non-Affiliate)		
16.	Dr K R Uma Devi	Member (Affiliate)		
17.	Dr Luke Elizabeth Hanna	Member (Affiliate)		
18.	Dr Bella Devaleenal	Member (Affiliate)		
19.	Dr M Muniyandi	Member (Affiliate)		
20.	Dr P K Bhavani	Member (Affiliate)		
21.	Dr R Balaji	Member (Affiliate)		

SOP Code: SOP/EC/011/05

4.1. Review of Resubmitted protocols

SOP Number: SOP/EC/011	Revision Number: 04	
SOP Author: **Dr R Balaji** **Signature**	**SOP Approver:** **Dr R Sridhar** **(Chair IEC)** **Signature**	**Effective Date :** **18 May 2022**
	Dr C Padmapriyadarsini **(Director)** **Signature**	**Supersedes :** **(Doc. version & Date)** **Version 4.0, dated 04 October 2018**

1. PURPOSE

This procedure describes how resubmitted study protocols are managed, re-reviewed and approved by the NIRT-IEC.

2. SCOPE

This SOP applies to study protocols that have been reviewed earlier with recommendations from NIRT-IEC for modification/revisions in the initial review process.

3. Responsibility

It is the responsibility of the NIRT-IEC Secretariat to ensure the completeness of the resubmitted documents and to notify the Committee that a protocol previously approved with conditions for revision has been resubmitted to the IEC for reconsideration. The MS will ensure that all the comments/suggestions of the IEC have been addressed by the PI

The resubmitted protocol review process would have been determined by the IEC at the time of the initial review. A re-submitted protocol may be reviewed by either an expedited review process or full board review.

4. Flow chart

No.	Activity	Responsibility
1	Receive resubmitted protocol package	IEC Secretariat
	↓	
2	Segregate for Full board or Expedited review	Member Secretary/IEC Secretariat
	↓	
3	Dispatch accordingly	IEC Secretariat
	↓	
4	Receive the resubmitted protocol package	IEC Members / Expedited Reviewers
	↓	
5	Review the revised protocol	IEC Members / Expedited Reviewers
	↓	
6	IEC Meeting	IEC Members
	↓	
7	Communicate to the IEC – Expedited review decision	Member Secretary/ Chair
	↓	
8	Document the decision and send it to PI	IEC Secretariat

5. DETAILED INSTRUCTIONS

5.1. Receive resubmitted protocol package, segregate and dispatch

The PI will be instructed to consider re-submitting the documents for expedited review based on the decision letter.
In case of re-submission for Full Board review, the PI will be instructed to consider re-submitting as per the stipulated timeline for the subsequent meetings.

NIRT-IEC Secretariat and MS will

- ✧ Check the package for:
  - IEC Initial Review decision letter.
  - Initial Review Submission / re-submission Form ***(Annexure code: AF/EC/010/05)***
  - NIRT SAC approval letter
  - Revised version of protocol and associated documents such as the informed consent document, data collection or case report forms, etc are included as part of the package.
  - Changes made to the documents should be listed in the protocol history page
  - Checklist for documents submitted by PI to NIRT-IEC ***(Annexure code: AF/EC/042/05)***

- Segregate for Full board or Expedited review based on the initial decision.
- Dispatch accordingly

5.2. Review the revised protocol (Expedited review)

- ✧ Reviewers will refer to IEC Initial Review decision letter as guidance for the review. Lead Discussants will be the reviewer in addition to the Chair and Vice-Chair.
- ✧ Consider whether the recommendation of the IEC has been followed.
- ✧ Refer to expedited review SOP **(SOP/EC/010/05)**

5.3. IEC meeting (Full board review)

- ✧ Initial Lead Discussants will be the reviewers; they will refer to IEC Initial Review decision letter as guidance for the review.
- ✧ During the meeting the PI presents a brief summary of the study and the changes made and if necessary the protocol to the IEC members.
- ✧ The Chair and members will discuss the protocol revision and decision will be taken based on consensus.
- ✧ For the decision of the committee and subsequent procedures -refer to Initial review of submitted protocols SOP (**SOP/EC/008/05)**

6. ANNEXURE

Annexure Code	Annexure title
AF/EC/010/05	Initial review submission / Resubmission form for Ethical clearance
AF/EC/042/05	Checklist for documents submitted by PI to NIRT-IEC

7. RELEVANT SOPs

SOP Code	SOP Title
SOP/EC/008/05	Initial Review of Submitted Protocols
SOP/EC/010/05	Expedited Review

GLOSSARY

Document	Documents mean the following: - Study Protocols and related documents (such as case report forms, informed consents, diary forms, scientific documents, reports, records, expert opinions or reviews) - IEC documents (SOPs, meeting minutes, and decisions) - Correspondance (experts, study participants, etc.) of any forms, such as printed or written papers, hard copies, electronic mails (e-mail), faxes, audio or video tapes, etc.
Expedited review	A review process by only three NIRT-IEC members who then report the decision to the full Board meeting. An expedited review is a *speedy* one for minor *changes to the approved protocol* and for *research proposal* with *minimal risk in nature*.
Full board review	A review process by all the NIRT-IEC members in a full Board meeting for a consensus decision making
IEC	Institutional Ethics Committee is an independent body whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection.
IEC members	Individuals serving as regular and alternate members on the institute's operational boards (i.e., IEC membership). These boards are constituted in accordance with the EC membership requirements set forth in ICMR Ethical guidelines for Biomedical research involving human participants
Secretariat	An office responsible for the secretarial, clerical, and administrative affairs of NIRT-IEC

Annexure Code: AF/EC/010/05

Initial review submission / Resubmission form for Ethical clearance

S No	Title	Particulars
1	Title of the research proposal	
2	NIRT-IEC No.	
3	Name of the Principal Investigator (PI) with Qualification, Designation, name of Section / Department	
4	Name of the Co-PI, Co-Investigator(s)(Co-I) with Qualification, Designation, name of Section / Department	
5	Source of funding & financial allocation for the project / trial	
6	Type of research (Please circle)	Clinical / Epidemiological / Operational / Laboratory (Bacteriology/Immunology/Biochemistry) / Socio-behavioural / Others
7	Expected duration of the project	----------years
8	Name of the Institution(s) where research is to be conducted	
9	Is the research proposal approved by the Scientific Advisory Committee of NIRT? If yes, month and year of approval	Yes / No
10	Is approval by ICMR Central Ethics Committee required for this project?	Yes / No
11	Will the research proposal be submitted to the Health Ministry Screening Committee (HMSC) for International Collaboration?	Yes / No
12	List of documents enclosed for ethical review (with version number & date)	
13	Research Proposal: Precise, yet relevant background information	
14	Research Proposal: Main objectives	
15	Study design	
16	Sample size	

17	Usefulness of the project / trial	
18	Expected 'benefits' to volunteer / community	
19	Explain all anticipated 'risks' (adverse events, injury, discomfort…) of the project	
20	Efforts taken to minimize the 'risks'	
21	Explain the plans to maintain confidentiality of records / data	
22	Whether compensation for travel and incidental expenses to the research participants be provided?	Yes / No If yes, details:
23	Research Participant Information sheet	
24	Describe the Informed Consent Process Mention : Written / Oral / Audio-visual	
25	Disclose Conflict of Interest, if any	
26	Specific ethical issues, as identified by the investigating team (eg) Vulnerability Storage of Biological samples	
27	Declaration of adherence to regulatory guidelines (please ✓ as appropriate)	□ Ethical Guidelines for Biomedical Research on Human participants, ICMR, 2017 □ Good Clinical Practice & Guidelines for Clinical Trials on Pharmaceutical products in India, CDSCO, DGHS, MoHFW, Govt of India, including Schedule Y 2005 and its revisions □ Others If Others, specify _____ _____ _____
28	Signature of the Principal Investigator with date	

Annexure code AF/EC/042/05

Checklist for documents submitted by PI to NIRT-IEC (To be filled by PI)

NIRT-IEC No:		**Submitted date:**	
Type of Submission:	☐ Initial Review ☐ Resubmission for re-review ☐ Protocol Amendments	☐ Ongoing review ☐ Study completed ☐ Protocol Termination	
Protocol Title:			
Name of Principal Investigator: **Designation:** **Department:**			
Institute:			

☐ **Initial Review Submitted Package**

- Initial Review Submission / re-submission Form
- NIRT- SAC approval
- PI's updated signed short CV and GCP training record.
- Protocol with version no. & date and to include section on Ethical Consideration
- Protocol-Related Documents with version no. & date
  - ☐ Patient Information sheet
  - ☐ Informed consent form (English)
  - ☐ Case report forms (CRF)
  - ☐ Informed consent form (Local vernacular)
  - ☐ Data collection forms
  - ☐ others……
  - ☐ Investigator's Brochure, if applicable

☐ **Resubmission for Re-review Submitted Package**

- IEC Initial Review decision letter
- Initial Review Submission / re-submission Form
- Revised Protocol with version no. & date
- Protocol history page listing the changes made to the documents
- Protocol-Related Documents with version no. & date
  - ☐ Patient Information sheet
  - ☐ Informed consent form (English)
  - ☐ Case report forms (CRF)
  - ☐ Informed consent form (Local vernacular)

☐ Data collection forms ☐ others……
☐ Investigator's Brochure, if applicable

☐ **Protocol Amendment Submitted Package**

- ❑ Letter of request for Amendment by PI
- ❑ Ongoing / completed / terminated protocol Review Submission Form
  - ❑ State/describe the amendment as annexure
  - ❑ Reason for the amendment
  - ❑ Any untoward effects to original protocol (ie. Study objective, design, outcome)
  - ❑ Expected risks to participants due to the amendment
- ❑ Amended Protocol with version no. & date
- ❑ Protocol history page listing the changes made to the documents
- ❑ Protocol-Related Documents with version no. & date

☐ Patient Information sheet ☐ Informed consent form (English)
☐ Case report forms (CRF) ☐ Informed consent form (Local vernacular)
☐ Data collection forms ☐ others……
☐ Investigator's Brochure, if applicable

☐ **Ongoing Review Package**

- ❑ Ongoing / completed / terminated protocol Review Submission Form
- ❑ Protocol amendment if any
- ❑ Study completed / terminated, if applicable

☐ **Study completed Package**

- ❑ Ongoing / completed / terminated protocol Review Submission Form
- ❑ Final report

☐ **Protocol Termination Package**

- ❑ Ongoing / completed / terminated protocol Review Submission Form
- ❑ Reasons for termination
- ❑ Minutes of other committee meetings that were held if any
- ❑ Final report if available

Signature of the Principal Investigator & date	

Receipt of documents from PI (To be filled by NIRT-IEC Secretariat)

NIRT-IEC No:		
Type of Submission:	☐ Initial Review ☐ Resubmission for re-review ☐ Protocol Amendments	☐ Ongoing review ☐ Study completed ☐ Protocol Termination
Protocol Title:		
Received by:		**Date received:**
Pending documents : Nil / Yes, If yes, details: ☐ Patient Information sheet ☐ Case report forms (CRF) ☐ Data collection forms ☐ Investigator's Brochure, if applicable ☐ Informed consent form (English) ☐ Informed consent form (Local vernacular) ☐ others……		
Received by:		**Date received:**

Acknowledgement of awareness of this SOP

S.No	Name	Capacity	Signature	Date
1.	Dr R Sridhar	Chairperson		
2.	Dr R Arun Kumar	Vice-Chairperson		
3.	Dr G Narendran	Member Secretary		
4.	Dr K Lily Therese	Member (Non-Affiliate)		
5.	Dr S Swarnalakshmi	Member (Non-Affiliate)		
6.	Dr Shyamala Nataraj	Member (Non-Affiliate)		
7.	Mrs Rajalakshmi	Member (Non-Affiliate)		
8.	Mrs Renu Lamech	Member (Non-Affiliate)		
9.	Dr V Gowri	Member (Non-Affiliate)		
10.	Mr D Sairamkumar	Member (Non-Affiliate)		
11.	Mrs Pushkala	Member (Non-Affiliate)		
12.	Dr S Chandrasekar	Member (Non-Affiliate)		
13.	Dr P M Ramesh	Member (Non-Affiliate)		
14.	Dr Padma Srikanth	Member (Non-Affiliate)		
15.	Dr Shuba Kumar	Member (Non-Affiliate)		
16.	Dr K R Uma Devi	Member (Affiliate)		
17.	Dr Luke Elizabeth Hanna	Member (Affiliate)		
18.	Dr Bella Devaleenal	Member (Affiliate)		
19.	Dr M Muniyandi	Member (Affiliate)		
20.	Dr P K Bhavani	Member (Affiliate)		
21.	Dr R Balaji	Member (Affiliate)		

SOP Code: SOP/EC/012/05

4.2. Review of Protocol Amendments

SOP Number: SOP/EC/012	Revision Number: 05	
SOP Author: **Dr Luke Elizabeth Hanna** **Signature** Luke Elizabeth Hanna	**SOP Approver:** **Dr R Sridhar** **(Chair IEC)** **Signature**	**Effective Date :** **18 May 2022**
	Dr C Padmapriyadarsini **(Director)** **Signature**	**Supersedes :** **(Doc. version & Date)** **Version 4.0, dated 4 October 2018**

1. PURPOSE

The purpose of this SOP is to describe how protocol amendments are managed and reviewed by the NIRT-IEC.

2. SCOPE

This SOP applies to previously approved study protocols but later being amended by the PI and submitted for approval to the NIRT-IEC. Protocol amendments may be subjected to either "expedited" review or full board review. Amendments made to protocols may not be implemented until reviewed and approved by the NIRT-IEC.

3. RESPONSIBILITY

It is the responsibility of the NIRT-IEC Secretariat to manage protocol amendments and the NIRT-IEC to approve the amendments.

4. FLOW CHART

No.	Activity	Responsibility
1	Receive the Amendment Package	NIRT-IEC Secretariat
	↓	
2	Inform the MS	NIRT-IEC Secretariat
	↓	
3	Determine whether Expedited or Full Board Review	MS and at least one affiliate NIRT-IEC member
	↓	
4	Dispatch accordingly	IEC Secretariat
	↓	
5	Receive amendment protocol package	Lead Discussants/ Expedited Reviewer(s)
	↓	
6	Review the amended protocol	Expedited Reviewer(s)// Lead Discussants
	↓	
7	IEC Meeting	IEC Members
	↓	
8	Communicate Full board review/ Expedited review decision	Members/Chair/MS
	↓	
9	Document the decision	IEC Secretariat

5. DETAILED INSTRUCTIONS

5.1. Receive the Amendment Package

- The amendment package will be prepared and submitted by the PI.
- Upon receipt of the amendment package, the NIRT-IEC Secretariat will check the following:

  Letter of request for Amendment of the Protocol by the Principal Investigator on an existing and previously approved protocol.

  - **Ongoing/Completed/Terminated protocol Review Submission Form *(Annexure code: AF/EC/011/05)*** - Check for completeness and for Principal Investigator's signature.

The Ongoing review with amendment submission should, upon applicability:

- State/describe the amendment(s) as annexure
- Give reason for the amendment
- State any untoward effect to the original protocol (i.e., Study objective, design, outcome) as a result of the amendment

- State expected risks to participants due to the amendment

- **Protocol and Related Documents to be submitted to the IEC Secretariat**

  - The amended version of the protocol and related documents
  - Changes made to the documents should be listed in the protocol history page
  - Checklist for documents submitted by PI to NIRT-IEC ***(Annexure code: AF/EC/042/05)***
  - ***Ongoing review form, if it is due for ongoing review during a full board meeting.***

5.2. Notify the MS of the NIRT-IEC

- Upon receipt of the amendment package, the Secretariat will inform the MS of the NIRT-IEC.
- The MS and one affiliate member will review the documents and determine whether the protocol amendment review will require expedited or full board review.
- Follow **SOP/EC/007/05** (Management of Protocol Submission) for preparing and distributing the documents.

5.3. Determine whether expedited or full board review

- For Expedited Review, the amended protocol/documents will be sent to the same primary reviewer(s) who initially reviewed the protocol.
- The Secretariat will include the protocol amendment on the agenda for the next IEC meeting if the decision is for full board review.

The documents will be dispatched accordingly

5.4. Expedited Review

- Refer to **SOP/EC/010/05** for Expedited Review procedure.

5.5. Full Board Review

- Refer to **SOP/EC/008/05** for Full Board Review procedure.

5.6. Protocol Amendment Review Process (Full Board Review)

5.6.1 Review amended protocols

- The amendments made to the protocol will be presented by the PI in the next full board meeting.
- After deliberation, the NIRT-IEC will decide on one of the following:
  - Approve the protocol amendment without any modification in any of the documents.
  - Require a modification to the proposed amendment in any of the submitted documents including the participant information sheet and informed consent form.
  - Require re-consenting of the recruited study participants for the amended protocol
  - Disapprove the amendment request, stating the reason – but allow the study to continue as previously approved.

5.7. Notify the Principal Investigator

- If the NIRT-IEC approves the protocol amendment, the Secretariat staff will communicate this decision to the PI ***(Annexure code: AF/EC/022/05 or AF/EC/024/05).***

- If the NIRT-IEC does not approve the protocol amendment, the decision will be notified to the investigator in writing along with the reason for disapproval of the amendment ***(Annexure code: AF/EC/023/05 or Annexure code: AF/EC/025/05).***

- If the NIRT-IEC suggests modifications to any of the study documents, the Secretariat will send a written communication to the PI asking him/her to make the necessary changes and resubmit the documents to NIRT-IEC ***(Annexure code: AF/EC/025/05).***

  The Secretariat will file the forms, minutes of the meeting including details of the discussion and the decision reached by the NIRT-IEC, as official record of the amendment review process.

5.8. Store documents

- The Secretariat will place the original documents, the approved version of the protocol and other documents pertaining to the amendment in the Study File.

6. ANNEXURE

Annexure Code	Annexure title
AF/EC/011/05	Ongoing / Completed / Terminated protocol review submission form

AF/EC/022/05	Letter to PI - Protocol Amendments Expedited Review and approval
AF/EC/023/05	Letter to PI- IEC Expedited review decision
AF/EC/024/05	Letter to PI - Protocol Amendments Full Board approval
AF/EC/025/05	Letter to PI - Protocol Amendments Full Board review decision
AF/EC/042/05	Checklist for documents submitted by PI to NIRT-IEC

7. RELEVANT SOPs

SOP Code	SOP Title
SOP/EC/007/05	Management of Protocol Submissions
SOP/EC/008/05	Initial Review of submitted Protocols
SOP/EC/010/05	Expedited Review

GLOSSARY

Document	Documents mean the following: - Study protocols and related documents (such as case report forms, informed consent forms, diary forms, scientific documents, reports, records, expert opinions or reviews) - IEC documents (SOPs, meeting minutes, and decisions) - Correspondance (from experts, study participants, etc.) of any form, such as printed or written papers, electronic mails (e-mail), faxes, audio or video tapes, etc.
Expedited review	A review process by at least two NIRT-IEC members who then report the decision at the full Board meeting. An expedited review is a *speedy* one for minor *changes to approved protocols* and *research proposals* with *minimal risk.*
Full board review	A review process by all the NIRT-IEC members in a full Board meeting for consensus decision making.
IEC	Institutional Ethics Committee is an independent body whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a clinical trial or research study and to provide public assurance of their protection.
Meeting	Deliberations between at least two (2) persons where such deliberations determine or result in the joint conduct or disposition of business.
Minutes	An official record of the business discussed and transacted at a meeting.
Protocol	A document that describes the objective(s), design, methodology, statistical Considerations, and organization of a study.
Protocol amendment	A written description of a change(s) to or formal clarification of.
Standard Operating Procedure	Detailed, written instructions, in a certain format, describing all activities 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 an operation, whilst maintaining high standards of Good Clinical Practice.
Secretariat	An office responsible for the secretarial, clerical, and administrative affairs of NIRT-IEC
Study file	Approved documents (protocols, protocol amendments, informed consent forms, advertisements, investigator and site details), records of communications and correspondence with the investigator, and reports (including but not limited to Continuing Review Reports, IND Safety Reports, Reports of injuries to subjects, Scientific Evaluations) that correspond to each study approved by the *NIRT-IEC.*

Annexure Code: AF/EC/022/05

Letter to PI - Protocol Amendments Expedited Review and Approval

ICMR - National Institute for Research in Tuberculosis

INSTITUTIONAL ETHICS COMMITTEE

(SIDCER Recognized Ethics Committee in the Asian and Western Pacific Region)

No: 1, Mayor Sathyamoorthy Road, Chetput, Chennai – 600 031, Tamil Nadu, India

Members (Non Affiliated)

Dr.
Vice Chair

Dr.
Chairperson

Dr.
Member-Secretary

Members (Affiliated)

No: ……/NIRT-IEC/YYYY Date:
…….

To

.....
.....
.....

Sir / Madam,

Sub: NIRT-IEC ID: ……..
"Title: ……..." – reg.

Ref: (i) Your Letter dated ……
(ii) NIRT IEC Letter No: …… dated ……

Receipt of the amendment to the above referenced protocol is acknowledged. This submission includes the following documents:
……
……..

The amended protocol and associated documents were reviewed and approved through expedited process

Member Secretary

cc to: The Director, National Institute for Research in Tuberculosis

Annexure Code: AF/EC/023/05

Letter to PI- IEC Expedited review decision

ICMR - National Institute for Research in Tuberculosis

INSTITUTIONAL ETHICS COMMITTEE

(SIDCER Recognized Ethics Committee in the Asian and Western Pacific Region)

No: 1, Mayor Sathyamoorthy Road, Chetput, Chennai – 600 031, Tamil Nadu, India

No: ……/NIRT-IEC/YYYY Date: …….

To

.....
.....
.....

Sir / Madam,

Sub: NIRT-IEC ID: ……..
"Title: ……..." – reg.

Ref: (i) Your Letter dated ……
(ii) NIRT IEC Letter No: …… dated …….

Receipt of the above referenced protocol / receipt of the amendment to the above referenced protocol is acknowledged. This submission includes the following documents:

……

The protocol / amended protocol was reviewed through expedited process.
In view of the following reasons,

the study protocol / amendments were not approved and needs to undergo a full board review.

Member Secretary

cc to:
The Director, National Institute for Research in Tuberculosis

Annexure Code: AF/EC/024/05

Letter to PI - Protocol Amendments Full Board approval

ICMR - National Institute for Research in Tuberculosis

INSTITUTIONAL ETHICS COMMITTEE

(SIDCER Recognized Ethics Committee in the Asian and Western Pacific Region)

No: 1, Mayor Sathyamoorthy Road, Chetput, Chennai – 600 031, Tamil Nadu, India

Members (Non Affiliated)

Dr.
Vice Chair

Dr.
Chairperson

Dr.
Member-Secretary

Members (Affiliated)

No: ……/NIRT-IEC/YYYY
Date: …….

To

.....
.....
.....

Sir / Madam,

The Institutional Ethics Committee met on ……. under the Chairmanship of ---------- and reviewed the Amendments to the project titled "…….....
.NIRT-IEC No: …….., which was presented by ……., NIRT

The Committee reviewed the following documents –

- and after deliberations, **approves the amendments** with the following **recommendations (if any):**

Member Secretary

cc to:
The Director, National Institute for Research in Tuberculosis

Annexure Code: AF/EC/025/05

Letter to PI - Protocol Amendments Full Board review decision

ICMR - National Institute for Research in Tuberculosis

INSTITUTIONAL ETHICS COMMITTEE

(SIDCER Recognized Ethics Committee in the Asian and Western Pacific Region)

No: 1, Mayor Sathyamoorthy Road, Chetput, Chennai – 600 031, Tamil Nadu, India

Members (Non Affiliated)

Dr. Vice Chair

Dr. Chairperson

Dr. Member-Secretary

Members (Affiliated)

No: ……/NIRT-IEC/YYYY Date: ……

To

.....
.....
.....

Sir / Madam,

The Institutional Ethics Committee met on ……. under the Chairmanship of ---------- and reviewed the Amendments to the project titled "…….....
.NIRT-IEC No: …….., which was presented by ……., NIRT

The Committee reviewed the following documents –

- and following a consensus decision, the amendments to the protocol and/or associated documents requires to be re-submitted with the following recommendations addressed

OR

- and after deliberations, disapproves the amendments for the following reasons

Member Secretary

cc to:

The Director, National Institute for Research in Tuberculosis

Annexure code AF/EC/042/05

Checklist for documents submitted by PI to NIRT-IEC (To be filled by PI)

NIRT-IEC No:		**Submitted date:**	
Type of Submission:	☐ Initial Review ☐ Resubmission for re-review ☐ Protocol Amendments	☐ Ongoing review ☐ Study completed ☐ Protocol Termination	
Protocol Title:			
Name of Principal Investigator: **Designation:** **Department:**			
Institute:			

☐ **Initial Review Submission Package**

- Initial Review Submission / Re-submission Form
- NIRT- SAC approval
- PI's updated signed short CV and GCP training record.
- Protocol with version no. & date, including a section on Ethical Considerations
- Protocol-related Documents with version no. & date
  - ☐ Patient Information sheet
  - ☐ Informed consent form (English)
  - ☐ Case report forms (CRF)
  - ☐ Informed consent form (Local vernacular)
  - ☐ Data collection forms
  - ☐ Others……
  - ☐ Investigator's Brochure, if applicable

☐ **Resubmission for Re-review Submission Package**

- IEC Initial Review decision letter
- Initial Review Submission / Re-submission Form
- Revised Protocol with version no. & date
- Protocol history page listing the changes made to the documents
- Protocol-related Documents with version no. & date
  - ☐ Patient Information sheet
  - ☐ Informed consent form (English)
  - ☐ Case report forms (CRF)
  - ☐ Informed consent form (Local vernacular)

- ☐ Data collection forms ☐ Others……
- ☐ Investigator's Brochure, if applicable

☐ **Protocol Amendment Submission Package**

- ❑ Letter of request for Amendment by PI
- ❑ Ongoing / completed / terminated protocol Review Submission Form
  - ❑ State/describe the amendment as annexure
  - ❑ Reason for the amendment
  - ❑ Any untoward effects to original protocol (ie. Study objectives, design, outcome)
  - ❑ Expected risk to participants due to the amendment
- ❑ Amended protocol with version no. & date
- ❑ Protocol history page listing the changes made to the documents
- ❑ Protocol-related documents with version no. & date
  - ☐ Patient Information sheet ☐ Informed consent form (English)
  - ☐ Case report forms (CRF) ☐ Informed consent form (Local vernacular)
  - ☐ Data collection forms ☐ Others……
  - ☐ Investigator's Brochure, if applicable

☐ **Ongoing Review Package**

- ❑ Ongoing / completed / terminated protocol Review Submission Form
- ❑ Protocol amendment if any
- ❑ Study completed / terminated, if applicable

☐ **Completed Study Package**

- ❑ Ongoing / completed / terminated protocol Review Submission Form
- ❑ Final report

☐ **Protocol Termination Package**

- ❑ Ongoing / completed / terminated protocol Review Submission Form
- ❑ Reasons for termination
- ❑ Minutes of other committee meetings that were held if any
- ❑ Final report if available

Signature of the Principal Investigator & date	

Receipt of documents from PI (To be filled by NIRT-IEC Secretariat)

NIRT-IEC No:		
Type of Submission:	☐ Initial Review ☐ Resubmission for re-review ☐ Protocol Amendments	☐ Ongoing review ☐ Study completed ☐ Protocol Termination
Protocol Title:		
Received by:		**Date received:**
Pending documents : Nil / Yes, If yes, details: ☐ Patient Information sheet ☐ Case report forms (CRF) ☐ Data collection forms ☐ Investigator's Brochure, if applicable ☐ Informed consent form (English) ☐ Informed consent form (Local vernacular) ☐ Others……		
Received by:		**Date received:**

Acknowledgement of awareness of this SOP

S.No	Name	Capacity	Signature	Date
1.	Dr R Sridhar	Chairperson		
2.	Dr R Arun Kumar	Vice-Chairperson		
3.	Dr G Narendran	Member Secretary		
4.	Dr K Lily Therese	Member (Non-Affiliate)		
5.	Dr S Swarnalakshmi	Member (Non-Affiliate)		
6.	Dr Shyamala Nataraj	Member (Non-Affiliate)		
7.	Mrs Rajalakshmi	Member (Non-Affiliate)		
8.	Mrs Renu Lamech	Member (Non-Affiliate)		
9.	Dr V Gowri	Member (Non-Affiliate)		
10.	Mr D Sairamkumar	Member (Non-Affiliate)		
11.	Mrs Pushkala	Member (Non-Affiliate)		
12.	Dr S Chandrasekar	Member (Non-Affiliate)		
13.	Dr P M Ramesh	Member (Non-Affiliate)		
14.	Dr Padma Srikanth	Member (Non-Affiliate)		
15.	Dr Shuba Kumar	Member (Non-Affiliate)		
16.	Dr K R Uma Devi	Member (Affiliate)		
17.	Dr Luke Elizabeth Hanna	Member (Affiliate)		
18.	Dr Bella Devaleenal	Member (Affiliate)		
19.	Dr M Muniyandi	Member (Affiliate)		
20.	Dr P K Bhavani	Member (Affiliate)		
21.	Dr R Balaji	Member (Affiliate)		

SOP Code: SOP/EC/013/05

4.3. Ongoing review of study protocols

Revisions in the Standard Operating Procedures from version 4.0, dated 4 October 2018 to Version 5.0, dated 18 May 2022

The following revisions are made in the Standard Operating Procedures from version 4.0, dated 4 October 2018 to Version 5.0, dated 18 May 2022 following the revision in the National Ethical guidelines for Biomedical and Health Research involving human participants, ICMR 2017 and NDCT Guidelines 2019.

Ongoing Review of Study Protocols	**SOP/EC/013/05**	5.1. Determine the date of an ongoing review: • "They will plan for ongoing review meeting at least two months ahead of the due date of the next IEC meeting" is modified as "They will plan for review of ongoing studies which are due for review in the upcoming IEC meeting" 5.2. Notify the PI • "NIRT-IEC Secretariat will inform the PI at least **two months in advance** of the due date for the ongoing review by a letter" is modified as "NIRT-IEC Secretariat will inform the PI **in advance** of the due date for the ongoing review by a letter" 5.3.1 Verify the contents of the package: The following point has been removed: • Check the information about the number of participants enrolled

		to date and since the time of the last review, an explanation for any "yes" answers on the application form and any information on the scientific development, either through the conduct of this study or similar research that may alter risks to research participants. • Adverse events, drop-outs if applicable. 5.6. Protocol Review Process The following point has been included: • The PI may defer an ongoing review of a protocol, in case of any unforeseen circumstances, by giving a formal request to the IEC with proper justification. In case, an ongoing review of protocol is deferred by the PI for more than 3 IEC Meetings, the respective study PI will receive a notice to justify the reason for not submitting the protocol for ongoing review. Based on the reply from PI, the committee will decide appropriately, whether to continue or terminate the study. • If the IEC Committee decides that a study is too longer than required or does not meet the required criteria, the committee may request the PI/ Head of the Institution to terminate the study or send it to DCGI if it is a regulatory study.

SOP Number: SOP/EC/013	Revision Number: 05	
SOP Author: Dr K R Uma Devi Signature	SOP Approver: Dr R Sridhar (Chair IEC) Signature	Effective Date : 18 May 2022
	Dr C Padmapriyadarsini (Director) Signature	Supersedes : (Doc. version & Date) Version 4.0, dated 04 October 2018

1. PURPOSE

This procedure describes how ongoing reviews of previously approved NIRT-IEC protocols are managed by the Ethics Committee.

The purpose of the ongoing review is to monitor the progress of the entire study, not just the changes in it, to ensure continuous protection of the rights and wellbeing of research participants.

2. SCOPE

This SOP applies to conducting any ongoing review of study protocols involving human participants at intervals appropriate to the degree of risk at least once a year. Depending upon the degree of risk to the participants, the nature of the studies, and the vulnerability of the study participants and duration of the study, the NIRT-IEC may choose to review or monitor the protocols more frequently.

3. RESPONSIBILITY

It is the responsibility of the NIRT-IEC Secretariat to remind the NIRT-IEC and the PI regarding study protocols that are due for ongoing review.

The NIRT-IEC is responsible for reviewing the progress made in the protocol, the occurrence of unexpected events or problems, and the rate of accrual of participants.

4. FLOW CHART

No.	Activity	Responsibility
1	Determine the date of ongoing review	NIRT-IEC Secretariat
	↓	
2	Notify the PI	NIRT-IEC Secretariat
	↓	
3	Manage ongoing review package upon receipt	NIRT-IEC Secretariat
	↓	
4	Notify the members of the NIRT-IEC	NIRT-IEC Secretariat
	↓	
5	Prepare meeting agenda	NIRT-IEC Secretariat
	↓	
6	Protocol review process	Members and Chair
	↓	
7	Store original documents	NIRT-IEC Secretariat
	↓	
8	Communicate decision to the PI	NIRT-IEC Secretariat

5. DETAILED INSTRUCTIONS

5.1. Determine the date of an ongoing review.

- NIRT-IEC Secretariat will look through the document archives for the due date of ongoing reviews.
- They will plan for review of ongoing studies which are due for review in the upcoming IEC meeting.

5.2. Notify the PI

- NIRT-IEC Secretariat will inform the PI **in advance** of the due date for the ongoing review by a letter ***(Annexure code: AF/EC/026/05) or email***
- They will allow the PI sufficient time to collate the information and submit the ongoing review form.

5.3. Manage ongoing review submission upon receipt

- NIRT-IEC Secretariat will receive the ongoing review submission form, brief review form ***(Annexure code: AF/EC/011A/05) along with*** associated documents, if any.
- Upon receipt of the package, the Secretariat of the NIRT-IEC will perform the following:

5.3.1 Verify the contents of the package

- Make sure that the contents of the package include:
- Ongoing Protocol Review Submission Form ***(Annexure code: AF/EC/011/05)***

- Check for complete information and for the presence of the required signatures.
- If extension of the study period is requested, whether proper justification for the same and the study findings are provided
- Check if the following are filled appropriately:
- If the study has not been initiated inform the reasons
- If the study has been completed include a final report
- If there are any changes to the protocol or consent forms, submit relevant documents and details
- List of annexures and attachments, if any
- Check for submission of the listed annexures and documents, if any
- Checklist for documents submitted by PI to NIRT-IEC ***(Annexure code: AF/EC/042/05)***

5.3.2 Store the ongoing review submission form in the Study file

5.4. Notify the Members of the NIRT-IEC / PI

- Distribute the ongoing review documents` to the members of the NIRT-IEC at least 2 weeks ahead of the meeting date.
- The following will be sent to the IEC members:
  - Cover letter from MS indicating the date, time and venue of the NIRT-IEC meeting ***(Annexure code: AF/EC/012/05)***
  - List of protocols due for ongoing review with S. No, NIRT-IEC No., Title of the protocol, Name of the PI, month and year of IEC approval
- Ongoing review documents/ Consolidated Brief review form ***(Annexure code: AF/EC/011A/05)***
- Keep copies of "sent" materials in the Correspondence file.
- Intimate to the PI the date, venue and time of the meeting to present before NIRT-IEC

5.5. Prepare meeting agenda.

- **SOP/EC/016/05** for procedures on the preparation of the meeting agenda.

5.6. Protocol Review Process

- The IEC will review the submitted ongoing review form, Brief Review form and relevant details. If required, the PI will be requested for clarifications.
- The minutes of the discussion are documented by the MS.
- For ongoing review within the study duration, the NIRT-IEC will acknowledge the submission with the recommendation as 'Accepted for continuation' or 'suggest resubmission'.
- At the time of completion of study duration, upon request from the PI of the study, the NIRT-IEC will decide on extended approval based on the study progress report.

- After the advent of Covid-19, the Member Secretary presents the details of progress of the particular study during the full board meeting. The PI is informed to be connected virtually or appear in person during the process of ongoing review and will be questioned by the IEC, if required, for clarification in any of the study session.
- The period of extended approval will be based on the PIs request and upto a maximum of one year.
- The NIRT-IEC Secretariat maintains and keeps the form and minutes of the meeting relevant to the ongoing review as part of the official record of the review process.
- The PI may defer an ongoing review of a protocol, in case of any unforeseen circumstances, by giving a formal request to the IEC with proper justification. In case, an ongoing review of protocol is deferred by the PI for more than 3 IEC Meetings, the respective study PI will receive a notice to justify the reason for not submitting the protocol for ongoing review. Based on the reply from PI, the committee will decide appropriately, whether to continue or terminate the study.
- If the IEC Committee decides that a study is too longer than required or does not meet the required criteria, the committee may request the PI/ Head of the Institution to terminate the study or send it to DCGI if it is a regulatory study.

5.6.1. Communication of the Decision to the PI

- The NIRT-IEC Secretariat will communicate the decision as 'acknowledgement with Recommendations' as: Accepted for continuation / suggested resubmission ***(Annexure code: AF/EC/027/05)*** / approval for study extension **(*Annexure code: AF/EC/028/05)*** to the PI.

5.7. Store original documents.

- All the relevant documents to the Ongoing Review will be placed in the respective study files.

6. ANNEXURE

Annexure Code	Annexure title
AF/EC/011/05	Ongoing protocol review submission form
AF/EC/011A/05	Ongoing protocol Brief review form
AF/EC/012/05	IEC meeting intimation letter to members
AF/EC/026/05	Letter to PI for ongoing review
AF/EC/027/05	Letter to PI – IEC Review of ongoing submission
AF/EC/028/05	Letter to PI – IEC Extension of Study Period
AF/EC/042/05	Checklist for documents submitted by PI to NIRT-IEC

7. RELEVANT SOPs

SOP Code	SOP Title
SOP/EC/016/05	Agenda Preparation, IEC Meeting Procedures and Minutes

Annexure Code: AF/EC/011/05

Ongoing / Completed / Terminated protocol review submission form

S No	Title	Particulars
1	NIRT-IEC Protocol Number	
2	Title of the research proposal	
3	Name of the Principal Investigator (PI) with Qualification and Designation	
4	Name of the Co-PI and Co-Investigator(s) with Qualification and Designation	
5	Duration of the project / trial (yrs)	
6	Source of funding & financial allocation for the project / trial	
7	Name of the Institute where research is being conducted	
8	Month / Year of IEC approval	
9	Number of the ongoing review (Not applicable for 'Yet to be initiated' studies)	
10	What are the study objectives?	
11	What is the sample size required?	
12	Has the project implementation begun?	Yes / No Date
13	Has study participant recruitment begun?	Yes / No Date
14	If study participant recruitment has not begun, give reasons and proceed to S No: 23	
15	How many study participants have been screened?	
16	How many study participants have been recruited?	
17	Is study participant recruitment continuing? If no, give reason	Yes / No / Not applicable
18	Are there any 'drop outs'? If yes, give details.	Yes / No / Not applicable
19	Are study participants still receiving active intervention? If no, give reasons.	Yes / No / Not applicable
20	Have there been any **adverse events**? If yes, give details.	Yes / No / Not applicable
21	Have there been any other **unexpected adverse events**? If yes, give details.	Yes / No / Not applicable
22	Have there been any **unanticipated study-related problems**? If yes, give details.	Yes / No / Not applicable
23	Is there any **new risk or benefit** information? If yes, give details	Yes / No

24	Are there any interim changes to the protocol or consent form? If yes, give details, including submission of revised protocol and consent form for approval. a) State/describe the amendment as an annexure	Yes / No
	b) Give reasons for the amendment	
	c) Any untoward effects to original protocol (ie. Study objective, design, outcome)	
	d) Expected risks to participants due to the amendment	
25	Does the scientific literature indicate changes in knowledge relevant to the conduct of the study? If yes, give details	
26	Is the study Yet to be initiated/ ongoing/ completed / terminated? If completed please provide the date and provide the Study summary (Participant recruitment completed & analysis ongoing) / Final report (Analysis completed) If terminated, please provide the date and details on the management of the enrolled participants (active and follow-up), if applicable	Yet to be initiated/ Ongoing / completed / terminated
27	Presentations / Publications, if any If yes, provide details	Yes / No
28	Do you require extension of the study period? If yes, please provide justification and summary of study findings as annexure	Yes / No
29	List of attachments for review, if any	
30	Remarks, if any	
31	Signature of the Principal Investigator with date	

Annexure Code: AF/EC/011A/05

BRIEF REVIEW FORM FOR
ONGOING REVIEW OF PROTOCOLS APPROVED BY NIRT IEC

S.No	IEC No.	Study Title	Name of the PI	Objectives	Current Status	Extension required (with Justification)
					Ongoing / Completed / Yet to be initiated / Terminated Sample Size: Study duration + Extension requested (if any): Date of IEC approval: Date of study initiation: Total screened: Total recruited: Adverse events (If any): Conclusion (if the study is completed) Reason for termination (if the study is terminated or withdrawn) Reason for not initiating the study (if it is yet to be initiated)	

Annexure Code: AF/EC/012/05

IEC meeting intimation letter to members

ICMR - National Institute for Research in Tuberculosis

INSTITUTIONAL ETHICS COMMITTEE

(SIDCER Recognized Ethics Committee in the Asian and Western Pacific Region)

No: 1, Mayor Sathyamoorthy Road, Chetput, Chennai – 600 031, Tamil Nadu, India

Dr
Member Secretary

e-mail:

No: ……./NIRT-IEC/20…. Date: ……

To
.....
.....
.....

Dear NIRT-IEC Member,

Please find enclosed new proposals (……Nos.) and ongoing review forms (……Nos.) for the forthcoming NIRT IEC meeting to be held on …….. Kindly review the proposals and make it convenient to attend the meeting on ……at ……..am. The venue is in ……, National Institute for Research in Tuberculosis, Chetput, Chennai – 600 031.

With regards,

Yours truly,

Member Secretary

Cc to:
Director, NIRT

Annexure Code: AF/EC/026/05

Letter to PI for ongoing review

ICMR - National Institute for Research in Tuberculosis

INSTITUTIONAL ETHICS COMMITTEE

(SIDCER Recognized Ethics Committee in the Asian and Western Pacific Region)

No: 1, Mayor Sathyamoorthy Road, Chetput, Chennai – 600 031, Tamil Nadu, India

No: ……/NIRT-IEC/20….. Date: ……

To

Sir / Madam,

Sub: Ongoing review of projects – forthcoming IEC meeting (date:……..) – reg.

The below mentioned protocol was approved by NIRT-IEC on …….:

- NIRT-IEC ID: …… "**Title: ----------**
  ……"

This project needs to undergo an interim ethical review. Kindly make the necessary arrangements to submit the filled-in submission form, along with their appropriate attachments, to the undersigned **not later than ……,** so as to enable including this in the agenda for review during the forthcoming IEC meeting.

Thanking you.

Yours truly,

Member Secretary

cc to:

The Director, National Institute for Research in Tuberculosis

Annexure code: AF/EC/027/05

Letter to PI – IEC Review of ongoing submission

ICMR - National Institute for Research in Tuberculosis

INSTITUTIONAL ETHICS COMMITTEE

(SIDCER Recognized Ethics Committee in the Asian and Western Pacific Region)

No: 1, Mayor Sathyamoorthy Road, Chetput, Chennai – 600 031, Tamil Nadu, India

No: ……/NIRT-IEC/2013 Date: ……..

To

Sir / Madam,

Ref: NIRT-IEC No: …….: "Title: ……." – reg.

The NIRT-Institutional Ethics Committee met on …… under the Chairmanship of …….. and reviewed the above referenced project (based on the 'ongoing protocol review submission form' submitted by you).

The Committee hereby acknowledges the submission.

Recommendations: Accepted for continuation / suggested resubmission:

Thanking you.

Yours truly,

Member Secretary

cc to:

The Director, National Institute for Research in Tuberculosis

Annexure code: AF/EC/028/05

Letter to PI – IEC Extension of Study Period

ICMR - National Institute for Research in Tuberculosis

INSTITUTIONAL ETHICS COMMITTEE

(SIDCER Recognized Ethics Committee in the Asian and Western Pacific Region)

No: 1, Mayor Sathyamoorthy Road, Chetput, Chennai – 600 031, Tamil Nadu, India

No: ……../NIRT-IEC/20….. Date: …….

To

Sir / Madam,

Ref: NIRT-IEC No: …….: "Title: ……" – reg.

The NIRT-Institutional Ethics Committee met on …….. under the Chairmanship of ……. and reviewed the above referenced project (based on the 'ongoing protocol review submission form' submitted by you).

The Committee hereby acknowledges the submission.

As the duration of the study is going to expire, based on your request for an extension of the study period for …….years, the committee approves extension/ disapproves extension of the study period for ----------years.

Thanking you.

Yours truly,

Member Secretary

cc to:

The Director, National Institute for Research in Tuberculosis

Annexure code AF/EC/042/05

Checklist for documents submitted by PI to NIRT-IEC (To be filled by PI)

NIRT-IEC No:		**Submitted date:**	
Type of Submission:	☐ Initial Review ☐ Resubmission for re-review ☐ Protocol Amendments	☐ Ongoing review ☐ Study completed ☐ Protocol Termination	
Protocol Title:			
Name of Principal Investigator: **Designation:** **Department:**			
Institute:			

☐ **Initial Review Submitted Package**

- ❑ Initial Review Submission / re-submission Form
- ❑ NIRT- SAC approval
- ❑ PI's updated signed short CV and GCP training record.
- ❑ Protocol with version no. & date and to include a section on Ethical Consideration
- ❑ Protocol-Related Documents with version no. & date
  - ☐ Patient Information sheet ☐ Informed consent form (English)
  - ☐ Case report forms (CRF) ☐ Informed consent form (Local vernacular)
  - ☐ Data collection forms ☐ others……
  - ☐ Investigator's Brochure, if applicable

☐ **Resubmission for Re-review Submitted Package**

- ❑ IEC Initial Review decision letter
- ❑ Initial Review Submission / re-submission Form
- ❑ Revised Protocol with version no. & date
- ❑ Protocol history page listing the changes made to the documents
- ❑ Protocol-Related Documents with version no. & date
  - ☐ Patient Information sheet ☐ Informed consent form (English)
  - ☐ Case report forms (CRF) ☐ Informed consent form (Local vernacular)

- ☐ Data collection forms ☐ others……
- ☐ Investigator's Brochure, if applicable

☐ **Protocol Amendment Submitted Package**

- ❑ Letter of request for Amendment by PI
- ❑ Ongoing / completed / terminated protocol Review Submission Form
  - ❑ State/describe the amendment as an annexure
  - ❑ Reason for the amendment
  - ❑ Any untoward effects to original protocol (ie. Study objective, design, outcome)
  - ❑ Expected risks to participants due to the amendment
- ❑ Amended Protocol with version no. & date
- ❑ Protocol history page listing the changes made to the documents
- ❑ Protocol-Related Documents with version no. & date
  - ☐ Patient Information sheet ☐ Informed consent form (English)
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  - ☐ Data collection forms ☐ others……
  - ☐ Investigator's Brochure, if applicable

☐ **Ongoing Review Package**

- ❑ Ongoing / completed / terminated protocol Review Submission Form
- ❑ Protocol amendment if any
- ❑ Study completed / terminated, if applicable

☐ **Study completed Package**

- ❑ Ongoing / completed / terminated protocol Review Submission Form
- ❑ Final report

☐ **Protocol Termination Package**

- ❑ Ongoing / completed / terminated protocol Review Submission Form
- ❑ Reasons for termination
- ❑ Minutes of other committee meetings that were held if any
- ❑ Final report if available

Signature of the Principal Investigator & date	

Receipt of documents from PI (To be filled by NIRT-IEC Secretariat)

NIRT-IEC No:		
Type of Submission:	☐ Initial Review ☐ Resubmission for re-review ☐ Protocol Amendments	☐ Ongoing review ☐ Study completed ☐ Protocol Termination
Protocol Title:		
Received by:		**Date received:**
Pending documents : Nil / Yes, If yes, details: ☐ Patient Information sheet ☐ Case report forms (CRF) ☐ Data collection forms ☐ Investigator's Brochure, if applicable ☐ Informed consent form (English) ☐ Informed consent form (Local vernacular) ☐ others……		
Received by:		**Date received:**

Acknowledgement of awareness of this SOP

S.No	Name	Capacity	Signature	Date
1.	Dr R Sridhar	Chairperson		
2.	Dr R Arun Kumar	Vice-Chairperson		
3.	Dr G Narendran	Member Secretary		
4.	Dr K Lily Therese	Member (Non-Affiliate)		
5.	Dr S Swarnalakshmi	Member (Non-Affiliate)		
6.	Dr Shyamala Nataraj	Member (Non-Affiliate)		
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18.	Dr D Bella Devaleenal	Member (Affiliate)		
19.	Dr M Muniyandi	Member (Affiliate)		
20.	Dr P K Bhavani	Member (Affiliate)		
21.	Dr R Balaji	Member (Affiliate)		

SOP Code: SOP/EC/014/05

4.4. Review of Final Reports

Revisions in the Standard Operating Procedures from version 4.0, dated 4 October 2018 to Version 5.0, dated 18 May 2022

The following revisions are made in the Standard Operating Procedures from version 4.0, dated 4 October 2018 to Version 5.0, dated 18 May 2022 following the revision in the National Ethical guidelines for Biomedical and Health Research involving human participants, ICMR 2017 and NDCT Guidelines 2019.

Review of Final Reports	**SOP/EC/014/05**	5.1. Before each IEC meeting • "Final report ***(Annexure code: AF/EC/048/05) is modified as "***Final report ***(Annexure code: AF/EC/048/05*****) along with a concise summary of the entire study"** 5.2. During the Board meeting • "The PI presents the study findings" is modified as "The PI/ MS presents the salient features of the study including details of Multi-centric sites, if applicable" The following point has been removed • Hold the files of multi-center studies, until all the study sites are closed. The following is included "Checklist for documents submitted by PI to NIRT-IEC ***(Annexure code: AF/EC/042/04)****"* 5.1 Before each IEC Meeting The following point has been included

		• PI has to submit Undertaking for Publication ***(Annexure code: AF/EC/029A/05)*** • An annexure titled "Undertaking for publication" **(Annexure code: AF/EC/029A/05)** has been included. 5.3 After the Board meeting, MS will The following point has been included • Request the PI for submission of Publications subsequently to the IEC (Annexure code: AF/EC/029A/05)

SOP Number: SOP/EC/014	Revision Number: 05	
SOP Author: Dr G Narendran Signature	SOP Approver: Dr R Sridhar (Chair IEC) Signature	Effective Date : 18 May 2022
	Dr C Padmapriyadarsini (Director, NIRT) Signature	Supersedes : (Doc. version & Date) Version 4.0, dated 04 October 2018

1. PURPOSE

The purpose of this SOP is to provide instructions on the review of Final Reports for any study previously approved by the NIRT-IEC.

2. SCOPE

This SOP applies to the review of the Final Report which is an obligatory review of the completed / terminated study submitted by the PI.

3. RESPONSIBILITY

It is the responsibility of the IEC secretariat to check the report for completeness

4. FLOW CHART

No.	Activity	Responsibility
1	Activities before the IEC meeting	IEC Secretariat
	↓	
2	Activities during the IEC meeting	IEC Secretariat / Members / Chair
	↓	
3	Activities after the IEC meeting	IEC Secretariat

5. DETAILED INSTRUCTIONS

5.1. Before each IEC meeting

- ✧ The Secretariat receives the submitted report along with the ongoing/completed/Terminated protocol review submission form ***(Annexure code: AF/EC/011/05)***
- ✧ Checklist for relevant documents submitted by PI to NIRT-IEC ***(Annexure code: AF/EC/042/05)***
- ✧ Final report ***(Annexure code: AF/EC/048/05*****) along with a concise summary of the entire study.**
- ✧ PI has to submit Undertaking for Publication ***(Annexure code: AF/EC/029A/05)***
- ✧ Refer to **SOP/EC/007/05** and **SOP/EC/013/05**

5.2. During the Board meeting

- o The PI/ MS presents the salient features of the study including details of Multi-centric sites, if applicable.The members will review the Final Report and discuss.
- o If appropriate to the discussions, the Chair may call for consensus on the action to be taken (Study file closed / further information if required)
- o MS summarizes the action taken.

5.3. After the Board meeting, MS will

- Note the decision in the meeting minutes
- Send the decision letter and acknowledgement of receipt of Completion report to the PI ***(Annexure code: AF/EC/029/05)***
- Archive the entire study protocol and the report and the study file is closed as per the decision. **(**refer to **SOP/EC/018/05)**
- Request the PI for submission of Publications subsequently to the IEC ***(Annexure code: AF/EC/029A/05)***

6. ANNEXURE

Annexure Code	Annexure title
AF/EC/011/05	Ongoing protocol review submission form
AF/EC/029/05	IEC Final report review decision letter
AF/EC/042/05	Checklist for documents submitted by PI to NIRT-IEC
AF/EC/029A/05	Undertaking for Publications

7. RELEVANT SOPs

SOP Code	SOP Title
SOP/EC/007/05	Management of Protocol Submissions
SOP/EC/013/05	Ongoing Review of Study Protocols
SOP/EC/018/05	Maintenance of Active Study Files

GLOSSARY

IEC	Institutional Ethics Committee is an independent body whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection.
Multi-centric studies	A clinical trial conducted according to a single protocol but at more than one site, and therefore, carried out by more than one investigator.
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.
Secretariat	An office responsible for the secretarial, clerical, and administrative affairs of NIRT-IEC

Annexure Code: AF/EC/011/05

Ongoing / Completed / Terminated protocol review submission form

S No	Title	Particulars
1	NIRT-IEC Protocol Number	
2	Title of the research proposal	
3	Name of the Principal Investigator (PI) with Qualification and Designation	
4	Name of the Co-PI and Co-Investigator(s) with Qualification and Designation	
5	Duration of the project / trial (yrs)	
6	Source of funding & financial allocation for the project / trial	
7	Name of the Institute where research is being conducted	
8	Month / Year of IEC approval	
9	Number of ongoing review (Not applicable for 'Yet to be initiated' studies)	
10	What are the study objectives ?	
11	What is the sample size required?	
12	Has the project implementation begun?	Yes / No Date
13	Has study participant recruitment begun?	Yes / No Date
14	If study participant recruitment has not begun, give reasons and proceed to S No: 23	
15	How many study participants have been screened?	
16	How many study participants have been recruited?	
17	Is study participant recruitment continuing? If no, give reason	Yes / No / Not applicable
18	Are there any 'drop outs'? If yes, give details.	Yes / No / Not applicable
19	Are study participants still receiving active intervention? If no, give reasons.	Yes / No / Not applicable
20	Have there been any **adverse events**? If yes, give details.	Yes / No / Not applicable
21	Have there been any other **unexpected adverse events**? If yes, give details.	Yes / No / Not applicable
22	Have there been any **unanticipated study-related problems**? If yes, give details.	Yes / No / Not applicable
23	Is there any **new risk or benefit** information? If yes, give details	Yes / No

24	Are there any interim changes to the protocol or consent form? If yes, give details, including submission of revised protocol and consent form for approval. a) State/describe the amendment as annexure	Yes / No
	b) Give reason for the amendment	
	c) Any untoward effects to original protocol (ie. Study objective, design, outcome)	
	d) Expected risks to participants due to the amendment	
25	Does the scientific literature indicate changes in knowledge relevant to the conduct of the study? If yes, give details	
26	Is the study Yet to be initiated/ ongoing/ completed / terminated? If completed please provide the date and provide the Study summary (Participant recruitment completed & analysis ongoing) / Final report (Analysis completed) If terminated, please provide the date and details on the management of the enrolled participants (active and follow-up), if applicable	Yet to be initiated/ Ongoing / completed / terminated
27	Presentations / Publications, if any If yes, provide details	Yes / No
28	Do you require extension of the study period? If yes, please provide justification and summary of study findings as annexure	Yes / No
29	List of attachments for review, if any	
30	Remarks, if any	
31	Signature of the Principal Investigator with date	

Annexure code: AF/EC/029/05

Letter to PI - IEC Final report review decision

ICMR - National Institute for Research in Tuberculosis

INSTITUTIONAL ETHICS COMMITTEE

(SIDCER Recognized Ethics Committee in the Asian and Western Pacific Region)

No: 1, Mayor Sathyamoorthy Road, Chetput, Chennai – 600 031, Tamil Nadu, India

No: ……../NIRT-IEC/20….. Date: …….

To

Sir / Madam,

Ref: NIRT-IEC No: ……: "Title: **……..**" – reg.

The NIRT-Institutional Ethics Committee met on …… under the Chairmanship of ……..and reviewed the above referenced project (based on the 'ongoing protocol review submission form' submitted by you).

The Committee hereby acknowledges the submission.

As the study is completed and the final report is submitted to IEC and approved the study file will be closed.

Thanking you.

Yours truly,

Member Secretary

cc to:

The Director, National Institute for Research in Tuberculosis

Annexure code: AF/EC/029A/05

Undertaking for Publications

Date: …….

As the Principal Investigator of the study titled "…….", I hereby solemnly declare the following with regard to publications of the study:

- We have published ……. (No's) manuscripts (for Completed publications)
- We have submitted …….(No's) Journals (in case of publications under process)
- We will be submitting …….(No's) manuscripts (future publications)

I will submit a copy of the same duly to the Ethics Committee.

(PRINCIPAL INVESTIGATOR NAME & SIGN)

Annexure code AF/EC/042/05

Checklist for documents submitted by PI to NIRT-IEC (To be filled by PI)

NIRT-IEC No:		**Submitted date:**	
Type of Submission:	☐ Initial Review ☐ Resubmission for re-review ☐ Protocol Amendments	☐ Ongoing review ☐ Study completed ☐ Protocol Termination	
Protocol Title:			
Name of Principal Investigator: **Designation:** **Department:**			
Institute:			

☐ **Initial Review Submitted Package**

- ❑ Initial Review Submission / re-submission Form
- ❑ NIRT- SAC approval
- ❑ PI's updated signed short CV and GCP training record.
- ❑ Protocol with version no. & date and to include section on Ethical Consideration
- ❑ Protocol-Related Documents with version no. & date
  - ☐ Patient Information sheet
  - ☐ Informed consent form (English)
  - ☐ Case report forms (CRF)
  - ☐ Informed consent form (Local vernacular)
  - ☐ Data collection forms
  - ☐ others……
  - ☐ Investigator's Brochure, if applicable

☐ **Resubmission for Re-review Submitted Package**

- ❑ IEC Initial Review decision letter
- ❑ Initial Review Submission / re-submission Form
- ❑ Revised Protocol with version no. & date
- ❑ Protocol history page listing the changes made to the documents
- ❑ Protocol-Related Documents with version no. & date

- ☐ Patient Information sheet
- ☐ Case report forms (CRF)
- ☐ Data collection forms
- ☐ Investigator's Brochure, if applicable
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- ❑ Letter of request for Amendment by PI
- ❑ Ongoing / completed / terminated protocol Review Submission Form
  - ❑ State/describe the amendment as annexure
  - ❑ Reason for the amendment
  - ❑ Any untoward effects to original protocol (ie. Study objective, design, outcome)
  - ❑ Expected risks to participants due to the amendment
- ❑ Amended Protocol with version no. & date
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  - ☐ Patient Information sheet
  - ☐ Case report forms (CRF)
  - ☐ Data collection forms
  - ☐ Investigator's Brochure, if applicable
  - ☐ Informed consent form (English)
  - ☐ Informed consent form (Local vernacular)
  - ☐ others……

☐ **Ongoing Review Package**

- ❑ Ongoing / completed / terminated protocol Review Submission Form
- ❑ Protocol amendment if any
- ❑ Study completed / terminated, if applicable

☐ **Study completed Package**

- ❑ Ongoing / completed / terminated protocol Review Submission Form
- ❑ Final report

☐ **Protocol Termination Package**

- ❑ Ongoing / completed / terminated protocol Review Submission Form
- ❑ Reasons for termination
- ❑ Minutes of other committee meetings that were held if any
- ❑ Final report if available

Signature of the Principal Investigator & date	

Receipt of documents from PI (To be filled by NIRT-IEC Secretariat)

NIRT-IEC No:		
Type of Submission:	☐ Initial Review ☐ Resubmission for re-review ☐ Protocol Amendments	☐ Ongoing review ☐ Study completed ☐ Protocol Termination
Protocol Title:		
Received by:		**Date received:**
Pending documents : Nil / Yes, If yes, details: ☐ Patient Information sheet ☐ Case report forms (CRF) ☐ Data collection forms ☐ Investigator's Brochure, if applicable ☐ Informed consent form (English) ☐ Informed consent form (Local vernacular) ☐ others……		
Received by:		**Date received:**

Acknowledgement of awareness of this SOP

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19.	Dr M Muniyandi	Member (Affiliate)		
20.	Dr P K Bhavani	Member (Affiliate)		
21.	Dr R Balaji	Member (Affiliate)		

SOP Code: SOP/EC/015/07

5.1. Review of Serious Adverse Event (SAE) Reports

Revisions in the Standard Operating Procedures from version 6.0, dated 3 September 2019 to Version 7.0, dated 18 May 2022.

The following revisions are made in the Standard Operating Procedures from version 6.0, dated 3 September 2019 to Version 7.0 dated 18 May 2022 following the release of New Drugs and Clinical Trial Rules, 2019.

Review of Serious Adverse Events (SAE) Reports	**SOP/EC/015/07**	3. Responsibility of SAE handling and composition of SRC The following point has been included: • From March 2021, with the introduction of the sugam portal, all Regulatory studies have started e-filing their SAE's to the portal. Hence, the same Table 5 will be sent to IEC secretariat for continuing the same procedures and the final decision of the IEC with regard to causality would be adjudicated and appropriately communicated to the DCGI either through cross tagging in the portal or direct email to CDSCO. 5.1 Receiving the SAE report from the PI or designee in prescribed format and reporting requirements to the IEC secretariat The following point has been included • The reference number issued by the CDSCO Sugam portal while filing has to be mentioned in the mail/hard copy sent to IEC.

		Initial SAE notification • "The initial SAE notification for clinical trials has to reach the IEC Secretariat within 24 hours of receiving the information about the SAE by the study staff (as hard copy or by e-mail in the prescribed format" is modified as "The initial SAE notification for clinical trials has to reach the IEC Secretariat within 24 hours of occurrence of the SAE or in some cases, receipt of the information about the SAE by the study staff (as hard copy or by e-mail in the prescribed format about the SAE. In the case of latter, proper justification of the delay has to be stated by the PI in the 24hrs report itself" SAE Follow-up detailed report • "This initial report should be followed by a detailed final report within 14 days of SAE occurrence after evaluating the causality of the SAE in relation to the study intervention. In case the SAE outcome has not been reached, an interim report on the status be sent as "track changes of the initial report". The final report should be sent not later than 15 days of the last interim report" is modified as "This initial report should be followed by a detailed final report within 14 days of SAE occurrence/ receipt of information, after carefully evaluating the causality of the SAE in relation to the study intervention. In case the SAE outcome has not been reached, the 14 day report has

		to be sent as usual which should be followed by the final report. If causality is clearly determined and found to be unrelated, the IEC will not further send the subsequent reports to the DCGI unless mandated or there is significant change of information in the last report based on which the causality could potentially change" The following points have been removed: • Any delay in reporting the final/follow up has to be justified and intimated. If the SAE is on-going and has not resolved within 14 days, follow up details should be submitted and the form should state as "Follow-up 1,2,3" etc. with the period of each not later than 15 days and changes tracked compared to the previous report. • The IEC secretariat will provide an acknowledgement for SAEs of clinical trials submitted to the IEC/SRC as "received" For offsite SAE's • "For all offsite SAEs of clinical trials, the SAE final report along with the evaluation report of IEC of that site has to be submitted by the PI within 30 days of occurrence or 16 days of reporting to the IEC of that site" is modified as "For all offsite SAEs of clinical trials, the evaluation of the SAE by the respective IEC to be enclosed and Notified to the IEC secretariat. This will include SUSARS also from other sites"

		5.2. Circulation of SAE report to SRC members • "The PI sends the SAE reports to the IEC secretariat with copies marked to MS of SRC and IEC. The SRC MS then circulates the final SAE report to other members of the SRC, Vice Chair and Chairperson by Email. In case of conflict of interest for any of the trials by the members, it needs to be declared by the members. Non-receipt of comments within 5 days of the mail from the SRC members, will be deemed as "Causality agreed as stated by the PI" unless there is a definite communication from the SRC member declining to comment with a valid reason. For clinical trials, the final SAE report will be circulated in real time and decision sent to PI/sponsor or DCGI within 30 days of receipt of the final report as per GSR 227(E) - New drugs and clinical trial rules, 2019. Whenever a consensus opinion is not obtained by circulation through email, then only a meeting is called for SAE review and the PI/Designee may even be called to present the case if required" **IS MODIFIED AS** "The PI sends the SAE reports to the IEC secretariat which is sent to the MS SRC. The SRC MS consolidates the SAE and scrupulously requests for missing details if any through the secretariat and once the details requested are complete, starts filling up the part II of the SRC evaluation report . The PART of the report is duly filled by the PI but can be modified as per relevance by the MS –SRC with copies marked to MS of SRC and

		IEC. The SRC MS then circulates the initial and final SAE report to along with the evaluation report to the other members of the SRC, Vice Chair and Chairperson by Email. In case of conflict of interest for any of the trials by the members, it needs to be declared by the members as well as the PI. Non-receipt of comments within 5 days of the mail from the SRC members, will be deemed as "Causality agreed as stated in the SRC evaluation report by the PI" unless there is a definite communication from the SRC member declining to comment with a valid reason. For clinical trials, the final SAE report will be circulated in real time and decision sent to PI/sponsor or DCGI within 30 days of receipt of the final report as per GSR 227(E) - New drugs and clinical trial rules, 2019. Whenever a consensus opinion is not obtained by circulation through email, then only a meeting is called for SAE review and the PI/Designee may even be called to present the case if required. The final decision is ratified by the Chairperson/Vice chairperson of the SRC committee. The report of causality is then communicated to the DCGI by the IEC Secretariat as detailed in 5.4" 5.3 Presentation of SAE in the SRC meeting and in the full board IEC meeting subsequently • "For all clinical trials and drug related SAE's where pharmacological intervention is done by NIRT, the circulation is

		done based on causality. If compensation is deemed to be required irrespective of the study or the study is a regulatory trial, circulation is done real time and for others at least 3 days before the full board meeting. All SAE's will be circulated by Email and opinion obtained. In case a consensus opinion is not arrived at or compensation is deemed mandatory for a particular SAE, then a SRC meeting will be scheduled on a specific date or preceding the scheduled meeting of the IEC (scheduled) if the latter falls within the reporting timelines set by the DCGI" is modified as "For all clinical trials and drug related SAE's where pharmacological intervention is prescribed as per the protocol , the circulation is done irrespective of causality. If compensation is deemed to be required, whether it is academic or regulatory, circulation is done real time and presented at the full board meeting. All SAE's will be circulated by Email and opinion obtained passively unless there is a specific comment or clarification raised by any of the SRC members In case a consensus opinion is not arrived at or compensation is deemed mandatory for a particular SAE, then a SRC meeting is called for on a specific date or preceding the scheduled meeting of the IEC (scheduled) if the latter falls within the reporting timelines set by the DCGI" 5.4 Communication of the SAE review decision by IEC to regulatory authority

		• "Through skype" is modified as "through e-platform. The following point has been included • In case the decision from IEC is delayed due to any technical reasons, it is appropriately informed to the CDSCO through email. 5.5 Communication of the SAE review decision by IEC to PI • "Decision of the IEC with regard to clinical trials / trials with pharmacological intervention, will be communicated to the PI after minutes of the full board meeting is approved (Annexure code AF/EC/032/04). In case further details are required, then the PI will be immediately intimated after the IEC meeting/SRC meeting or can be asked to present the SAE in person" **is modified as** "Decision of the IEC with regard to clinical trials / trials with pharmacological intervention, will be communicated to the head of the institution after minutes of the full board meeting is approved. Unless there is a compensation which is required to be paid by the PI, the communication letter is not routinely sent to the PI. Any communication with regard to want of information for better determination of causality is done only through email after the advent of Covid pandemic Feb 2020. In case further details are required, then the PI will be immediately intimated after the IEC meeting/SRC meeting or can be asked to present the SAE in person and clarify accordingly, if required. If mandated by the sponsor, acknowledgement will be

		given either as signature on hardcopy duly attested by the secretariat or reply by mail". 5.6. Discussions in NIRT IEC Full Board meeting with regard to SAE and compensation • "SAEs and the SRC recommendations will be put forth and ratified" is modified as "SAEs and the SRC recommendations will be presented put forth and ratified in the Full Board Meeting. However, considering the timelines set forth by CDSCO for reporting SAEs in regulatory trials, the 30 day period will be obeyed while submitting it to CDSCO and the SAE will be presented in the subsequent IEC Meeting" **The following point has been included:** 5.7 Covid mandated changes that will be continued till further revisions (the clause of Force majeure) For clinical trials and pharmacological interventions, from February 2020, with Covid striking globally, changes have been made in the operational guidelines of the NIRT-IEC as done for various other committees. IEC became paperless and all communications were sent through Emails only. It was informed that no communication would be sent to PI unless there is a possible causality of the SAE to the study medication that required compensation, in which case this would be communicated to the PI through the head of the institution and the sponsor. In all other cases, the SAEs would be circulated to the SRC committee and uploaded in the Sugam

		Portal in the case of regulatory trials and presented in the full board meeting conducted through zoom platform and causality ratified irrespective of the nature of the trial. Confidentiality is maintained as the zoom account is a paid private connection of ICMR-NIRT. No further communication was made to anybody. However the body of the minutes would contain a section on SAE's that would be projected during the meeting and that would be copied to the head of the institution for necessary action. For non-pharmacological studies, it was decided that the PI will report the SAEs only at the time of annual review submission as indicated earlier Changes have been made in annexures 1) Annexure AF/EC/50/04 (Part I – to be filled by the PI)

SOP Number: SOP/EC/015	Revision Number: 07	
SOP Author: Dr G Narendran Signature	SOP Approver: Dr R Sridhar (Chair IEC) Signature	Effective Date : 18 May 2022
	Dr C Padmapriyadarsini (Director) Signature	Supersedes : (Doc. version & Date) Version 6.0, dated 03 September 2019

1. PURPOSE

The purpose of this SOP is to provide instructions to enumerate the role of both the PI's and IEC secretariat on reporting and filing of SAE's for clinical trials and for non-pharmacological interventional studies

2. SCOPE

This SOP applies to the reporting of SAE's by the PI, role of SRC and the flow of SAE from PI to the regulatory authority including compensation if applicable.

3. Responsibility of SAE handling and composition of SRC

SAE's occurring in all clinical trials have to be submitted to (Serious Adverse Events Review Committee) SRC through the IEC secretariat as spelt out in the prevailing ICMR ethical guidelines.
The SAE's are handled by a committee called Serious Adverse event Reporting committee or SRC, a sub-committee of the IEC, facilitated by the IEC secretariat. The members of SRC comprise of the

- Chair (Preferably Clinical Pharmacologist, Non-Affiliate IEC member)
- Subject expert /Physician
- Legal expert (Non-Affiliate IEC members)
- MS of IEC
- Member-Secretary (Affiliate IEC member – Physician)

The IEC, through its Serious Adverse Event Review Committee (SRC), will assess individual safety of the study participants, including causality to study medication and

compensation as per New drugs and clinical trial rules, 2019 whereas the overall safety of the study would be evaluated during ongoing review.

From March 2021, with the introduction of the Sugam portal, all Regulatory studies have started e-filing their SAE's to the portal. Hence, the same Table 5 will be sent to IEC secretariat for continuing the same procedures and the final decision of the IEC with regard to causality would be adjudicated and appropriately communicated to the DCGI either through cross tagging in the portal or direct email to CDSCO.

4**. Flow chart explaining the movement of SAE from the PI to the regulatory authority**

No.	Activity	Responsibility
1	Receiving the SAE report from the PI or designee in prescribed format	MS of SRC/IEC, IEC Secretariat
	↓	
2	Circulation of SAE report to SRC members	MS of SRC/IEC,IEC secretariat
	↓	
3	Consolidation of decision / opinion regarding causality through email /expedited process (or meeting, if indicated)	SRC members, IEC SRC and MS, Chair and vice chair
	↓	
4	SRC scheduled meeting (if consensus not reached through email) and Presentation of SAE in full board meeting (either scheduled/unscheduled depending on the timelines)	SRC MS/MS IEC
	↓	
5	Notification to PI for clarification regarding causality if required	IEC Secretariat
	↓	
6	Communication of the SAE review decision if necessary to Sponsor and PI (in case compensation needs to be paid) for non-regulatory trials (within 105 days of SAE occurrence) and all the SAEs irrespective of causality to the Licensing Authority for regulatory trials within 30 calendar days of being notified to the IEC	IEC Secretariat after full board presentation

5. DETAILED INSTRUCTIONS

5.1 Receiving the SAE report from the PI or designee in prescribed format and reporting requirements to the IEC secretariat

For onsite SAE's

Clinical Trials

All related / unrelated, expected/unexpected SAEs must be reported by the PI for clinical trials. The following documents have to be submitted by the PI:

- Prescribed format for reporting SAE for academic and regulatory clinical trials **(Annexure code: AF/EC/030/05)-table 5**
- Review of Serious Adverse Events (SAE) by IEC PART-1 (to be filled by the Investigator/designee) **(Annexure code AF/EC/050/05)** Part –II of the SRC Evaluation report appropriately by the IEC.

The SAE should be in PDF format and duly signed by the PI/Designee. The responsibility of sending the SAE to DCGI and to the sponsor simultaneously as applicable and to the head of the institution and HOD clinic is purely that of the PI.

The PIs should clearly label the file as "SAE initial/final, IEC no of the study and then the study participant's ID" in that order. The reference number issued by the CDSCO Sugam portal while filing has to be mentioned in the mail/hard copy sent to IEC

Initial SAE notification

The initial SAE notification for clinical trials has to reach the IEC Secretariat within 24 hours of occurrence of the SAE or in some cases, receipt of the information about the SAE by the study staff (as hard copy or by e-mail in the prescribed format about the SAE. In the case of latter, proper justification of the delay has to be stated by the PI in the 24hrs report itself

- Serious Adverse Event (SAE) Report form for all clinical trials **(Annexure code: AF/EC/030/05).**

The PI should specify and justify the reasons in case of longer than usual period of reporting.

SAE Follow-up detailed report

This initial report should be followed by a detailed final report within 14 days of SAE occurrence/ receipt of information, after carefully evaluating the causality of the SAE in relation to the study intervention. In case the SAE outcome has not been reached, the 14 day report has to be sent as usual which should be followed by the final report. If causality is clearly determined and found to be unrelated, the IEC will not further send the subsequent reports to the DCGI unless mandated or there is significant

information in the last report based on which the causality could potentially change. Serious Adverse Event (SAE) Report form for all clinical trials **(Annexure code: AF/EC/030/05).**

- Review of Serious Adverse Events (SAE) by IEC PART-1 (to be filled by the investigator/designee) **(Annexure code AF/EC/050/05)** and part -II appropriately by the IEC committee.
- NIRT-IEC Serious Adverse Event (SAE) decision letter for clinical trials /for compensation (Annexure code: AF/EC/032/04) has been removed with the advent of Covid pandemic. All doubts/queries and clarifications pertaining to SAE's regarding causality to be passed on to the PI whenever applicable through email communication only. For all other SAEs that do not demand compensation and which are adjudicated as unrelated, no further information will be sent to the PI. The decision of the full board meeting which includes discussion on SAEs is submitted to the Head of the Institution.

Non-Pharmacological / Observational Studies

For studies other than clinical trials, which do not involve any pharmacological intervention, the SAE's can be submitted in the prescribed format **(Annexure code: AF/EC/049/05)** at the time of submission of annual review report. During annual review of these studies, the PIs should attach the SAE's occurring in that year as an annexure in the prescribed format.

For offsite SAE's

For all offsite SAEs of clinical trials, the evaluation of the SAE by the respective IEC to be enclosed and Notified to the IEC Secretariat. This will include SUSARS also from other sites.

5.2. Circulation of SAE report to SRC members

The PI sends the SAE reports to the IEC secretariat which is sent to the MS SRC. The SRC MS consolidates the SAE and scrupulously requests for missing details if any through the secretariat and once the details requested are complete, starts filling up the part II of the SRC evaluation report. The PART of the report is duly filled by the PI but can be modified as per relevance by the MS –SRC. The SRC MS then circulates the initial and final SAE report along with the evaluation report to the other members of the SRC, Vice Chair and Chairperson by Email. In case of conflict of interest for any of the trials by the members, it needs to be declared by the members as well as the PI. Non-receipt of comments within 5 days of the mail from the SRC members, will be deemed as "Causality agreed as stated in the SRC evaluation report by the PI" unless there is a definite communication from the SRC member declining to comment with a valid reason. For clinical trials, the final SAE report will be circulated in real

time and decision sent to PI/sponsor or DCGI within 30 days of receipt of the final report as per GSR 227(E) - New drugs and clinical trial rules, 2019. Whenever a consensus opinion is not obtained by circulation through email, then only a meeting is called for to review the SAE and the PI/Designee may even be called to present the case if required. The final decision is ratified by the Chairperson/Vice chairperson of the SRC committee. The report of causality is then communicated to the DCGI by the IEC Secretariat as detailed in 5.4

5.3 Presentation of SAE in the SRC meeting and in the full board IEC meeting subsequently

For all clinical trials and drug related SAE's where pharmacological intervention is prescribed as per the protocol, the circulation is done irrespective of causality. If compensation is deemed to be required, whether it is academic or regulatory, circulation is done real time and presented at the full board meeting. All SAE's will be circulated by Email and opinion obtained passively unless there is a specific comment or clarification raised by any of the SRC members In case a consensus opinion is not arrived at or compensation is deemed mandatory for a particular SAE, then a SRC meeting is called for on a specific date or preceding the scheduled meeting of the IEC (scheduled) if the latter falls within the reporting timelines set by the DCGI. In case the SRC wants further clarification, the PI will be requested to present in the SRC meeting and this will be intimated through the IEC secretariat to the PI. The PI should have all relevant records of the patient available with him/her during the presentation.

For non- pharmacological intervention studies, the SAE will be presented by the PI during the time of annual review of that study, with the hard copies of the prescribed format **(Annexure Code: AF/EC/049/05)** submitted as Annexures along with ongoing review submission form.

5.4 Communication of the SAE review decision by IEC to regulatory authority

Once, a consensus opinion is obtained, it is communicated to the regulatory authority in the prescribed format for regulatory trials with details of compensation if applicable / and to the head of the institution/Sponsor in case of non-regulatory trials; within 30 days of receipt of the final report / occurrence of SAE (**Annexure code: AF/EC/050/05 – Part I and Part II).** If further details are required or there is a disagreement, an emergency meeting is called for by the MS SRC/IEC, either in person or through e-platform to clarify the doubts and a final decision will be arrived at, before sending to regulatory authority, within 1 month of receipt of the final report from the PI. A copy of the SAE review report will be retained in the IEC secretariat in the SRC file as well as in the study file. Any delay that can be justified due to want of information is permitted with prior intimation to the IEC and to the DCGI

simultaneously by the PI /Sponsor. In case the decision from IEC is delayed due to any technical reasons, it is appropriately informed to the CDSCO through email.

5.5 Communication of the SAE review decision by IEC to PI

Decision of the IEC with regard to clinical trials / trials with pharmacological intervention, will be communicated to the head of the institution after minutes of the full board meeting is approved. Unless there is a compensation which is required to be paid by the PI, the communication letter is not routinely sent to the PI. Any communication with regard to want of information for better determination of causality is done only through email after the advent of Covid pandemic Feb 2020. In case further details are required, then the PI will be immediately intimated after the IEC meeting/SRC meeting or can be asked to present the SAE in person and clarify accordingly, if required. If mandated by the sponsor, acknowledgement will be given either as signature on hardcopy duly attested by the secretariat or reply by mail

5.6. Discussions in NIRT IEC Full Board meeting with regard to SAE and compensation

- SAEs and the SRC recommendations will be presented and ratified in the Full Board Meeting. However, considering the timelines set forth by CDSCO for reporting SAEs in regulatory trials, the 30 day period will be obeyed while submitting it to CDSCO and the SAE will be presented in the subsequent IEC Meeting.
- In any study, where the SAE's are more than anticipated , the IEC may indulge in further discussions and take appropriate action that includes :
  - Probe or request for additional information regarding SAE's
  - Request an amendment to the protocol or the consent form.
  - Call for a monitoring visit
  - Recommend for withholding, Suspension or termination of the offending arm or the study itself as the case mandates
  - Inform the sponsor and regulatory heads regarding the need for detailed work up / analysis.

5.7 Covid mandated changes that will be continued till further revisions (the clause of Force majeure)

For clinical trials and pharmacological interventions, from February 2020, with Covid striking globally, changes have been made in the operational guidelines of the NIRT-IEC as done for various other committees. IEC became paperless and all communications were sent through Emails only. It was informed that no communication would be sent to PI unless there is a possible causality of the SAE to the study medication that required compensation, in which case this would be communicated to the PI through the head of the institution and the sponsor. In all

other cases, the SAEs would be circulated to the SRC committee and uploaded in the Sugam Portal in the case of regulatory trials and presented in the full board meeting conducted through zoom platform and causality ratified irrespective of the nature of the trial. Confidentiality is maintained as the zoom account is a paid private connection of ICMR-NIRT. No further communication was made to anybody. However the body of the minutes would contain a section on SAE's that would be projected during the meeting and that would be copied to the head of the institution for necessary action.

For non-pharmacological studies, it was decided that the PI will report the SAEs only at the time of annual review submission as indicated earlier

6. ANNEXURE

Annexure Code	Annexure title
AF/EC/030/05	Serious Adverse Event (SAE) Report form for all clinical trials
AF/EC/031/05	SRC meeting intimation letter
AF/EC/049/05	SAE reporting (For studies of non-pharmacological intervention)
AF/EC/050/05	Review of Serious Adverse Events (SAE) by IEC – Part I Review of Serious Adverse Events (SAE) by IEC – Part II

7. GLOSSARY

Clinical trial	Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational Product, and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy.
Conflict of Interest	A situation in which a person, such as a public official, an employee, or a professional, has a private or personal interest sufficient to appear to influence the objective exercise of his or her official duties. There are three key elements in this definition: financial interest; official duties; professional interest. A conflict of interest occurs when: • An individual's private interest differs from his or her professional obligations to the institute. • Professional actions or decisions occur that an independent observer might reasonably question. • A conflict depends upon situation and not on the character or actions of the individual. • Potential conflicts of interest must be disclosed and managed as per policy.
Clinical trial related injury/ death liable for compensation	Death / Injury due to any one of the following reasons 1. Adverse effect of investigational product 2. Any clinical trial procedures 3. Violation of the approved protocol, scientific misconduct or negligence by Sponsor or his representative / Investigator 4. Failure of investigational product to provide intended therapeutic effect where standard care though available was not provided to the subject as per the clinical trial protocol 5. Use of placebo in a placebo controlled trial where standard care though available was not provided to the subject as per the clinical trial protocol 6. Adverse effects due to concomitant medication excluding standard care, necessitated as part of approved protocol 7. Injury to the child in-utero because of participation of parent in clinical trial
Licensing authority - Drugs Controller General of India (DCGI)	DCGI is responsible for approval of licenses of specified categories of drugs such as blood and blood products, IV fluids, vaccines and sera in India, appropriate authorities for rDNA products etc.

Principal Investigator	A person responsible for the conduct of the research study at the study site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.
Ratification	Formal approval/ sanction of a decision
Secretariat	An office responsible for the secretarial, clerical, and administrative affairs of NIRT-IEC
SRC	A sub-committee of the NIRT-IEC comprising of – Chair (Clinical Pharmacologist - Non-Affiliate IEC member), Member-Secretary (Affiliate IEC member – Physician), Physician, Legal expert (Non-Affiliate IEC members) and MS of IEC.
SAE (Serious Adverse Event)	Untoward medical occurrence in a clinical trial resulting in • Death • Life threatening • In-patient hospitalisation (if the study is conducted as an out-patient) • Prolongation of existing hospitalisation (if the study is conducted as an in-patient) • Persistent or significant disability or incapacity • Congenital anomaly or birth defect

Annexure: AF/EC/030/05

Serious Adverse Event (SAE) Report form for all Clinical trials

DATA ELEMENTS FOR REPORTING SERIOUS ADVERSE EVENTS OCCURRING IN A CLINICAL TRIAL OR BIOAVAILABILITY OR BIOEQUIVALENCE STUDY

Protocol Title *	
DCGI Clinical trial number NIRT-IEC Number	
CTRI Registration No. (Mandatory for Clinical Trial Permitted after 15/06/09)	
Sponsor(Address with contact no and Email)	
Clinical trial site address	
Initial / Follow-up (FU)	
In case of follow-up: Date of initial or recently submitted report information	
Type of SAE	**Death / Hospitalisation / Others** **If others, specify:**

***this table is optional as this has not figured in table 5 in NDCT rules 2019 .to be checked**

1. Patient Details:

Initials*:	
Patient ID*:	
Gender:	
Age:	
Date of birth:	
Weight:	
Height:	

2. Suspected Drugs

Generic name of the drug*:	
Indication(s) for which suspect drug was prescribed or tested:	
Dosage form and strength:	

Daily dose and regimen: (Specify units - e.g., mg, ml, mg/kg)	
Route of administration:	
Starting date and time of day:	
Stopping date and time, or duration of treatment:	

3. Other Treatment:

*(Provide the same information for **concomitant drugs** (including non prescription/OTC drugs) and non-drug therapies, as for the suspected drug(s).)*

Sl No	Generic Name of the drug	Indication(s)	Dosage form and strength (units)	Daily dose and regimen (units)	Route	Start Date	Stop Date

4. Details of Serious Adverse Event

(Full description of the event including body site and severity, as well as the criterion (or criteria) for considering the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the event)

SAE Term:	
Severity:	
Seriousness Criteria:	
Start date (and time) of onset of reaction:	
Stop date (and time) or duration of reaction:	
De – challenge information:	
Re – challenge information:	
Setting (e.g., hospital, out-patient clinic, home, nursing home):	

SAE description	
Relationship to the study Drug by PI: Related / Unrelated	
Reasoning for Relatedness/Un-relatedness by PI	

5. Outcome

(Information on recovery and any sequelae; results of specific tests and/or treatment that may have been conducted, For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction; Any post-mortem findings, Other information: anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse; family history; findings from special investigations etc.)

Information on recovery and any sequelae: Not recovered/ not resolved, Recovered/ resolved, Recovered with sequel, Recovering/ resolving, unknown, Fatal, Lost to follow-up) – Include the appropriate response

Outcome	

Results of specific tests:

Name of investigation	Date of investigation	Investigation Result

Treatment drug(s) details

(Include details of treatment provided)

Sl No	Generic Name of the drug	Indication(s)	Dosage form and strength (units)	Daily dose and regimen (units)	Route	Start Date	Stop Date

Additional details for Fatal SAE report:

Cause of death:	
Possible relationship to the suspected reaction:	
Any post-mortem findings:	
Autopsy (or any other) report details:	

Other information: anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse; family history; findings from special investigations etc.:

6. Details about the investigator

Name:	
Address:	
Telephone number:	

Profession (specialty):	
Date of reporting the event to Licensing Authority:	
Date of reporting the event to Ethics Committee overseeing the site:	
Signature of the Investigator	

Annexure Code: AF/EC/031/05 (only in case physical meeting is called for)

SRC meeting intimation letter

Date:

To

SRC member

Dear ----------,

The SRC meeting is scheduled to be held on **date, day** at **time** at **venue.** The following Serious Adverse Events (SAE) will be reviewed in the meeting.

S.No.	Protocol title NIRT-IEC No.	Type of SAE	Name of PI & designation

You are requested to attend.

Thanking you.

Yours sincerely,

SRC Member – Secretary

Cc

Director, NIRT
Chairperson, IEC

Annexure Code: AF/EC/049/05

SAE reporting

(For studies of non-pharmacological intervention)

Study Title :	
IEC number:	Patient Name and study ID :
Reason for reporting SAE (circle appropriate) 1. Death 2.Cancer 3. Congenital birth defects 4. Development of permanent disability 5.Hospitalisation or prolongation of hospitalisation 6.Any other requiring reporting as per PIs discretion / as per protocol	
Date of SAE : SAE Outcome: Date of SAE Outcome:	
Details of SAE: *(Full description of the event including body site and severity, as well as the criterion (or criteria) for considering the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the event. Give details clearly mentioning whether the patient is on any drugs from the programme / Outside the study protocol)*	
If study has no drug given as intervention, did the SAE occur during study related procedures: Yes / No If yes, what was the procedure and what precautionary measures were taken?	
Probable antecedent cause of death if any:	……/ Not Applicable
Causality with respect to your study procedures as judged by the investigator Unrelated related :	
PI /Designee signature or e-sign	
Causality with respect to study as judged by the SRC/IEC : unrelated / related	
Instructions to PI :	
Signature of SRC/IEC Chair/MS	

Annexure code: AF/EC/050/05

Review of Serious Adverse Events (SAE) by IEC PART-1

(to be filled by the Investigator/designee)

1. Protocol IEC number
2. Title of the study
3. Name of Principal Investigator

4. Type of SAE
5. SAE occurrence date
6. SAE report date
7. Investigational agent details
8. Summary of event

Annexure code: AF/EC/050/05

Review of Serious Adverse Events (SAE) by IEC –PART 2
(Applicable to clinical trials and to be filled by the SRC MS/ IEC MS)

1**. Date of SAE circulation**:

Summary of discussion:

2.**Clinical trial related injury/death** – decision if SAE is due to any of the following criteria- please tick appropriate rows

- Adverse effect of investigational product
- Any clinical trial procedures
- Violation of the approved protocol, scientific misconduct or negligence by Sponsor or his representative / Investigator
- Failure of investigational product to provide intended therapeutic effect where standard care though available was not provided to the subject as per the clinical trial protocol
- Use of placebo in a placebo controlled trial where standard care though available was not provided to the subject as per the clinical trial protocol
- Adverse effects due to concomitant medication excluding standard care, necessitated as part of approved protocol
- Injury to the child in-utero because of participation of parent in clinical trial

4. **Causality assessment** – definite /probable/possible/unlikely /unrelated to study medication

5. **Decision of IEC if related to study medication /procedure**

- Payment for medical management
- Financial compensation for trial related injury
- Financial compensation to nominees of trial subjects in case of death
- Financial compensation for the child injured in-utero because of participation of parent in clinical trial

6.**Financial compensation**

- Amount to be paid

Comments :

Signature of IEC Chair-Person and date:

Acknowledgement of awareness of this SOP

S.No	Name	Capacity	Signature	Date
1.	Dr R Sridhar	Chairperson		
2.	Dr R Arun Kumar	Vice-Chairperson		
3.	Dr G Narendran	Member Secretary		
4.	Dr K Lily Therese	Member (Non-Affiliate)		
5.	Dr S Swarnalakshmi	Member (Non-Affiliate)		
6.	Dr Shyamala Nataraj	Member (Non-Affiliate)		
7.	Mrs Rajalakshmi	Member (Non-Affiliate)		
8.	Mrs Renu Lamech	Member (Non-Affiliate)		
9.	Dr V Gowri	Member (Non-Affiliate)		
10.	Mr D Sairamkumar	Member (Non-Affiliate)		
11.	Mrs Pushkala	Member (Non-Affiliate)		
12.	Dr S Chandrasekar	Member (Non-Affiliate)		
13.	Dr P M Ramesh	Member (Non-Affiliate)		
14.	Dr Padma Srikanth	Member (Non-Affiliate)		
15.	Dr Shuba Kumar	Member (Non-Affiliate)		
16.	Dr K R Uma Devi	Member (Affiliate)		
17.	Dr Luke Elizabeth Hanna	Member (Affiliate)		
18.	Dr Bella Devaleenal	Member (Affiliate)		
19.	Dr M Muniyandi	Member (Affiliate)		
20.	Dr P K Bhavani	Member (Affiliate)		
21.	Dr R Balaji	Member (Affiliate)		

SOP Code: SOP/EC/016/05

8.1. Agenda Preparation, IEC Meeting Procedures and Minutes

Revisions in the Standard Operating Procedures from version 4.0, dated 4 October 2018 to version 5.0, dated 18 May 2022

The following revisions are made in the Standard Operating Procedures from version 4.0, dated 4 October 2018 to Version 5.0, dated 18 May 2022 following the revision in the National Ethical guidelines for Biomedical and Health Research involving human participants, ICMR 2017 and NDCT Guidelines 2019.

Title of Standard Operating Procedure (SOP)	SOP Code	Revisions
Agenda Preparation, IEC Meeting Procedures and Minutes	**SOP/EC/016/05**	5.1.1. Check the filled up forms for completeness and ascertain the review process • "Will review the Initial / Ongoing Review Form for completeness" is modified as "Will review the Initial / Ongoing Review Form along with Brief review form for completeness" 5.2. During the meeting The following points have been included: • Based on the suggestion given by IEC National Expert, the ongoing study details would be presented by the MS, IEC in the presence physical/ virtual presence of the PI. The latter would be asked to defend or clarify any queries raised by the committee. 5.3. Decision making The following point is included: • The Chair conveys the final decision

		of the committee to the MS to be incorporated into the minutes. 5.5.3. Approval of the minutes and the decision • "The Chair approves by signing and dating the minutes of the NIRT-IEC meeting" is modified as "The Chair approves by signing and dating the minutes of the NIRT-IEC meeting or the Chair approves the minutes by email confirmation" 5.5.5. Distributing the minutes and communicating the decisions • "The NIRT-IEC Secretariat will Email the approved minutes to the NIRT-IEC members" is modified as "The NIRT-IEC Secretariat will Email the approved minutes to the NIRT-IEC members and Head of the Institution" The following point has been added: • In case of studies connected to the MS IEC, an alternative affiliate member will sign the approval due to COI. Annexure form : AF/EC/034/04 - "Request to Administrative Officer for Meeting arrangements" is updated as "Common Indent Form for purchase of items for Full Board Meeting"

SOP Number: SOP/EC/016	Revision Number: 05	
SOP Author: Dr G Narendran Signature	SOP Approver: Dr R Sridhar (Chair IEC) Signature	Effective Date : 18 May 2022
	Dr C Padmapriyadarsini (Director) Signature	Supersedes : (Doc. version & Date) Version 4.0, dated 4 October 2018

1. PURPOSE

The purpose of this SOP is to identify the administrative process and provide instructions for the preparation, review, approval and distribution of meeting agenda, minutes and action, and notification letters of NIRT-IEC meetings.

2. SCOPE

This SOP applies to administrative processes concerning the preparation of the agenda for all NIRT-IEC meetings, divided into three stages: before, during and after the meeting.

3. RESPONSIBILITY

It is the responsibility of the NIRT IEC Secretariat to prepare the agenda for the NIRT-IEC meeting and to ensure the validity of the minutes of meeting. The MS should review and approve the agenda for the forthcoming meeting and prepare the minutes during the meeting with help from other IEC Members. This will be initially reviewed by the members and finally reviewed and approved by the Chair.

4. FLOW CHART

No.	Activity	Responsibility
1	Before each meeting	NIRT-IEC Secretariat and MS
	↓	
2	During the meeting	Chair, NIRT-IEC Secretariat and Members
	↓	
3	Decision making	NIRT-IEC Members
	↓	
4	After the IEC meeting	NIRT-IEC Secretariat and MS
	↓	
5	Preparing the meeting minutes	NIRT-IEC Secretariat, Members and MS
	↓	
6.	Review of the meeting minutes	IEC members, Vice-Chair and Chair
	↓	
7	Approval of the meeting minutes	Chair
	↓	
8.	Notification of the decision	IEC Secretariat and MS

5. DETAILED INSTRUCTIONS

5.1. Before each IEC meeting

5.1.1. Check the filled up forms for completeness and ascertain the review process.

- The NIRT-IEC secretariat and MS:
  - Will review the Initial / Ongoing Review Form along with Brief review form for completeness.
  - Use the criteria and the procedures as described in the corresponding SOPs when ascertaining the review process.
    - ❖ SOP/EC/010/05 for Expedited Review
    - ❖ SOP/EC/008/05 for Initial Review of Submitted Protocols
    - ❖ SOP/EC/011/05 for Review of Resubmitted Protocols
    - ❖ SOP/EC/012/05 for Review of Protocol Amendments
    - ❖ SOP/EC/013/05 for Ongoing Review of Study Protocols
    - ❖ SOP/EC/014/05 for Review of Final Reports

5.1.2. Send the protocol and related documents to IEC members

- NIRT-IEC Secretariat will send the protocols for review by the IEC member. To refer the following
- SOP/EC/008/05 for Initial Review of Submitted Protocols

- SOP/EC/011/05 for Review of Resubmitted Protocols
- SOP/EC/013/05 for Ongoing Review of Study Protocols
- SOP/EC/014/05 for Review of Final Reports

5.1.3 Prepare for the meeting

- NIRT-IEC Secretariat will prepare the following about 1 to 2 weeks prior to the scheduled meeting date.
  - Make a room reservation on the scheduled meeting date and time ***(Annexure code: AF/EC/033/05)***
  - Give a request in common indent form for the items required for meeting arrangements ***(Annexure code: AF/EC/034/05)***
- Make sure that the room, equipment and facilities are available for the meeting day.

5.1.4. Prepare meeting agenda

- The MS/IEC Secretariat will prepare the meeting agenda, according to the format shown in **AF/EC/035/05 - Format for Scheduled meeting agenda**
- The meeting agenda will be prepared one week prior to the meeting and circulated to the members through Email or whatsapp.

5.1.5. Contact NIRT-IEC members

The NIRT-IEC Secretariat will contact the IEC members about 1-2 weeks prior to the meeting to check their availability to satisfy the quorum requirements.

5.1.6. Inform the Principal Investigators

The NIRT IEC Secretariat will inform all the PIs through email about one week prior to the meeting about the date, time and venue of the meeting. The list of new / ongoing protocols that will be reviewed will be intimated to the PIs. ***(Annexure code: AF/EC/036/05)***

5.2. During the meeting

- NIRT-IEC MS ensures that the quorum is met.
- Hard copies of the Emailed agenda signed by the MS is circulated to all the IEC members
- The meeting proceeds according to the agenda; however, the Chairperson may allow some alterations as appropriate.
- After the remarks of the Chair and Director (if applicable), the MS requests for ratification of the minutes of previous meeting and informs about the date of the next scheduled / unscheduled meeting
- The IEC members fill the Declaration of Conflict of Interest (COI) form ***(AF/EC/007/05)*** in case of COI in the protocols discussed **(**refer to **SOP/EC/004/05)**

- The PIs present their new / ongoing studies, respond to the queries of the IEC members and leave the room
- In case the PI of the ongoing study cannot be present during the meeting, a Coinvestigator/ member of the study team may present the study protocol.
- Based on the suggestion given by IEC National Expert, the ongoing study details would be presented by the MS, IEC in the presence physical/ virtual presence of the PI. The latter would be asked to defend or clarify any queries raised by the committee.

5.3. Decision making

- The MS summarizes the discussions
- The decision on the study will be taken on the basis of consensus.
- The MS minutes the discussions and decisions after each presentation.
- IEC members who have declared COI, will leave the room and will not take part in the decision making process.
- The Chair conveys the final decision of the committee to the MS to be incorporated into the minutes.

5.4. After the Board meeting

Preparation of minutes and the correspondences

5.4.1. Assembling the meeting minutes and decisions

- NIRT-IEC Secretariat and MS compile the minutes
- Format shown in **AF/EC/037/05** is used for compiling the minutes
- The discussions and decisions are compiled in a concise manner.

5.4.2. Contents of the NIRT-IEC Meeting Minutes

- The official minutes of the IEC meeting consist of, but are not limited to, the following:
  - Location where the meeting was held
  - Meeting date
  - Meeting starting and ending time
  - IEC members Present
  - Members who could not attend the meeting and reasons for the same
- Requirements for each study or activity requesting Approval:
  - NIRT-IEC No.
  - Title of the study
  - Name of PI
  - Designation of PI
  - Affiliation of PI
  - Name of the presenter of the study
  - List of documents reviewed with version no. and date
  - Lead Discussants

- Discussion of key issues
- Risk/ Benefit ratio assessment
- Recommendations of the IEC
- If approved, the IEC approval validity period and frequency of ongoing review
- In addition to the above, in case of a clinical trial, the SAE reporting procedure
- In addition, for multicentric trials IEC approval of the other participating sites will be requested.
- If decision is resubmission, the recommendations of IEC and the modality of further review
- If decision is disapproval, appropriate reasons will be stated

- Requirements for each ongoing / Completed / Yet to be initiated Review Report:
  - NIRT-IEC No.
  - Title of the study
  - Name of PI
  - Designation of PI
  - Affiliation of PI
  - Date of IEC approval of the original protocol.
  - Name of the presenter of the study
  - Date of initiation of the study.
  - Discussion of key issues
  - Recommendation of IEC.
- Ratification of study new protocols approved by expedited / exempt process:
  - NIRT-IEC No.
  - Title of the study
  - Name of PI
  - Designation of PI
  - Affiliation of PI
  - Date of expedited / exempt review approval of the original protocol
  - Information of key issues to the EC
  - Ratification by IEC
- Ratification of study protocols amendments approved by expedited process
  - NIRT-IEC No.
  - Title of the study
  - Name of PI
  - Designation of PI
  - Affiliation of PI
  - Date of expedited / exempt review approval of the original protocol
  - Information of key issues to the EC
  - Ratification by IEC
- Review of SAE reports , ratification of SRC minutes and compensation, perusal of Central SAE committee decision
  - NIRT-IEC No.

- Title of the study
- Name of PI
- Designation of PI
- Affiliation of PI
- Date of IEC approval of the original protocol.
- Type of SAE
- SRC meeting minute details
- Type of compensation
- Ratification by IEC
- Perusal of Central SAE committee decision

- Review of protocol deviations
  - NIRT-IEC No.
  - Title of the study
  - Name of PI
  - Designation of PI
  - Affiliation of PI
  - Date of IEC approval of the original protocol.
  - Details of protocol deviation
  - Discussion and recommendation by IEC

5.5.3. Approval of the minutes and the decision

- The MS along with other members will prepare the minutes.
- The minutes will be Email to the IEC members for their comments.
- The Chair will check the correctness and completeness of the minutes.
- The Chair approves by signing and dating the minutes of the NIRT-IEC meeting or the Chair approves the minutes by email confirmation.

5.5.4. Filing the minutes

- The NIRT – IEC Secretariat places the original version of the minutes in the minutes file

5.5.5. Distributing the minutes and communicating the decisions

- The NIRT-IEC Secretariat will Email the approved minutes to the NIRT-IEC members and Head of the Institution.
-
- The MS will sign and send the appropriate communications of the IEC decision to the PI ***(Annexure code: AF/EC/013/05, AF/EC/014/05, AF/EC/023/05, AF/EC/024/05, AF/EC/025/05, AF/EC/027/05, AF/EC/028/05, AF/EC/029/05)***
- ***Copies of IEC meeting minutes and decision letters given to PI's will be sent to Head of the Institution.***
- ***In case of studies connected to the MS IEC, an alternative affiliate member will sign the approval due to COI.***
- NIRT-IEC Secretariat will keep a copy of the communications in the respective study file.

6. ANNEXURE

Annexure Code	Annexure title
AF/EC/007/05	Declaration of Conflict of Interest
AF/EC/033/05	Request for venue and audio-visual arrangements.
AF/EC/034/05	Common Indent Form for purchase of items for Full Board Meeting
AF/EC/035/05	Format for Scheduled meeting agenda
AF/EC/036/05	PI intimation on list of ongoing / new protocols for IEC review
AF/EC/037/05	Format for IEC meeting minutes
AF/EC/013/05	Certificate of Institutional Ethics Committee approval
AF/EC/014/05	IEC initial review decision letter
AF/EC/023/05	Certificate of Institutional Ethics Committee (Expedited) approval
AF/EC/024/05	Certificate of Institutional Ethics Committee (Protocol Amendment) approval
AF/EC/025/05	IEC Protocol amendment review decision letter
AF/EC/027/05	Letter of IEC acknowledgement of submission of ongoing study
AF/EC/028/05	Extended certificate of Institutional Ethics Committee approval
AF/EC/029/05	IEC Final report review decision letter

7. RELEVANT SOPs

SOP Code	SOP Title
SOP/EC/004/05	Conflict of Interest Agreement
SOP/EC/008/05	Initial Review of Submitted Protocols
SOP/EC/010/05	Expedited Review
SOP/EC/011/05	Review of Resubmitted Protocols
SOP/EC/012/05	Review of Protocol Amendments
SOP/EC/013/05	Ongoing Review of Study Protocols
SOP/EC/014/05	Review of Final Reports

GLOSSARY

Conflict of Interest	A situation in which a person, such as a public official, an employee, or a professional, has a private or personal interest sufficient to appear to influence the objective exercise of his or her official duties. There are three key elements in this definition: financial interest; official duties; professional interest. A conflict of interest occurs when: • An individual's private interest differs from his or her professional obligations to the institute. • Professional actions or decisions occur that an independent observer might reasonably question. • A conflict depends upon situation and not on the character or actions of the individual. • Potential conflicts of interest must be disclosed and managed as per policy.
Expedited review	A review process by only three NIRT-IEC members who then report the decision to the full Board meeting. An expedited review is a *speedy* one for minor *changes to the approved protocol* and for *research proposal* with *minimal risk in nature*.
IEC	Institutional Ethics Committee is an independent body whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection.
IEC members	Individuals serving as regular and alternate members on the institute's operational boards (i.e., IEC membership). These boards are constituted in accordance with the EC membership requirements set forth in ICMR Ethical guidelines for Biomedical research involving human participants
Meeting	Deliberations between at least two (2) persons where such deliberations determine or result in the joint conduct or disposition of business.
Minutes	An official record of the business discussed and transacted at a meeting, ..
Multi-centric studies	A clinical trial conducted according to a single protocol but at more than one site, and therefore, carried out by more than one investigator.
Ongoing review	Review of IEC approved studies at periodic intervals
Protocol	A document that describes the objective (s), design, methodology, statistical considerations, and organization of the study
Protocol amendment	A written description of a change(s) to or formal clarification of
Quorum	Number of IEC members required to act or take decision on any motion presented to the Board for action.
Ratification	Formal approval/ sanction of a decision
Standard Operating	Detailed, written instructions, in a certain format, describe all activities and action undertaken by an organization to achieve uniformity of the

Procedure	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.
Secretariat	An office responsible for the secretarial, clerical, and administrative affairs of NIRT-IEC
SRC	A sub-committee of the NIRT-IEC comprising of – Chair (Clinical Pharmacologist - Non-Affiliate IEC member), Member-Secretary (Affiliate IEC member – Physician), Physician, Legal expert (Non-Affiliate IEC members) and MS of IEC.
SAE (Serious Adverse Event)	Untoward medical occurrence in a clinical trial resulting in • Death • Life threatening • In-patient hospitalisation (if the study is conducted as an out-patient) • Prolongation of existing hospitalisation (if the study is conducted as an in-patient) • Persistent or significant disability or incapacity • Congenital anomaly or birth defect

Annexure Code : AF/EC/007/05

Undertaking for declaration of Conflict of Interest

Date:

To

The Chairperson,

NIRT-IEC.

I,……. solemnly, declare that, I am not involved in multiple interests, financial or otherwise that could possibly influence my motivation or decision-making in the capacity of Member/Member-Secretary of the National Institute for Research in Tuberculosis – Institutional Ethics Committee (NIRT-IEC) .

Yours sincerely,

Signature :_____

Name :_____

Date :_____

Annexure Code: AF/EC/013/05

Certificate of Institutional Ethics Committee Full Board Initial approval

ICMR - National Institute for Research in Tuberculosis

INSTITUTIONAL ETHICS COMMITTEE

(SIDCER Recognized Ethics Committee in the Asian and Western Pacific Region)

No: 1, Mayor Sathyamoorthy Road, Chetput, Chennai – 600 031, Tamil Nadu, India

Dr.
Vice Chair

Dr.
Chairperson

Dr.
Member Secretary

Members (Non Affiliated)

Members (Affiliated)

No: 000/NIRT-IEC/YEAR Date:

Certificate of Institutional Ethics Committee Approval

The Institutional Ethics Committee met on …….

under the Chairmanship of ……and reviewed the project titled

"……

…….....

NIRT-IEC No: ……., which was presented

by ……., NIRT.

ICMR - National Institute for Research in Tuberculosis

INSTITUTIONAL ETHICS COMMITTEE

(SIDCER Recognized Ethics Committee in the Asian and Western Pacific Region)

No: 1, Mayor Sathyamoorthy Road, Chetput, Chennai – 600 031, Tamil Nadu, India

The following Institutional Ethics Committee members attended the meeting held in the …… Room, National Institute for Research in Tuberculosis, Chennai.

Name	**Capacity**

Conflict of Interest:

ICMR - National Institute for Research in Tuberculosis

INSTITUTIONAL ETHICS COMMITTEE
(SIDCER Recognized Ethics Committee in the Asian and Western Pacific Region)

No: 1, Mayor Sathyamoorthy Road, Chetput, Chennai – 600 031, Tamil Nadu, India

The Committee reviewed the following documents –

- After deliberations, ---------- the project with the following **recommendations:**

Ongoing project review will be conducted:

Note to PI:

1. The study is approved for the study duration of …….. years. Kindly apply for extension of IEC approval if extension of study duration is required along with appropriate justification and summary of study findings.
2. The ongoing review details of the study have to be submitted as per the frequency mentioned above.
3. Report of Serious Adverse Events (SAE) has to be submitted as per NDCT Rules, 2019.
4. Deviations in the protocol and justification for the same may be submitted wherever appropriate.
5. Approval of IEC has to be obtained prior to implementing any change/amendment in study procedures/protocol and any amendment in other sites has to be promptly informed to our IEC Secretariat.
6. Please be informed that the IEC is empowered to monitor the study at any point of time if the need arises with prior intimation.

Member Secretary

To: Principal Investigator,
Designation
National Institute for Research in Tuberculosis

cc to:

Director, National Institute for Research in Tuberculosis

Annexure Code: AF/EC/014/05

ICMR - National Institute for Research in Tuberculosis

INSTITUTIONAL ETHICS COMMITTEE

(SIDCER Recognized Ethics Committee in the Asian and Western Pacific Region)

No: 1, Mayor Sathyamoorthy Road, Chetput, Chennai – 600 031, Tamil Nadu, India

Members (Non Affiliated)

Dr.
Vice Chair

Dr.
Chairperson

Dr.
Member-Secretary

Members (Affiliated)

No: 000/NIRT-IEC/YEAR Date:

To: Principal Investigator,
Designation
National Institute for Research in Tuberculosis

The Institutional Ethics Committee met on …….

under the Chairmanship of ---------- and reviewed the project titled

"…….....

.NIRT-IEC No: …….., which was presented by

……., NIRT

ICMR - National Institute for Research in Tuberculosis (ICMR)
(Formerly Tuberculosis Research Centre)

INSTITUTIONAL ETHICS COMMITTEE

No: 1, Mayor Sathyamoorthy Road, Chetput, Chennai – 600 031, Tamil Nadu, India

The Committee reviewed the following documents –

- and following a consensus decision, the project requires to be re-submitted with the following recommendations addressed

OR

- and after deliberations, disapproves the project for the following reasons

Member Secretary

cc to:

Director, National Institute for Research in Tuberculosis

Annexure Code: AF/EC/023/05

Letter to PI- IEC Expedited review decision

ICMR - National Institute for Research in Tuberculosis

INSTITUTIONAL ETHICS COMMITTEE

(SIDCER Recognized Ethics Committee in the Asian and Western Pacific Region)

No: 1, Mayor Sathyamoorthy Road, Chetput, Chennai – 600 031, Tamil Nadu, India

No: ……/NIRT-IEC/2013 Date:
…….

To

.....
.....
.....

Sir / Madam,

Sub: NIRT-IEC ID: ……..
"Title: ……...." – reg.

Ref: (i) Your Letter dated ……
(ii) NIRT IEC Letter No: …… dated …….

Receipt of the above referenced protocol / Receipt of the amendment to the above referenced protocol is acknowledged. This submission includes the following documents:

……

The protocol / amended protocol was reviewed through expedited process.
In view of the following reasons,

the study protocol / amendments were not approved and needs to undergo a full board review.

Member Secretary

cc to:
The Director, National Institute for Research in Tuberculosis

Annexure Code: AF/EC/024/05

Letter to PI - Protocol Amendments Full Board approval

ICMR - National Institute for Research in Tuberculosis

INSTITUTIONAL ETHICS COMMITTEE

(SIDCER Recognized Ethics Committee in the Asian and Western Pacific Region)

No: 1, Mayor Sathyamoorthy Road, Chetput, Chennai – 600 031, Tamil Nadu, India

Members (Non Affiliated)

Dr.
Vice Chair

Dr.
Chairperson

Dr.
Member-Secretary

Members (Affiliated)

No: ……/NIRT-IEC/2013
Date: …….

To

.....
.....
.....

Sir / Madam,

The Institutional Ethics Committee met on ……. under the Chairmanship of ---------- and reviewed the Amendments to the project titled "…….....
.NIRT-IEC No: …….., which was presented by ……., NIRT

The Committee reviewed the following documents –

- and after deliberations, **approves the amendments** with the following **recommendations (if any):**

Member Secretary

cc to:
The Director, National Institute for Research in Tuberculosis

Annexure Code: AF/EC/025/05

Letter to PI - Protocol Amendments Full Board review decision

ICMR - National Institute for Research in Tuberculosis

INSTITUTIONAL ETHICS COMMITTEE

(SIDCER Recognized Ethics Committee in the Asian and Western Pacific Region)

No: 1, Mayor Sathyamoorthy Road, Chetput, Chennai – 600 031, Tamil Nadu, India

Members (Non Affiliated)

Dr.
Vice Chair

Dr.
Chairperson

Dr.
Member-Secretary

Members (Affiliated)

No: ……/NIRT-IEC/2013 Date: ……

To

.....
.....
.....

Sir / Madam,

The Institutional Ethics Committee met on ……. under the Chairmanship of ---------- and reviewed the Amendments to the project titled "…….....
.NIRT-IEC No: ……., which was presented by ……., NIRT

The Committee reviewed the following documents –

- and following a consensus decision, the amendments to the protocol and or associated documents requires to be re-submitted with the following recommendations addressed

OR

- and after deliberations, disapproves the amendments for the following reasons

Member Secretary

cc to:
The Director, National Institute for Research in Tuberculosis

Annexure code: AF/EC/027/05

Letter to PI – IEC Review of ongoing submission

ICMR - National Institute for Research in Tuberculosis

INSTITUTIONAL ETHICS COMMITTEE

(SIDCER Recognized Ethics Committee in the Asian and Western Pacific Region)

No: 1, Mayor Sathyamoorthy Road, Chetput, Chennai – 600 031, Tamil Nadu, India

No: ……/NIRT-IEC/2022 Date: ……..

To

Sir / Madam,

Ref: NIRT-IEC No: …….: "Title: ……." – reg.

The NIRT-Institutional Ethics Committee met on …… under the Chairmanship of …….. and reviewed the above referenced project (based on the 'ongoing protocol review submission form' submitted by you).

The Committee hereby acknowledges the submission.

Recommendations: Accepted for continuation / suggested resubmission:

Thanking you.

Yours truly,

Member Secretary

cc to:

The Director, National Institute for Research in Tuberculosis

Annexure code: AF/EC/028/05

Letter to PI – IEC Extension of Study Period

ICMR - National Institute for Research in Tuberculosis

INSTITUTIONAL ETHICS COMMITTEE

(SIDCER Recognized Ethics Committee in the Asian and Western Pacific Region)

No: 1, Mayor Sathyamoorthy Road, Chetput, Chennai – 600 031, Tamil Nadu, India

No: ……../NIRT-IEC/20….. Date: …….

To

Sir / Madam,

Ref: NIRT-IEC No: …….: "Title: ……" – reg.

The NIRT-Institutional Ethics Committee met on …….. under the Chairmanship of ……. and reviewed the above referenced project (based on the 'ongoing protocol review submission form' submitted by you).

The Committee hereby acknowledges the submission.

As the duration of the study is going to expire, based on your request for an extension of the study period for …….years, the committee approves extension/ disapproves extension of the study period for ----------years.

Thanking you.

Yours truly,

Member Secretary

cc to:

The Director, National Institute for Research in Tuberculosis

Annexure code: AF/EC/029/05

Letter to PI - IEC Final report review decision

ICMR - National Institute for Research in Tuberculosis

INSTITUTIONAL ETHICS COMMITTEE

(SIDCER Recognized Ethics Committee in the Asian and Western Pacific Region)

No: 1, Mayor Sathyamoorthy Road, Chetput, Chennai – 600 031, Tamil Nadu, India

No: ……../NIRT-IEC/20….. Date: …….

To

Sir / Madam,

Ref: NIRT-IEC No: ……: "Title: **……..**" – reg.

The NIRT-Institutional Ethics Committee met on …… under the Chairmanship of ……..and reviewed the above referenced project (based on the 'ongoing protocol review submission form' submitted by you).

The Committee hereby acknowledges the submission.

As the study is completed and the final report is submitted to IEC and approved the study file will be closed.

Thanking you.

Yours truly,

Member Secretary

cc to:

The Director, National Institute for Research in Tuberculosis

Annexure Code: AF/EC/033/05

National Institute for Research in Tuberculosis

Director's Office

Meeting Room Request Form

Name of the Indenter	:
Designation	:
Division/Department	:
Room(s) Required	: ☐ Sriram Prasad Tripathy Conference Room, Patient Care Building ☐ Fox Mitchison Room, Lab Building ☐ Robert Koch Auditorium, Lab Building ☐ Sanjeevi Room, Lab Building ☐ CVR Conference Room, Lab Building ☐ Dining Hall, Patient Care Building
Date	: From _____ To _____
Time	: From _____ To _____
Purpose of requirement	: ☐ Meeting ☐ Conference/Symposium ☐ Guest Lecture/ Seminar ☐ Workshop ☐ Training ☐ Others
Name of the Meeting / Conference / Workshop	:
Item Required	: ☐ LCD Projector ☐ Laptop ☐ Collar Mic * ☐ Mic * ☐ None of the above *For Auditorium & New Conference Room only
Signature & Date	:
HOD's Signature & Date	:
For Director's Office Use only Room (s) / Auditorium Signature & Date	: ☐ Available ☐ Not Available :

Annexure Code: AF/EC/034/05

Common Indent Form for purchase of items for Full Board Meeting

NATIONAL INSTITUTE FOR RESEARCH IN TUBERCULOSIS
CHETPET, CHENNAI-31

Department/Section:

COMMON INDENT FORM

Date:

Name of the item in indented **Type: Yes or No**	Capital equipment	Stationary	Chemicals/ reagents / media (Perishables/ Non Perishable)	Consumables	AMC/CAM
	○	○	○	○	○

Funding Source	**ICMR** ○	**PROJECT Name**
	Project ○	

S.No	Item Name	Brand	Quantity required	Appx. Cost	Available

Purpose of the item (with brand name & available source) with proper justification	
Has approval of SAC/Director/ funding agency (document to be enclosed)	Yes ○ No ○
Indented by	Name: Designation:

Annexure Code: AF/EC/035/05

Format for Scheduled meeting agenda

Date and Time of meeting :

Venue of meeting:

1. **NIRT-IEC Chairperson's Remarks**
2. **Director's remarks (if applicable)**
3. **Review of activities – Member Secretary**
   - Approval of the minutes of the meeting held in previous meeting
   - Date of forthcoming scheduled IEC meeting –
   - Others as applicable
4. **Declaration of Conflict of Interest**
5. **Review of New Protocols / re-submissions**

   NIRT IEC No---------- "**Title of study"** Name of PI, Designation and Affiliation

   Lead Discussant 1:

   Lead Discussant 2:
6. **Review of Protocol amendments**

   NIRT IEC No---------- "**Title of study"** Name of PI, Designation and Affiliation
7. **Review of Ongoing protocols (Initiated studies)**

   NIRT IEC No---------- "**Title of study"** Name of PI, Designation and Affiliation
8. **Review of Completed protocols**

   NIRT IEC No---------- "**Title of study"** Name of PI, Designation and Affiliation
9. **Review of "Yet to be initiated " protocols**

   NIRT IEC No---------- "**Title of study"** Name of PI, Designation and Affiliation

10. **Ratification of new protocols approved by expedited / exempt process**
    NIRT IEC No---------- "**Title of study"** Name of PI, Designation and Affiliation
11. **Ratification of protocol amendments approved by expedited process**
    NIRT IEC No---------- "**Title of study"** Name of PI, Designation and Affiliation
12. **Review of SAE, ratification of SRC meeting minutes and compensation , perusal of Central SAE Committee decision (if applicable)**
13. **Review of protocol deviations**
14. **Any other, as decided by the Chair, Member Secretary**

Annexure Code: AF/EC/036/05

PI intimation on list of ongoing / new protocols for IEC review
(Through e-mail)

Respected All,

The NIRT Institutional Ethics Committee meeting (Offline/Online/Hybrid) is scheduled to be held on _____.

Please find the list of studies that will be reviewed in this forthcoming meeting. The PIs are requested to present their respective studies to the committee for approval. The PIs who are having New submissions and Amendment have to present their studies by attending the meeting in person in SPT conference Hall at 09:00 AM on 18.06.2022 (Saturday).

The ongoing / completed/ Yet to be Initiated Studies will be presented by the Member Secretary. **The PIs who are having ongoing and completed studies will be joining the meeting via zoom and PIs are requested to be ready with their power point presentations for their respective ongoing/completed/ Yet to be Initiated studies and be ready to answer the queries, if any, raised by the committee Members.** The power point presentation should contain the following details within 4 slides.

- Slide 1 - Protocol Title, NIRT-IEC number, date of IEC approval, date of study initiation and duration of study
- Slide 2 - Background, Study Objectives, Outcome and Sample size
- Slide 3 - Status update of the protocol
- Slide 4 - Salient findings and Ethical issues, if any

The Ongoing study PIs will be intimated by the IEC Secretariat staff when to join the meeting via zoom. The zoom link for the meeting is _____.

Thanks,

Best regards,

Member-Secretary

Annexure Code: AF/EC/037/05

Format for IEC meeting minutes

No: Date:

Minutes of the Committee Meeting

Venue:
Date & Time :

At the **Scheduled** meeting of **date**, the following members were in attendance:

Name	Capacity
:	Chairperson (Non-Affiliate)
:	Member Secretary (Affiliate)

Non-Affiliate Members

Affiliate Members

Administrative Staff

The meeting was called to order at **Time**.

Chair, Director, Member-Secretary and other's remarks:
(Important events, instructions and decisions will also be part of the remarks)

The meeting proceeded to the discussion on the new protocols.

Review of New Protocols and Resubmissions

NIRT-IEC No "**Title "** PI name : , Designation

List of documents reviewed:

Discussion: Name of PI, Designation presented the project details.

Lead Discussant 1:

Lead Discussant 2:

The protocol was reviewed along with the associated documents.

Discussions

Following a consensus opinion, the protocol and all the submissions were **approved** / requested to be **re-submitted** with the following recommendations:

If approved,

Ongoing Reviews to be conducted:

Note to PI:

Review of Protocol Amendments

NIRT-IEC No "**Title "** PI name : , Designation (Approved on date)

Name of presentor:

Discussion:

Decision:

Review of Ongoing studies

NIRT-IEC No "**Title "** PI name : , Designation (Approved on date)

Name of presentor:

Discussion:

Decision:

Review of Completed studies

NIRT-IEC No "**Title "** PI name : , Designation (Approved on date)

Name of presentor:

Discussion:
Decision:

Review of "Yet to be initiated" studies

NIRT-IEC No "**Title "** PI name : , Designation (Approved on date)

The MS briefed the committee members on the study status.

Discussion:

Decision:

Ratification of new protocol approved by expedited / exempt process

NIRT-IEC No "**Title "** PI name : , Designation (Approved on date)

List of documents reviewed:

The MS informed the committee that the above mentioned protocol and associated documents were submitted to the Chair and Vice-Chair for expedited / exempt review and was approved.

The MS briefed the committee members on the study details.

The committee ---------- the decision of expedited /exempt approval.

Ratification of protocol amendments approved by expedited process

NIRT-IEC No "**Title "** PI name : , Designation (Approved on date)

List of documents reviewed:

The MS informed the committee that the above mentioned protocol and associated documents were submitted to the Chair and Vice-Chair for expedited review and was approved.

The MS briefed the committee members on the amendments.

The committee ---------- the decision of expedited approval.

Review of SAE, ratification of SRC meeting minutes and compensation and perusal of Central SAE committee decision (if applicable)

The List of SAE's discussed is included in a tabular column and archived into the overall minutes.

Review of protocol deviations

NIRT-IEC No "**Title "** PI name : , Designation (Approved on date)

The MS briefed the committee members on the study details.
Discussion & decisions

The meeting was adjourned at Time.

Date: **Signature of Chair**

Acknowledgement of awareness of this SOP

S.No	Name	Capacity	Signature	Date
1.	Dr R Sridhar	Chairperson		
2.	Dr R Arun Kumar	Vice-Chairperson		
3.	Dr G Narendran	Member Secretary		
4.	Dr K Lily Therese	Member (Non-Affiliate)		
5.	Dr S Swarnalakshmi	Member (Non-Affiliate)		
6.	Dr Shyamala Nataraj	Member (Non-Affiliate)		
7.	Mrs Rajalakshmi	Member (Non-Affiliate)		
8.	Mrs Renu Lamech	Member (Non-Affiliate)		
9.	Dr V Gowri	Member (Non-Affiliate)		
10.	Mr D Sairamkumar	Member (Non-Affiliate)		
11.	Mrs Pushkala	Member (Non-Affiliate)		
12.	Dr S Chandrasekar	Member (Non-Affiliate)		
13.	Dr P M Ramesh	Member (Non-Affiliate)		
14.	Dr Padma Srikanth	Member (Non-Affiliate)		
15.	Dr Shuba Kumar	Member (Non-Affiliate)		
16.	Dr K R Uma Devi	Member (Affiliate)		
17.	Dr Luke Elizabeth Hanna	Member (Affiliate)		
18.	Dr Bella Devaleenal	Member (Affiliate)		
19.	Dr M Muniyandi	Member (Affiliate)		
20.	Dr P K Bhavani	Member (Affiliate)		
21.	Dr R Balaji	Member (Affiliate)		

SOP Code: SOP/EC/017/05

8.2. Unscheduled meeting

Revisions in the Standard Operating Procedures from version 4.0, dated 4 October 2018 to version 5.0, dated 18 May 2022

The following revisions are made in the Standard Operating Procedures from version 4.0, dated 4 October 2018 to Version 5.0, dated 18 May 2022 following the revision in the National Ethical guidelines for Biomedical and Health Research involving human participants, ICMR 2017 and NDCT Guidelines 2019.

Title of Standard Operating Procedure (SOP)	SOP Code	Revisions
Unscheduled Meeting	**SOP/EC/017/05**	2. SCOPE • "Unscheduled meetings may be scheduled to review / approve new studies that require full Board review" is modified as "Unscheduled meetings may be scheduled to review / approve new studies that require full Board review during the interim period between two IEC Meetings conducted for the sake of conserving valuable time and timely scrutiny and approval of projects of immense national / international importance or in case there are too many projects to be reviewed in the routine meeting" 3. RESPONSIBILITY • "NIRT-IEC MS will request for an unscheduled meeting stating the reasons in the routine IEC meeting and fix the date after consensus decision" is modified as "As per the request of the Head of the Institution, NIRT-IEC MS will request for an unscheduled meeting stating the reasons and fix the date of IEC

		Meeting in consensus with Head of the Institution, Chair and Vice-chair" 5.1. Fixing the date of Unscheduled meeting • "During the scheduled NIRT-IEC meeting, the IEC MS will request the IEC members for an unscheduled meeting mentioning the reasons" is modified as "If the reason for organizing the meeting is due to too many proposals, then the decision is taken in the preceding scheduled NIRT-IEC meeting and the IEC MS will request the IEC members for an available date mentioning the reasons in consensus with Chair, Vice-Chair and Head of the Institution" The following point has been included • The usual timelines for submission to IEC Secretariat, Circulation to Lead Discussants will be waived. The following point has been included: • The date of the unscheduled meeting will be fixed following a consensus decision.

SOP Number: SOP/EC/017	Revision Number: 05	
SOP Authors: Dr D Bella Devaleenal Signature Dr G Narendran Signature	SOP Approver: Dr R Sridhar (Chair IEC) Signature Dr C Padmapriyadarsini (Director) Signature	Effective Date : 18 May 2022 Supersedes : (Doc. version & Date) Version 4.0, dated 04 October 2018

1. PURPOSE

The purpose of this SOP is:

to define and determine logistics for calling an unscheduled meeting; in order to provide instructions on the review and approval of study activities using the Unscheduled Meeting Procedure.

2. SCOPE

This SOP applies to calling and conducting Unscheduled meetings of NIRT-IEC.

Unscheduled meetings may be scheduled to review / approve new studies that require full Board review during the interim period between two IEC Meetings conducted for the sake of conserving valuable time and timely scrutiny and approval of projects of immense national/international importance or in case there are too many projects to be reviewed in the routine meeting.

3. RESPONSIBILITY

As per the request of the Head of the Institution, NIRT-IEC MS will request for an unscheduled meeting stating the reasons and fix the date of IEC Meeting in consensus with Head of the Institution, Chair and Vice-chair.

The same procedure will be followed as per ICMR guidelines for emergency approvals during Public Health Emergencies. Meeting will be held as per physical/ virtual platform based on the facilities available during emergency period with permission from Head of the Institution and Chairperson of the Ethics.

4. FLOW CHART

No.	Activity	Responsibility
1	Fixing the date of Unscheduled meeting	Chair, Vice-Chair and Head of the Institution
	↓	
2	Preparing for the Unscheduled meeting	NIRT-IEC Secretariat
	↓	
3	Proposal review during the meeting	NIRT-IEC Members
	↓	
4	After the meeting	NIRT-IEC Secretariat

5. DETAILED INSTRUCTIONS

5.1. Fixing the date of Unscheduled meeting

- The NIRT-IEC MS will decide to call an Unscheduled meeting based on appropriate reasons, need based urgency and importance of the study proposed as communicated by the Head of the Institution.
- The usual timelines for submission to IEC Secretariat, Circulation to Lead Discussants will be waived as appropriate.
- If the reason for organizing the meeting is due to too many proposals, then the decision is taken in the preceding scheduled NIRT-IEC meeting and the IEC MS will request the IEC members for an available date mentioning the reasons in consensus with Chair, Vice-Chair and Head of the Institution.

5.2. Preparing for Unscheduled meeting

- The NIRT-IEC Secretariat prepares the documents for distribution to the members.
- Refer to the relevant SOPs
  SOP/EC/007/05 - Management of protocol submission
  SOP/EC/008/05 - Initial review of submitted protocols
  SOP/EC/010/05 – Expedited review
  SOP/EC/016/05 - Agenda Preparation, IEC Meeting Procedures and Minutes
- During the preparation of Unscheduled meeting use the Format for Un - scheduled meeting agenda ***(Annexure code: AF/EC/038/05)*** and PI intimation on list of new protocols for IEC review ***(Annexure code: AF/EC/039/05)***

5.3. Proposal review during the meeting

- Determine if there is a quorum.
  Follow the relevant SOPs
  SOP/EC/008/05 - Initial review of submitted protocols

SOP/EC/016/05 - Agenda Preparation, IEC Meeting Procedures and Minutes

5.4. After the meeting

Follow the related **SOP/EC/016/05 -** Agenda Preparation, IEC Meeting Procedures and Minutes

Use the Format for Un-scheduled IEC meeting minutes ***(Annexure code: AF/EC/037/05)*** for the preparation of minutes.

6. ANNEXURE

Annexure Code	Annexure title
AF/EC/037/05	Format for IEC meeting minutes
AF/EC/038/05	Format for Unscheduled meeting agenda
AF/EC/039/05	PI intimation on list of new protocols for IEC review

7. RELEVANT SOPs

SOP Code	SOP Title
SOP/EC/007/05	Management of Protocol Submissions
SOP/EC/008/05	Initial Review of Submitted Protocols
SOP/EC/010/05	Expedited Review
SOP/EC/016/05	Agenda Preparation, IEC Meeting Procedures and Minutes

GLOSSARY

Expedited review	A review process by only two to three NIRT-IEC members, as deemed appropriate, who then report the decision to the full Board meeting. An expedited review is a *speedy* one for minor *changes to the approved protocol* and for *research proposal* with *minimal risk in nature*.
Full board review	A review process by all the NIRT-IEC members in a full Board meeting for a consensus decision making
IEC	Institutional Ethics Committee is an independent body whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection.
IEC members	Individuals serving as regular and alternate members on the institute's operational boards (i.e., IEC membership). These boards are constituted in accordance with the EC membership requirements set forth in ICMR Ethical guidelines for Biomedical research involving human participants
Meeting	Deliberations between at least two (2) persons where such deliberations determine or result in the joint conduct or disposition of business.
Minutes	An official record of the business discussed and transacted at a meeting, ..
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.

Annexure Code: AF/EC/037/05

Format for IEC meeting minutes

No: Date:

Minutes of the Committee Meeting

Venue:
Date & Time :

At the **Unscheduled** meeting of **date** , the following members were in attendance:

Name	Capacity
	: Chairperson (Non-Affiliate)
	: Member Secretary (Affiliate)

Non-Affiliate Members

Affiliate Members

Administrative Staff

The meeting was called to order at **Time**.

Chair, Director, Member-Secretary and other's remarks

The meeting proceeded to the discussion on the new protocols.

Review of New Protocols and Resubmissions

NIRT-IEC No "**Title "** PI name : , Designation

List of documents reviewed:

Discussion: Name of PI, Designation presented the project details.

Lead Discussant 1:

Lead Discussant 2:

The protocol was reviewed along with the associated documents.

Discussions

Risk/Benefit ratio:

Following a consensus opinion, the protocol and all the submissions were **approved** / requested to be **re-submitted** with the following recommendations:

If approved,

Ongoing Reviews to be conducted:

Other types of submissions that could be entertained in the Meeting:

Note to PI:

Review of Protocol Amendments

NIRT-IEC No "**Title "** PI name : , Designation (Approved on date)

Name of presenter:

Discussion:

Decision:

Review of Ongoing studies

NIRT-IEC No "**Title "** PI name : , Designation (Approved on date)

Name of presenter:

Discussion:

Decision:

Review of Completed studies

NIRT-IEC No "**Title "** PI name : , Designation (Approved on date)

Name of presenter:

Discussion:

Decision:

Review of "Yet to be initiated" studies

NIRT-IEC No **"Title "** PI name : , Designation (Approved on date)

The MS briefed the committee members on the study status.

Discussion:

Decision:

Ratification of new protocol approved by expedited / exempt process

NIRT-IEC No "**Title "** PI name : , Designation (Approved on date)

List of documents reviewed:

The MS informed the committee that the above mentioned protocol and associated documents were submitted to the Chair and Vice-Chair for expedited / exempt review and was approved.

The MS briefed the committee members on the study details.

The committee ---------- the decision of expedited /exempt approval.

Ratification of protocol amendments approved by expedited process

NIRT-IEC No "**Title "** PI name : , Designation (Approved on date)

List of documents reviewed:

The MS informed the committee that the above mentioned protocol and associated documents were submitted to the Chair and Vice-Chair for expedited review and was approved.

The MS briefed the committee members on the amendments.

The committee ---------- the decision of expedited approval.

Review of SAE, ratification of SRC meeting minutes and compensation and perusal of Central SAE committee decision (if applicable)

NIRT-IEC No "**Title "** PI name : , Designation (Approved on date)

The MS briefed the committee members on the study details.
Discussion & decisions

Review of protocol deviations

NIRT-IEC No "**Title "** PI name : , Designation (Approved on date)

The MS briefed the committee members on the study details.
Discussion & decisions

The meeting was adjourned at Time.

Date: **Signature of Chair**

Annexure Code: AF/EC/038/05

Format for Unscheduled meeting agenda

Date and Time of meeting:

Venue of meeting:

NIRT-IEC Chairperson and Director's remarks including reason for conducting the unscheduled meeting

Review of activities – Member Secretary

- Others as applicable

Declaration of Conflict of Interest:

Review of New Protocols

NIRT IEC No ---------- "**Title of study"** Name of PI, Designation and Affiliation

Lead Discussant 1:

Lead Discussant 2:

Ratification of new protocols approved by expedited / exempt process

NIRT IEC No---------- "**Title of study"** Name of PI, Designation and Affiliation

Ratification of protocol amendments approved by expedited process

NIRT IEC No---------- "**Title of study"** Name of PI, Designation and Affiliation

Review of SAE, ratification of SRC meeting minutes and compensation, perusal of Central SAE Committee decision (if applicable)

Review of protocol deviations

Any other, as decided by the Chair, Member Secretary

Annexure Code: AF/EC/039/05

PI intimation on list of new protocols for IEC review
(Through e-mail)

Dear ----------

The NIRT-IEC meeting is scheduled to be held on **date, time, venue.**

Please find the attached list of new protocols to be reviewed in the meeting.

Please be prepared for a presentation of approximately 15 - 20 mts duration for the new protocol review.

You are requested to attend.

Yours Sincerely

Member-Secretary

NIRT-IEC

ATTACHMENT DETAILS

List of new protocols to be reviewed at the NIRT-IEC meeting on date, venue

S.NO	NIRT IEC NO	Protocol Title	Name of the PI, Designation

Acknowledgement of awareness of this SOP

S.No	Name	Capacity	Signature	Date
1.	Dr R Sridhar	Chairperson		
2.	Dr R Arun Kumar	Vice-Chairperson		
3.	Dr G Narendran	Member Secretary		
4.	Dr K Lily Therese	Member (Non-Affiliate)		
5.	Dr S Swarnalakshmi	Member (Non-Affiliate)		
6.	Dr Shyamala Nataraj	Member (Non-Affiliate)		
7.	Mrs Rajalakshmi	Member (Non-Affiliate)		
8.	Mrs Renu Lamech	Member (Non-Affiliate)		
9.	Dr V Gowri	Member (Non-Affiliate)		
10.	Mr D Sairamkumar	Member (Non-Affiliate)		
11.	Mrs Pushkala	Member (Non-Affiliate)		
12.	Dr S Chandrasekar	Member (Non-Affiliate)		
13.	Dr P M Ramesh	Member (Non-Affiliate)		
14.	Dr Padma Srikanth	Member (Non-Affiliate)		
15.	Dr Shuba Kumar	Member (Non-Affiliate)		
16.	Dr K R Uma Devi	Member (Affiliate)		
17.	Dr Luke Elizabeth Hanna	Member (Affiliate)		
18.	Dr Bella Devaleenal	Member (Affiliate)		
19.	Dr M Muniyandi	Member (Affiliate)		
20.	Dr P K Bhavani	Member (Affiliate)		
21.	Dr R Balaji	Member (Affiliate)		

SOP Code: SOP/EC/018/05

9.1. Maintenance of Active study files

Revisions in the Standard Operating Procedures from version 4.0, dated 4 October 2018 to version 5.0, dated 18 May 2022

The following revisions are made in the Standard Operating Procedures from version 4.0, dated 4 October 2018 to Version 5.0, dated 18 May 2022 following the revision in the National Ethical guidelines for Biomedical and Health Research involving human participants, ICMR 2017 and NDCT Guidelines 2019.

Title of Standard Operating Procedure (SOP)	SOP Code	Revisions
Maintenance of Active study files	**SOP/EC/018/05**	5.2. Maintain the active study files • "Send all closed study files to archive" is modified as "Send all the soft copies of closed study files to archive" • "Store the closed study files for at least 3 years after the study closure" is modified as "Store the hard copies of the closed study files for *at least 3 years* after the study closure after which it will be disposed off with permission from Head of the Institution; for clinical trials, it will be 5 years from completion of the trial" The following points have been included: • Due to Covid Mandated changes, hard copies were not stored as the IEC meetings were purely conducted in the Virtual platform. However, the soft copies have been duly maintained.

STANDARD OPERATING PROCEDURES
Version 5.0, dated 18 May 2022

SOP Number: SOP/EC/018	Revision Number: 05	
SOP Author: **Dr P K Bhavani** **Signature**	**SOP Approver:** **Dr R Sridhar (Chair IEC)** **Signature**	**Effective Date :** **18 May 2022**
	Dr C Padmapriyadarsini **(Director)** **Signature**	**Supersedes :** **(Doc. version & Date)** **Version 4.0, dated 4 October 2018**

1. PURPOSE

To provide instructions for preparation and maintenance of active study files and other related documents approved by the NIRT-IEC

2. SCOPE

This SOP applies to all active study files and their related documents that are maintained in the NIRT-IEC Secretariat.

3. RESPONSIBILITY

It is the responsibility of NIRT-IEC Secretariat to ensure that all study files are prepared, maintained and kept securely for a period of three years after completion of the study under a proper system that ensures confidentiality and facilitates retrieval at any time.

4. FLOW CHART

No.	Activity	Responsibility
1	Organize the contents of the active study files	NIRT-IEC Secretariat
	↓	
2	Maintain the active study files	NIRT-IEC Secretariat

5. DETAILED INSTRUCTION

5.1. Organize the contents of the active study files

- NIRT-IEC Secretariat will get the master copy of the study protocol and related documents.
- They will create a study specific file with the number assigned by the NIRT-IEC written on the file cover. After Covid pandemic, soft copies of the study specific file is stored in the computer with access control.
- Check if a study file contains all submitted and approved documents, to include, the following documents:
  - Original applications and any updates received during the study.
  - Investigator's brochures or similar documents
  - Approval letters and other correspondence sent to the investigator.
  - Documents with the version no. and date (protocols, amendment if any, Informed consent documents with translations in the relevant languages, advertising materials, CRF etc.)
  - Adverse reports or Investigational New Drug (IND) safety reports received
  - Ongoing review forms and reports
  - Final report
  - Any other, as applicable

5.2. Maintain the active study files

- Assign the approved study files with unique number given by the IEC Secretariat
- Combine related documents of the approved study files appropriately.
- Keep all active and potential study packages in a secure file cabinet.
- Maintain the study files in an easily accessible and secure place until the final report is reviewed and accepted by the IEC.
- Send all the soft copies of closed study files to archive.
- Store the hard copies of the closed study files for ***at least 3 - 5 years*** after the study closure after which it will be disposed off with permission from Head of the Institution **(SOP/EC/019/05);** for clinical trials, it will be 5 years from completion of the trial.
- Due to Covid Mandated changes, hard copies were not stored as the IEC meetings were purely conducted in the Virtual platform. However, the soft copies have been duly maintained and kept under access control.

6. RELEVANT SOPs

SOP Code	SOP Title
SOP/EC/19/05	Archival and Retrieval of documents

GLOSSARY

Case report form	Case Record Form or Case Report Form is a printed, optical or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial participant.
Document	Documents mean the following: - Study Protocols and related documents (such as case report forms, informed consents, diary forms, scientific documents, reports, records, expert opinions or reviews) - IEC documents (SOPs, meeting minutes, and decisions) - Correspondance (experts, Study participants, etc.) of any forms, such as printed or written papers, hard copies, electronic mails (e-mail), faxes, audio or video tapes, etc.
IEC	Institutional Ethics Committee is an independent body whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection.
Informed Consent Document	Informed Consent Document is a written, signed and dated paper confirming participant's willingness to voluntarily participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the participant's decision to participate.
Investigational New Drugs (IND)	Investigational New Drugs means substance with potential therapeutic actions during the process of scientific studies in humans in order to verify their potential effects and safety for human use and to get approval for marketing.
Investigator's brochure	Investigator's brochure is a compilation of the clinical and nonclinical data on the investigational product(s) that are relevant to the study of the product(s) in human subjects..
Ongoing review	Review of IEC approved studies at periodic intervals
Protocol	A document that describes the objective (s), design, methodology, statistical considerations, and organization of the study
Protocol amendment	A written description of a change(s) to or formal clarification of
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.

Secretariat	An office responsible for the secretarial, clerical, and administrative affairs of NIRT-IEC
Study file	Approved and supporting and documents (protocols, protocol amendments, informed consents, advertisements, investigator and site information), records containing communications and correspondence with the investigator, and reports (including but not limited to Continuing Review Reports, IND Safety Reports, reports of injuries to subjects, scientific evaluations) that correspond to each study approved by the *NIRT-IEC*

Acknowledgement of awareness of this SOP

S.No	Name	Capacity	Signature	Date
1.	Dr R Sridhar	Chairperson		
2.	Dr R Arun Kumar	Vice-Chairperson		
3.	Dr G Narendran	Member Secretary		
4.	Dr K Lily Therese	Member (Non-Affiliate)		
5.	Dr S Swarnalakshmi	Member (Non-Affiliate)		
6.	Dr Shyamala Nataraj	Member (Non-Affiliate)		
7.	Mrs Rajalakshmi	Member (Non-Affiliate)		
8.	Mrs Renu Lamech	Member (Non-Affiliate)		
9.	Dr V Gowri	Member (Non-Affiliate)		
10.	Mr D Sairamkumar	Member (Non-Affiliate)		
11.	Mrs Pushkala	Member (Non-Affiliate)		
12.	Dr S Chandrasekar	Member (Non-Affiliate)		
13.	Dr P M Ramesh	Member (Non-Affiliate)		
14.	Dr Padma Srikanth	Member (Non-Affiliate)		
15.	Dr Shuba Kumar	Member (Non-Affiliate)		
16.	Dr K R Uma Devi	Member (Affiliate)		
17.	Dr Luke Elizabeth Hanna	Member (Affiliate)		
18.	Dr Bella Devaleenal	Member (Affiliate)		
19.	Dr M Muniyandi	Member (Affiliate)		
20.	Dr P K Bhavani	Member (Affiliate)		
21.	Dr R Balaji	Member (Affiliate)		

SOP Code: SOP/EC/019/05

9.2. Archival and Retrieval of Documents

Revisions in the Standard Operating Procedures from version 4.0, dated 4 October 2018 to version 5.0, dated 18 May 2022

The following revisions are made in the Standard Operating Procedures from version 4.0, dated 4 October 2018 to Version 5.0, dated 18 May 2022 following the revision in the National Ethical guidelines for Biomedical and Health Research involving human participants, ICMR 2017 and NDCT Guidelines 2019.

Title of Standard Operating Procedure (SOP)	SOP Code	Revisions
Archival and Retrieval of Documents	**SOP/EC/019/05**	2. Scope The following point has been included: • This SOP is confined to studies that have been completed and completion report approved. For all other studies, routine email communications to Ethics Secretariat justifying the reason for request would suffice. 5.1. After receiving the study final study report The following point has been included: • The IEC Secretariat will circulate to IEC Members. 5.3. Retrieving Documents • "Retrieval of documents can only be done with an IEC Document request form signed and dated by the IEC MS" is modified as "Retrieval of documents can only be done with an IEC Document request form signed

		and dated by the IEC MS after obtaining appropriate permission from the Head of the Institution and the signature of the person requiring these documents through a signed confidentiality agreement form"

SOP Number: SOP/EC/019	Revision Number: 05	
SOP Author: Dr Luke Elizabeth Hanna Signature Luke Elizabeth Hanna	SOP Approver: Dr R Sridhar (Chair IEC) Signature	Effective Date : 18 May 2022
	Dr C Padmapriyadarsini (Director) Signature	Supersedes : (Doc. version & Date) Version 5.0, dated 04 October 2018

1. PURPOSE

To provide instructions for storing closed study files and administrative documents in a secure manner while maintaining access for review by auditors and inspectors.

2. SCOPE

- This SOP is confined to studies that have been completed and completion report approved. For all other studies, routine email communications to Ethics Secretariat justifying the reason for request would suffice.

3. RESPONSIBILITY

It is the responsibility of the IEC Secretariat to maintain closed study files and administrative documents for the specified period of time.

4. FLOW CHART

No.	Activity	Responsibility
1	Receipt of the final study report	IEC secretariat
	↓	
2	Review and decision on closure of study file	IEC Members
	↓	

3	Archival of study files and administrative documents	IEC secretariat
	↓	
4	Retrieval of documents when required	IEC secretariat

5. DETAILED INSTRUCTION

5.1. After receiving the final study report

- The IEC Secretariat will circulate to IEC Members.
- IEC Members will review the Final Report of the study.
- IEC will approve the final report and give the approval to close the study **(**refer to **SOP /EC/014/05).**

5.2. Archival of study and administrative documents

- The IEC Secretariat will remove the study file from the active study filing area and place it in the area marked for storing completed study files.
- Enter the number of the completed study into the data base under the head 'completed studies'. Maintain a list of closed study documents and administrative documents
  (Administrative documents include past board membership information, correspondence, etc.)
- Place the documents in the appropriate storage area, so that it may be easily retrieved.

5.3. Retrieval of Documents

- Retrieval of documents can only be done with an IEC Document request form ***(Annexure code: AF/EC/040/05)*** signed and dated by the IEC MS after appropriate permission from the Head of the Institution and after obtaining the signature of the person requiring these documents through a signed confidentiality agreement form.
- The requestor must also sign and date the log of requested IEC documents ***(Annexure code: AF/EC/041/05)***
- The Secretariat will retrieve the archived documents as per the request.
- If the requestor requires Xerox copies of any of the archived documents, it will be provided after submission of a request through a separate letter addressed to the Head of the Institution. The Secretariat will provide the copies to the requestor after obtaining signature in the confidentiality agreement form(refer to **SOP/EC/020/05)**
- The Secretariat will return the file back to its place.
- The Secretariat will record when the document has been returned for storage with sign and date.

6. ANNEXURE

Annexure Code	Annexure title
AF/EC/040/05	IEC Document Request Form
AF/EC/041/05	Log of Requested IEC Documents

7. RELEVANT SOPS

SOP Code	SOP Title
SOP/EC/014/05	Review of Final Reports
SOP/EC/020/05	Maintaining Confidentiality of IEC Documents

GLOSSARY

Document	Documents mean the following: - Study protocols and study related documents (such as case report forms, informed consent forms, diary forms, scientific documents, reports, records, expert opinions or reviews) - IEC documents (SOPs, meeting minutes, decisions) - Correspondence (experts, study participants, etc.) of any form such as printed or written papers, electronic mails (e-mail), faxes, audio or video tapes, etc.
IEC	Institutional Ethics Committee is an independent body whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a clinical trial or research study and to provide public assurance of their protection.
IEC members	Individuals serving as regular and alternate members on the institute's operational board (i.e., IEC membership). This board is constituted in accordance with the EC membership requirements set forth in the ICMR Ethical guidelines for Biomedical research involving human participants.
Secretariat	An office responsible for the secretarial, clerical, and administrative affairs of NIRT-IEC.
Study file	Approved study related documents (protocols, protocol amendments, informed consent forms, advertisements, investigator and site information), records (communications and correspondence with the investigator), and reports (including but not limited to Continuing Review Reports, IND Safety Reports, Reports of injuries to subjects, Scientific Evaluations) approved by the NIRT-IEC.

Annexure Code: AF/EC/040/05

IEC Document Request Form

Name of Document requested:	Date
Requested by:	
☐ IEC Chair ☐ PI of study ☐ Non-affiliated IEC Member	
☐ Other Authorities	
Purpose of the request:	
Signature of the requestor:	
TO BE FILLED BY NIRT-IEC SECRETARIAT	
Retrieved by:	Date & time:
Returned by:	Date & time:
Archived by:	Date & time:
Approved by:	Date & time:

Annexure Code: AF/EC/041/05

Log of Requested IEC Documents

#	Name of IEC document	# of Copies	Name of Recipient	Signature of Recipient	Secretariat Initials	Date

Acknowledgement of awareness of this SOP

S.No	Name	Capacity	Signature	Date
1.	Dr R Sridhar	Chairperson		
2.	Dr R Arun Kumar	Vice-Chairperson		
3.	Dr G Narendran	Member Secretary		
4.	Dr K Lily Therese	Member (Non-Affiliate)		
5.	Dr S Swarnalakshmi	Member (Non-Affiliate)		
6.	Dr Shyamala Nataraj	Member (Non-Affiliate)		
7.	Mrs Rajalakshmi	Member (Non-Affiliate)		
8.	Mrs Renu Lamech	Member (Non-Affiliate)		
9.	Dr V Gowri	Member (Non-Affiliate)		
10.	Mr D Sairamkumar	Member (Non-Affiliate)		
11.	Mrs Pushkala	Member (Non-Affiliate)		
12.	Dr S Chandrasekar	Member (Non-Affiliate)		
13.	Dr P M Ramesh	Member (Non-Affiliate)		
14.	Dr Padma Srikanth	Member (Non-Affiliate)		
15.	Dr Shuba Kumar	Member (Non-Affiliate)		
16.	Dr K R Uma Devi	Member (Affiliate)		
17.	Dr Luke Elizabeth Hanna	Member (Affiliate)		
18.	Dr Bella Devaleenal	Member (Affiliate)		
19.	Dr M Muniyandi	Member (Affiliate)		
20.	Dr P K Bhavani	Member (Affiliate)		
21.	Dr R Balaji	Member (Affiliate)		

SOP Code: SOP/EC/020/05

9.3. Maintaining confidentiality of IEC documents provided to IEC Members and PI

Revisions in the Standard Operating Procedures from version 4.0, dated 04 October 2018 to version 5.0, dated 18 May 2022

The following revisions are made in the Standard Operating Procedures from version 4.0, dated 04 October 2018 to Version 5.0, dated 18 May 2022 following the revision in the National Ethical guidelines for Biomedical and Health Research involving human participants, ICMR 2017 and NDCT Guidelines 2019.

Title of Standard Operating Procedure (SOP)	SOP Code	Revisions
Maintaining confidentiality of IEC documents provided to IEC Members and PI	**SOP/EC/020/05**	5.3. Copy Authorization • "Members of the IEC are allowed to ask for copies" is modified as "Members of the IEC are allowed to ask for copies with proper justification and reasoning" • "Researchers may request copies of their own protocol documents only" is modified as "Researchers may request copies of their own protocol documents alone which will be admitted with a mail to the IEC Secretariat and copy marked to the MS" • "The Member Secretary of the IEC may ask for help, but is responsible for maintaining confidentiality of all documents" is modified as "The Member Secretary/ IEC Secretariat is responsible for maintaining confidentiality of all documents"

		5.4. Log of Copies The following point has been included: • Due to Covid mandated changes, communications are done through e-copies as a routine. It is the duty of the respective PI to take print-out for their records.

SOP Number: SOP/EC/020	Revision Number: 05	
SOP Author: Dr M Muniyandi Signature	SOP Approver: Dr R Sridhar (Chair IEC) Signature	Effective Date : 18 May 2022
	Dr C Padmapriyadarsini (Director) Signature	Supersedes : (Doc. version & Date) Version 4.0, dated 04 October 2018

1. PURPOSE

The sources of violation of confidentiality are usually found in the day-to-day use of copies of original documents. This SOP therefore describes how to handle request for copies of documents and protection of confidentiality of documents.

2. SCOPE

This SOP applies to all kinds of handling, distribution and storage of submitted study protocols, IEC documents, and correspondence with experts, auditors and the general public.

3. RESPONSIBILITY

Maintaining confidentiality of study protocols, IEC documents, and correspondence with experts and auditors is mandatory. IEC members, Secretariat staff, and others as appropriate would have signed confidentiality agreements with the NIRT-IEC.

4. FLOW CHART

No.	Activity	Responsibility
1	Access to IEC documents	IEC members and Secretariat
	↓	
2	Classify confidential documents	IEC Secretariat

	↓	
3	Copy confidential documents	IEC Secretariat
	↓	
4	File 'Log of Copies' given from IEC	IEC Secretariat

5. DETAILED INSTRUCTIONS

5.1. Access to IEC Documents

5.1.1. Members of the IEC

- Shall have access to all IEC documents.
- Are free to request copies of original documents to be perused within the institute.

5.2. Classify confidential documents

- **Types of documents**

The types of documents includes but not exclusive of :

- Study protocols and related documents (blank forms of case report forms, informed consent documents, diary forms, scientific documents, expert opinions or reviews)
- Administrative documents
- IEC documents (SOPs, meeting minutes, advice and decisions)
- All correspondances to regulatory authorities.
- Insurances and SOPs

5.3. Copy Authorization

- Members of the IEC are allowed to ask for copies with proper justification and reasoning.
- Researchers may request copies of their own protocol documents alone which will be admitted with a mail to the IEC Secretariat and copy marked to the MS.
- Only staff members of the Secretariat of the IEC are allowed to make such copies of the requested documents.
- The Member Secretary/ IEC Secretariat is responsible for maintaining confidentiality of all documents.

5.4. Log of Copies

- A Log of Requests for IEC Documents ***(Annexure code: AF/EC/041/05)*** must be kept by the Secretariat.
- The log should include: the name and signature of the individual receiving the copy; the initial of the IEC Secretariat staff who made the copy; the number of copies made and the date that the copies were made.
- Due to Covid mandated changes, communications are done through e-copies as a routine. It is the duty of the respective PI to take print-out for their records.

6. ANNEXURE

Annexure No.	Annexure Code	Annexure title
Annexure 1	AF/EC/006/05	Confidentiality agreement form (Members / Non- Members)
Annexure 2	AF/EC/041/05	Log of Requested IEC Documents

GLOSSARY

Confidentiality	Prevention of disclosure, to other than authorized individuals, of IEC's information and documents
Document	Documents mean the following: - Study Protocols and related documents (such as case report forms, informed consents, diary forms, scientific documents, reports, records, expert opinions or reviews) - IEC documents (SOPs, meeting minutes, and decisions) - Correspondence (experts, study participants, etc.) of any forms, such as printed or written papers, hard copies, electronic mails (e-mail), faxes, audio or video tapes, etc.
IEC	Institutional Ethics Committee is an independent body whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection.
IEC members	Individuals serving as regular members on the institute's operational boards (i.e., IEC membership). These boards are constituted in accordance with the EC membership requirements set forth in ICMR Ethical guidelines for Biomedical research involving human participants
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.
Secretariat	An office responsible for the secretarial, clerical, and administrative affairs of NIRT-IEC

Annexure Code - AF/EC/006/05

Confidentiality Agreement Form

Date: ___ / ___ / _____

From

To

The Chairperson
Institutional Ethics Committee
ICMR-National Institute for Research in Tuberculosis
No: 1, Sathyamoorthy Road, Chetput
Chennai – 600 031, Tamil Nadu, India.

Sir / Madam,

I do hereby agree not to use the National Institute for Research in TB - Institutional Ethics Committee (NIRT-IEC) related confidential and proprietary information for personal gain, nor disclose such information to third parties (other than in the course of performing my ethics committee related duties), nor copy or reproduce such information in any medium, except where I am required to do so by law, regulation, or court order. I understand that my obligation to abide by this 'confidentiality statement' shall continue indefinitely, even though my service with NIRT-IEC may end.

Thanking you.

Yours Sincerely,

Signature

Cc :
The Director, National Institute for Research in TB

Annexure Code: AF/EC/041/05

Log of Requested IEC Documents

#	Name of IEC document	# of Copies	Name of Recipient	Signature of Recipient	Secretariat Initials	Date

Acknowledgement of awareness of this SOP

S.No	Name	Capacity	Signature	Date
1.	Dr R Sridhar	Chairperson		
2.	Dr R Arun Kumar	Vice-Chairperson		
3.	Dr G Narendran	Member Secretary		
4.	Dr K Lily Therese	Member (Non-Affiliate)		
5.	Dr S Swarnalakshmi	Member (Non-Affiliate)		
6.	Dr Shyamala Nataraj	Member (Non-Affiliate)		
7.	Mrs Rajalakshmi	Member (Non-Affiliate)		
8.	Mrs Renu Lamech	Member (Non-Affiliate)		
9.	Dr V Gowri	Member (Non-Affiliate)		
10.	Mr D Sairamkumar	Member (Non-Affiliate)		
11.	Mrs Pushkala	Member (Non-Affiliate)		
12.	Dr S Chandrasekar	Member (Non-Affiliate)		
13.	Dr P M Ramesh	Member (Non-Affiliate)		
14.	Dr Padma Srikanth	Member (Non-Affiliate)		
15.	Dr Shuba Kumar	Member (Non-Affiliate)		
16.	Dr K R Uma Devi	Member (Affiliate)		
17.	Dr Luke Elizabeth Hanna	Member (Affiliate)		
18.	Dr Bella Devaleenal	Member (Affiliate)		
19.	Dr M Muniyandi	Member (Affiliate)		
20.	Dr P K Bhavani	Member (Affiliate)		
21.	Dr R Balaji	Member (Affiliate)		

SOP Code: SOP/EC/021/05

3.2. Protocol review with Assessment forms

SOP Number: SOP/EC/021	Revision Number: 05	
SOP Author: **Dr R Balaji** **Signature**	**SOP Approver:** **Dr R Sridhar** **(Chair IEC)** **Signature**	**Effective Date :** **18 May 2022**
	Dr C Padmapriyadarsini **(Director)** **Signature**	**Supersedes :** **(Doc. version & Date)** **Version 4.0, dated 04 October 2018**

1. PURPOSE

This SOP describes how the NIRT-IEC members use the assessment forms while reviewing the study protocols initially submitted for approval (full board review / expedited review). The Protocol Assessment Form and Lead Discussant Assessment form are designed to standardize the review process and to facilitate reporting, recommendation and comments given to each individual protocol.

2. SCOPE

This SOP applies to the review and assessment of all protocols submitted for initial review and approval from the NIRT-IEC. The specific questions in the Assessment Form must be adequately addressed in the protocol itself and/or protocol-related documents under review.

Relevant points made during discussion and deliberation about a specific protocol should be recorded in the form.

3. RESPONSIBILITY

It is the responsibility of the Lead Discussants to fill the assessment form along with decision and comments they might have after reviewing each study protocol. The NIRT-IEC Secretariat is responsible for recording and filing the decision, relevant points and deliberation about a specific protocol.

Lead Discussants for initial review of protocols will be assigned by MS in consultation with the Chair from among the IEC members - Lead Discussant-1 will be the subject expert and Lead Discussant-2 will be the lay representative. PI will be invited to present the protocol to the board in case of full board review. Lead Discussant-1 will lead the discussions on the protocol and Lead Discussant-2 will discuss in detail about the informed consent form and any other relevant points.

The reviewers for the Expedited Review process are the Chair, Vice- Chair / Non-affiliate member who is a subject expert.

4. Flow chart

No.	Activity	Responsibility
1.	Summarize the protocol general information in Protocol Assessment Form	NIRT-IEC Secretariat
	↓	
2.	Review the Study Protocol	NIRT-IEC Lead Discussants
	↓	
3.	Examine qualification of Investigators and study sites	NIRT-IEC Lead Discussants
	↓	
4.	Review the informed consent process	NIRT-IEC Lead Discussant
	↓	
5.	Examine community involvement and impact	NIRT-IEC Lead Discussant
	↓	
6.	Fill in the Assessment form / Email to IEC Secretariat	NIRT-IEC Lead Discussants
	↓	
7.	Gather Assessment Reports electronically or soft copies	NIRT-IEC Secretariat

5. Detailed instructions

5.1 Summarize the protocol in the Protocol Assessment Form

The NIRT-IEC Secretariat will record general information about the protocol in the Lead Discussant Assessment form ***(Annexure code AF/EC/043/05)*** such as:

- NIRT-IEC No.
- Title of the protocol
- Protocol Version No. & date
- Reviewer's name
- Date

- The protocol and the associated documents along with the assessment form will be sent to the IEC members 2 weeks ahead of the full board meeting.
- In addition, the Lead Discussants among the IEC members will be identified and sent the Lead Discussant Assessment form ***(Annexure code AF/EC/043/05)***
- They will be requested to bring the filled-in assessment form for the board meeting to facilitate review, discussion and decision making. During Covid,

the email communication was taken as the approval due to difficulty in retrieving these documents and that the IEC was conducted in virtual platform.

- Protocol assessment form ***(Annexure code AF/EC/043/05- Part I)*** will be used for exempt from review and initial expedited review decisions.

5.2. Review the study protocol

The Lead Discussants will review and assess the protocol and associated documents for the following

- Need for human participants for study
- Objectives of the study
- Review of literature
- Sample size
- Methodology and data management
- Inclusion/exclusion criteria
- Control arms (placebo, if any)
- Withdrawal or discontinuation criteria
- ***Examine the qualification of investigators and of study sites***.
  - Consider whether study and training background of the participating investigators related to the study
  - Examine disclosure or declaration of potential conflicts of interest
  - Can facilities and infrastructure at study sites accommodate the study?
  - Non-physician principal investigators (PI) should be advised by a physician when necessary.

  - ***Review the informed consent process***
    - Voluntary, non-coercive recruitment/participation/withdrawal
    - Procedures for obtaining informed consent
    - Contents of the patient information sheet - title, objective, study design and procedures
    - Contents and language of the informed consent document
    - Translation of the informed consent document in the local language used – plain and easy to understand by general public
    - Contact persons with address and phone numbers for questions about participant's rights and study or injury
    - Privacy and confidentiality
    - Risks and discomforts – physical / mental / social
    - Alternative treatment
    - Benefits – to participants and to others
    - Compensation for participation / for injury – reasonable / unreasonable
    - Involvement of vulnerable participants

- Provisions for medical/psychosocial support
- Treatment for study related injuries
  - Use of biological materials
  - New Findings / information
  - Authorization or Release of information
  - Copy of signed and dated consent form
  - Signatures with dates of participant, person conducting informed consent discussion, investigator and witness

- ***Examine community involvement and impact***.
  - Community consultation
  - Involvement of local researchers and institutions in the protocol design, analysis and publication of the results
  - Contribution to development of local capacity for research and treatment
  - Benefit to local communities
  - Availability of study results

5.3. During the board meeting

- After the PI presents the study, the IEC members will discuss the protocol based on the observations made by the Lead Discussant in the Lead Discussant Assessment form ***(Annexure code AF/EC/043/05)*****. (Refer to SOP/EC/008/05).**
- The Lead Discussants will initiate the discussion.
- The Lead Discussants will give the signed and dated Lead Discussant Assessment form ***(Annexure code AF/EC/043/05)*** to the NIRT-IEC Secretariat after the discussions and decision making process in the board meeting

5.4. Gather the assessment report

- The NIRT-IEC Secretariat will collect the filled-in, signed and dated Lead Discussant Assessment form ***(Annexure code AF/EC/043/05)*** from each Lead Discussant.
- Organize the forms in order and file them in the respective study folders

6. Initial Expedited Review Process

- Protocol Assessment form ***(Annexure code AF/EC/043/05- Part I)*** will be sent to the reviewers of the expedited review process
- They will review the protocol and related documents and fill the Protocol Assessment form ***(Annexure code AF/EC/043/05- Part I)***

- They will send the signed filled – in form along with the expedited review decision letter ***(Annexure code: AF/EC/020/05) or*** communicate through email their comments if any in addition to approval / rejection

6. ANNEXURE

Annexure Code	Annexure title
AF/EC/043/05	Lead Discussant Form
AF/EC/043/05	Informed consent review form (Lead Discussant Form – Part II)

7. RELEVANT SOPs

SOP Code	SOP Title
SOP/EC/008/05	Initial Review of submitted protocols

GLOSSARY

Document	Documents mean the following: - Study Protocols and related documents (such as case report forms, informed consents, diary forms, scientific documents, reports, records, expert opinions or reviews) - IEC documents (SOPs, meeting minutes, and decisions) - Correspondence (experts, study participants, etc.) of any forms, such as printed or written papers, hard copies, electronic mails (e-mail), faxes, audio or video tapes, etc.
IEC	Institutional Ethics Committee is an independent body whose responsibility is to ensure the protection of the rights, safety and well-being of human participants involved in a trial and to provide public assurance of that protection.
IEC members	Individuals serving as regular and alternate members on the institute's operational boards (i.e., IEC membership). These boards are constituted in accordance with the EC membership requirements set forth in ICMR Ethical guidelines for Biomedical research involving human participants
Protocol	A document that describes the objective (s), design, methodology, statistical considerations, and organization of the study
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.
Secretariat	An office responsible for the secretarial, clerical, and administrative affairs of NIRT-IEC

Annexure Code: AF/EC/043/05

LEAD DISCUSSANT ASSESSMENT FORM

Part – 1

Protocol Assessment form

NIRT-IEC No:			**Date (D/M/Y):**		
Protocol title:					
Protocol version no. & date:					
NIRT-IEC Member name:					
1. Is SAC approval available : Yes ☐ No ☐					
2. Need for the study (Check Background & Justification sections of protocol)					
		Yes	**No**	**NA**	**Comment:**
1	Background and justification - sufficient?				
2	Literature review – adequate?				
3	Need for human participants justified?				
4	Does the study contribute to development of local capacity for Research / Treatment?				
3. Scientific value (Check Methods section of protocol)					
5	Methodology – clear and well-described?				
6	Study Design - appropriate?				
7	Is the use of placebo justified?				
8	Inclusion Criteria - appropriate				
9	Exclusion Criteria - appropriate				
10	Laboratory methods – clear, well defined and feasible?				

11	Follow-up procedures well defined?				
12	Are study end points well defined?				
13	Are unbiased assessments used?				
14	Sample size adequate?				
15	Statistical methods proposed - appropriate				
16	Is there a provision for interim analysis in interventional studies				
4. Fair participant selection (Check Methods section of protocol)					
17	Inclusion Criteria - appropriate				
18	Exclusion Criteria - appropriate				
19	Is the recruitment of participants voluntary, non-coercive				
20	Is there an Inducement for participation?				
21	Is participant deception avoided?				
5. Favourable risk-benefit ratio					
22	Risks and benefits assessment – acceptable?				
23	Are predictable risks minimized?				
24	Tests and procedures that are more than minimal risk cautiously used				
25	Provision for Medical/Psychosocial Support				
26	Is participant discontinuation and withdrawal criteria appropriate?				
27	Provision for treatment of Study-Related Injuries				
28	Provision for compensation (where applicable)				
29	Does the study benefit the individual?				
30	Does the study benefit the local community?				

6.	**Informed consent**				
31	Are procedures for obtaining informed consent appropriate (written/verbal)?				
32	Content of the information sheet and consent form clear and contain necessary details?				
33	Translations of all forms consistent?				
34	Contact details of PI given in both information sheet & consent forms?				
7.	**Respect for human participants**				
35	Privacy and confidentiality ensured				
36	Are vulnerable populations involved?				
	26.1 If yes, is it justifiable to conduct the study in that population?				
37	Are blood/ tissue samples sent abroad?				
	27.1 If samples are sent, is it mentioned in the ICF?				
38	Has the fate of the study mentioned once the study is over?				
39	Is appropriate consent included for storage of biological samples?				
8.	**Others**				
40	Are facilities and infrastructure of Participating Sites appropriate?				
41	Is community Consultation addressed if required?				
42	Is disclosure or Declaration of potential Conflicts of Interest addressed?				
43	Is the PI adequately qualified to do the study?				
44	Are qualification and experience of the Participating Investigators appropriate?				

Comments :

Decision*: Approved /Minor modification s/ Major modifications /rejected*

Part – 2 (to be filled in case of full board review)

INFORMED CONSENT REVIEW FORM

(Participant Information sheet and Informed Consent Form Checklist)

Participant Information sheet date and Version:

Informed Consent Form Date and Version:

Are the following items included in the Participant Information sheet?

A statement that the trial / study involves research	**Y**	**N**		
Purpose of the trial/ study	**Y**	**N**		
Trial// study treatments and the probability of random assignment	**Y**	**N**	**NA**	
Trial / study procedures to be followed, including all invasive procedures			**Y**	**N**
Those aspects of the trial /study that are experimental			**Y**	**N**
Expected duration of patient's participation			**Y**	**N**
Approximate number of participants involved in the trial/study			**Y**	**N**

Reasonably foreseeable risks or inconveniences to the participant		**Y**	**N**
Expected benefits to the participant (or no intended clinical benefit)		**Y**	**N**
Alternative procedures or treatments, and their potential benefits/risks		**Y**	**N**
Participant's responsibilities		**Y**	**N**
Compensation and / or treatment in the event of trial-related injury	**Y**	**N**	**NA**
Dissemination of new information in a timely manner		**Y**	**N**
Foreseeable circumstances/ reasons for termination of patient's participation		**Y**	**N**
Contact(s) for further information or in the event of trial/study-related injury		**Y**	**N**
Participation in the trial/study is voluntary. Refusal to participate, or withdrawal from the trial, at any time, is without penalty or loss of benefits to which the participant is otherwise entitled		**Y**	**N**
The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation		**Y**	**N**
The investigator will inform the participant's primary physician about the Patient's participation in the study if the participant agrees		**Y**	**N**
Anticipated prorated payment, if any	**Y**	**N**	**NA**
Anticipated prorated expenses, if any	**Y**	**N**	**NA**
Monitor, auditor, EC and regulatory authority are granted direct access to personal medical records without violating the confidentiality of the participant		**Y**	**N**
Confidentiality: personal information will not be made publicly available, including if study results are published		**Y**	**N**

Are the following items included in the Informed Consent Form (signature sheet) ?

Consent Statement	**Y**	**N**
Reference made to voluntariness, confidentiality , compensation, rights	**Y**	**N**

Consent for Storage of biological samples (if applicable**)**	**Y**	**N**
A space for participant's name / signature / date	**Y**	**N**
A space for witness name / signature / date	**Y**	**N**
A space for investigator's name / signature / date	**Y**	**N**

Other

Investigator's name, protocol #, version date, and page # of #	**Y**	**N**
Was the language used as non-technical as practical, and was it understandable to the participant ?	**Y**	**N**

Comments:

Decision*: Approved /Minor modifications/ Major modifications /rejected*

Signature of the reviewer:

Date of review (DD/MM/YY):

Acknowledgement of awareness of this SOP

S.No	Name	Capacity	Signature	Date
1.	Dr R Sridhar	Chairperson		
2.	Dr R Arun Kumar	Vice-Chairperson		
3.	Dr G Narendran	Member Secretary		
4.	Dr K Lily Therese	Member (Non-Affiliate)		
5.	Dr S Swarnalakshmi	Member (Non-Affiliate)		
6.	Dr Shyamala Nataraj	Member (Non-Affiliate)		
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17.	Dr Luke Elizabeth Hanna	Member (Affiliate)		
18.	Dr Bella Devaleenal	Member (Affiliate)		
19.	Dr M Muniyandi	Member (Affiliate)		
20.	Dr P K Bhavani	Member (Affiliate)		
21.	Dr R Balaji	Member (Affiliate)		

SOP Code: SOP/EC/0022/05

6.1. Management of Protocol non-compliance (protocol deviation / violation)

Revisions in the Standard Operating Procedures from version 4.0, dated 4 October 2018 to version 5.0, dated 28 July 2022

The following revisions are made in the Standard Operating Procedures from version 4.0, dated 4 October 2018 to Version 5.0, dated 18 May 2022 following the revision in the National Ethical guidelines for Biomedical and Health Research involving human participants, ICMR 2017 and NDCT Guidelines 2019.

Title of Standard Operating Procedure (SOP)	SOP Code	Revisions
Management of protocol non-compliance (protocol deviation / violation)	**SOP/EC/0022/05**	5.2. Board discussion and decision The following have been included: The NIRT-IEC Chair, Member Secretary and members will decide on: • continuing the study with training of study team • continuing the study with frequent monitoring • continuing the study with on-site monitoring visits • Study suspension • Study termination

SOP Number: SOP/EC/022	Revision Number: 05	
SOP Author: Dr M Muniyandi Signature	SOP Approver: Dr R Sridhar (Chair IEC) Signature	Effective Date : 18 May 2022
	Dr C Padmapriyadarsini (Director) Signature	Supersedes : (Doc. version & Date) Version 4.0, dated 28 July 2022

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.

2. SCOPE

This SOP applies to all NIRT-IEC approved research protocols involving human participants.

3. RESPONSIBILITY

The NIRT-IEC Secretariat is responsible for collecting and recording the protocol non-compliance list (protocol deviation / violation). The NIRT-IEC Chair and members are responsible to discuss and decide action for the protocol non-compliance (protocol deviation / violation)

4. FLOW CHART

No.	Activity	Responsibility
1	Collecting and recording the protocol non-compliance list (protocol deviation / violation).	NIRT-IEC Secretariat
	↓	
2	Board discussion and decision	NIRT-IEC members, MS and Chair
	↓	
3	Notify the investigator	NIRT-IEC Secretariat
	↓	
4	Keep records and follow up	NIRT-IEC Secretariat

5. DETAILED INSTRUCTIONS

5.1 Collecting and recording the list of protocol non-compliance (protocol deviation / violation)

The NIRT-IEC secretariat will

- Compile the list of protocol non-compliance (protocol deviation / violation) ***(Annexure code AF/EC/044/05)*** if reported by the Investigator / Sponsor to the IEC separately for each study.
- Ensure that the list of protocol non-compliance (protocol deviation / violation) are included in the agenda of the forthcoming NIRT-IEC meeting.

5.2 Board discussion and decision

The NIRT-IEC Chair, Member Secretary and members will

- discuss the protocol non-compliance (protocol deviation / violation) based on the risks to study participants and compliance with regulatory requirements. ***(Annexure code: AF/EC/051/05)***
- Instruct the PI through the Head of Institution for
  - ➢ continuing the study with training of study team
  - ➢ continuing the study with frequent monitoring
  - ➢ continuing the study with on-site monitoring visits
- or recommend the following
  - ➢ Study suspension
  - ➢ Study termination

5.3 Notify the investigator

- The MS record the NIRT-IEC's decision in the Protocol Deviation / Violation NIRT-IEC review report (Annexure Code **AF/EC/051/05)**.
- The IEC Secretariat will draft and type a notification letter. ***(Annexure code AF/EC/045/04)***
- Get the Chairperson to sign and date the letter.
- ➢ ICMR-NIRT-IEC Secretariat will send the original copy of the notification letter to the investigator.

5.4 Keep records and follow up

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

6. ANNEXURE

Annexure Code	Annexure title
AF/EC/044/05	Protocol Deviation / Violation notification to IEC by Principal Investigator
AF/EC/045/05	Letter to PI – Notification of Protocol Deviation / Violation
AF/EC/051/05	Protocol Deviation / Violation NIRT-IEC review report

7. GLOSSARY

Protocol deviation	Accidental or unintentional changes to, or non-compliance with the research protocol that does not increase risk or decrease benefit or; does not have a significant effect on the subject's rights, safety or welfare; and/or on the integrity of the data. A deviation may be due to the research subject's non-adherence, or an unintentional change to or non-compliance with the research protocol on the part of a researcher. Examples of a deviation include: A rescheduled study visit Failure to collect an ancillary self-report questionnaire Subject's refusal to complete scheduled research activities
Protocol violation	Accidental or unintentional change to, or non-compliance with the IEC approved protocol without prior sponsor and IRB approval. Violations generally increase risk or decrease benefit, affects the subject's rights, safety, or welfare, or the integrity of the data.

	Examples of protocol violations: Failure to obtain valid informed consent (e.g., obtained informed consent on a non-date stamped form) Loss of laptop computer that contained identifiable, private information about subjects Accidental distribution of incorrect study medication or dose Not following inclusion/exclusion criteria

Annexure Code: AF/EC/044/05

Protocol Deviation / Violation notification to IEC by Principal Investigator

NIRT-IEC No:	Date:……
Study Title:	
Principal Investigator:	Contact No.:
Sponsor:	Contact No.:

☐ Protocol deviation	☐ Protocol violation
Description:	
Impact on the participant's risk / benefit:	
Corrective measures, if any:	
Reported by:…….	Received by:…….
Date:…….	Date:…….

Annexure Code: AF/EC/051/05

Protocol Deviation / Violation NIRT-IEC review report

DATE OF NIRT-IEC MEETING:	
NIRT-IEC No:	
Study Title:	
Principal Investigator:	
Sponsor:	
☐ Protocol deviation ☐ Protocol violation	
NIRT-IEC Discussion	
NIRT-IEC Decision: ➢ continuing the study with training of study team ➢ continuing the study with frequent monitoring ➢ continuing the study with on-site monitoring visits ➢ Study suspension ➢ Study termination	
Signature of Member-Secretary: Date:	Date notified to the Principal Investigator:

Annexure Code: AF/EC/045/05

Letter to PI – Notification of Protocol Deviation / Non-Compliance / Violation

ICMR - National Institute for Research in Tuberculosis

INSTITUTIONAL ETHICS COMMITTEE

(SIDCER Recognized Ethics Committee in the Asian and Western Pacific Region)

No: 1, Mayor Sathyamoorthy Road, Chetput, Chennai – 600 031, Tamil Nadu, India

Members (Non Affiliated)

Dr.
Vice Chair

Dr.
Chairperson

Dr.
Member-Secretary

Members (Affiliated)

No: ……/ ICMR-NIRT-IEC/2022
Date: …….

To
.....
.....
.....

Sir / Madam,

Sub: ICMR-NIRT-IEC ID: ……..
"Title: ……..." – reg.

Ref: Protocol Deviation / Violation Report dated

Receipt of the Protocol Deviation / Violation to the above referenced protocol is acknowledged. This was discussed in the NIRT-IEC meeting dated ----------.

The ICMR-NIRT-IEC decision is ----------

Chair

To: Principal Investigator
cc to:
The Director, National Institute for Research in Tuberculosis

Acknowledgement of awareness of this SOP

S.No	Name	Capacity	Signature	Date
1.	Dr R Sridhar	Chairperson		
2.	Dr R Arun Kumar	Vice-Chairperson		
3.	Dr G Narendran	Member Secretary		
4.	Dr K Lily Therese	Member (Non-Affiliate)		
5.	Dr S Swarnalakshmi	Member (Non-Affiliate)		
6.	Dr Shyamala Nataraj	Member (Non-Affiliate)		
7.	Mrs Rajalakshmi	Member (Non-Affiliate)		
8.	Mrs Renu Lamech	Member (Non-Affiliate)		
9.	Dr V Gowri	Member (Non-Affiliate)		
10.	Mr D Sairamkumar	Member (Non-Affiliate)		
11.	Mrs Pushkala	Member (Non-Affiliate)		
12.	Dr S Chandrasekar	Member (Non-Affiliate)		
13.	Dr P M Ramesh	Member (Non-Affiliate)		
14.	Dr Padma Srikanth	Member (Non-Affiliate)		
15.	Dr Shuba Kumar	Member (Non-Affiliate)		
16.	Dr K R Uma Devi	Member (Affiliate)		
17.	Dr Luke Elizabeth Hanna	Member (Affiliate)		
18.	Dr Bella Devaleenal	Member (Affiliate)		
19.	Dr M Muniyandi	Member (Affiliate)		
20.	Dr P K Bhavani	Member (Affiliate)		
21.	Dr R Balaji	Member (Affiliate)		

SOP Code: SOP/EC/0023/05

6.2. Response to research participant requests / complaints

SOP Number: SOP/EC/023	Revision Number: 05	
SOP Author: **Dr M Muniyandi** **Signature**	**SOP Approver:** **Dr R Sridhar** **(Chair IEC)** **Signature**	**Effective Date :** **18 May 2022**
	Dr C Padmapriyadarsini **(Director)** **Signature**	**Supersedes :** **(Doc. version & Date)** **Version 4.0, dated 04 October 2018**

1. PURPOSE

The NIRT-IEC considers protection of the rights and welfare of the human subjects participating in a clinical investigation/research approved by the NIRT-IEC as its primary responsibility. Informed Consent documents reviewed by the NIRT-IEC routinely contain the statement, "In case of violation of your rights as a research participant you can contact the NIRT-IEC Secretariat at *phone number.*" On some occasions, the first contact for a participant/patient would be the NIRT-IEC Secretariat.

This procedure provides guidelines for dealing with and accommodating requests by participants/patients regarding their rights as a participant 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 NIRT-IEC.

3. RESPONSIBILITY

The Institute's policy designates the Secretariat of the NIRT-IEC responsible for communicating with participants/patients regarding their rights as study participants.

It is the responsibility of all NIRT-IEC Secretariat and ICMR-NIRT-IEC members acting on behalf of the NIRT-IEC to facilitate participant/patient requests within the scope of their responsibilities.

4. FLOW CHART

No.	Activity	Responsibility
1	Receive the request	NIRT-IEC Secretariat
	↓	
2	Take action	NIRT-IEC Chair and or Designated Member (Physician and Legal expert)
	↓	
3	File the request document	NIRT-IEC Secretariat

5. DETAILED INSTRUCTIONS

5.1 Receive the request.

- The NIRT-IEC secretariat will receive the inquiry or requests from research participants/patients.
- Record the request and information in the Study Participant request/complaint record form ***(Annexure code AF/EC/046/04)***
- The MS will refer the inquiry to the NIRT-IEC Chair in writing.
- The Chair shall
    - request follow-up information,
    - provide advice as required,
    - instruct to inform the other designated NIRT-IEC members (Physician and legal expert) about the inquiry,
    - instruct to convene an emergency meeting of designated NIRT-IEC members or to follow-up at the next NIRT-IEC meeting.

5.2 Take Action

- The NIRT-IEC Chair and designated members will investigate the factual details
- The MS will
    - ➢ record the minutes of the meeting and any action taken

- fill the Study Participant request /complaint the record form ***(Annexure code AF/EC/046/04)***
- sign and date the form.
- inform the research participant in writing
- report to the NIRT-IEC about the action taken and the outcomes.

5.3 File the request document

NIRT-IEC secretariat will

- Keep the Study Participant request / complaint record form ***(Annexure code AF/EC/046/04)*** in the "Participant request / complaint" file.
- Keep a copy in the study file.
- Store the file in the appropriately labeled shelf.

6. ANNEXURE

Annexure Code	Annexure title
AF/EC/046/05	Study Participant request / complaint record form

GLOSSARY

IEC	Institutional Ethics Committee is an independent body whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection.
IEC members	Individuals serving as regular and alternate members on the institute's operational boards (i.e., IEC membership). These boards are constituted in accordance with the EC membership requirements set forth in ICMR Ethical guidelines for Biomedical research involving human participants
Protocol violation	Accidental or unintentional change to, or non-compliance with the IEC approved protocol without prior sponsor and IRB approval. Violations generally increase risk or decrease benefit, affects the subject's rights, safety, or welfare, or the integrity of the data. Examples of protocol violations: Failure to obtain valid informed consent (e.g., obtained informed consent on a non-date stamped form) Loss of laptop computer that contained identifiable, private information about subjects Accidental distribution of incorrect study medication or dose Not following inclusion/exclusion criteria
Secretariat	An office responsible for the secretarial, clerical, and administrative affairs of NIRT-IEC
Study file	Approved and supporting and documents (protocols, protocol amendments, informed consents, advertisements, investigator and site information), records containing communications and correspondence with the investigator, and reports (including but not limited to Continuing Review Reports, IND Safety Reports, reports of injuries to subjects, scientific evaluations) that correspond to each study approved by the *NIRT-IEC*

Annexure Code: AF/EC/046/05

Study Participant request / complaint record Form

Date Received:	
Received by :	
Request from :	❑ Telephone call No……... ❑ Fax No……..…. ❑ Mailed letter / Date…… ……. ❑ E-mail / Date…… ❑ Walk-in / Date / Time…….. ❑ Other, specify …….
Participant's Name:	
Contact Address: Phone:	
Title of the Participating Study	
Starting date of participation :	
Nature of request / complaint	
Receiver signature and date:	
DATE OF NIRT-IEC DECISION:	
NIRT-IEC No:	
Study Title:	
Principal Investigator:	
Sponsor:	
NIRT-IEC Discussion:	
Action taken:	
Signature of Member-Secretary: Date:	Date informed to study particiapant:

Acknowledgement of awareness of this SOP

S.No	Name	Capacity	Signature	Date
1.	Dr R Sridhar	Chairperson		
2.	Dr R Arun Kumar	Vice-Chairperson		
3.	Dr G Narendran	Member Secretary		
4.	Dr K Lily Therese	Member (Non-Affiliate)		
5.	Dr S Swarnalakshmi	Member (Non-Affiliate)		
6.	Dr Shyamala Nataraj	Member (Non-Affiliate)		
7.	Mrs Rajalakshmi	Member (Non-Affiliate)		
8.	Mrs Renu Lamech	Member (Non-Affiliate)		
9.	Dr V Gowri	Member (Non-Affiliate)		
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17.	Dr Luke Elizabeth Hanna	Member (Affiliate)		
18.	Dr Bella Devaleenal	Member (Affiliate)		
19.	Dr M Muniyandi	Member (Affiliate)		
20.	Dr P K Bhavani	Member (Affiliate)		
21.	Dr R Balaji	Member (Affiliate)		

SOP Code: SOP/EC/024/05

6.3. Management of study termination

SOP Number: SOP/EC/024	Revision Number: 05	
SOP Author: **Dr K R Uma Devi** **Signature**	**SOP Approver:** **Dr R Sridhar** **(Chair IEC)** **Signature**	**Effective Date :** **18 May 2022**
	Dr C Padmapriyadarsini **(Director)** **Signature**	**Supersedes :** **(Doc. version & Date)** **Version 4.0, dated 04 October 2018**

1. PURPOSE

This procedure describes how an NIRT-IEC proceeds and manages the termination of a research study. Protocols are usually terminated at the recommendation of the NIRT-IEC, Data Safety Monitoring Board (DSMB), sponsor or other authorized bodies or based on study PI's request after the reasons are found acceptable by NIRT-IEC.

2. SCOPE

This SOP applies to any study approved by NIRT-IEC that is being recommended for termination before its scheduled completion.

3. RESPONSIBILITY

It is the responsibility of the NIRT-IEC Chair to terminate any study that the NIRT-IEC has previously approved when the safety or benefit of the study participants is doubtful / at risk and any other appropriate reasons. The NIRT-IEC Secretariat is responsible for management of the termination process.

4. FLOW CHART

No.	Activity	Responsibility
1	Receive recommendation for study termination	Investigator and NIRT-IEC Secretariat
	↓	
2	Discuss during the Board meeting	NIRT-IEC Members
	↓	
3	Notify the Principal Investigator	NIRT-IEC Secretariat
	↓	
4	Store the Protocol Documents	NIRT-IEC Secretariat

5. DETAILED INSTRUCTIONS

5.1 Receive recommendation for study termination.

- The NIRT-IEC will receive recommendation and comments from DSMB, NIRT-IEC members, Sponsor or other authorized bodies for study protocol termination.
- Receive the study protocol termination package prepared and submitted by the principal investigator.
  - Ongoing / completed / terminated protocol review submission form ***(AF/EC/011/05)***
  - Reasons for termination
  - Minutes of other committee meetings that were held if any
  - Final report if available
  - Checklist for documents submitted by PI to NIRT-IEC ***(AF/EC/042/05)***

Refer to SOP/EC/014/05
Initial and date the package upon receipt.

5.2. During the Board meeting

- The PI presents the study findings in case requested or gist presented by the Member Secretary.
- The members will review the results, reasons, and accrual data and discuss.
- If appropriate to the discussions, the Chair may call for consensus on the action to be taken (Study terminated and file closed / Study terminated and further information if required)
- Hold the files of multi-center studies, until all the study sites are closed.
- Member Secretary summarizes the action taken.

5.3. After the Board meeting, Member Secretary will

- Note the decision in the meeting minutes
- Send the decision letter to the PI **(AF/EC/029/05)**
- Archive the entire study protocol and the report and the study file is closed as per the decision. **(Refer SOP/EC/19/05)**

6. ANNEXURE

Annexure Code	Annexure title
AF/EC/011/05	Ongoing / completed / terminated protocol review submission form
AF/EC/042/05	Checklist for documents submitted by PI to NIRT-IEC
AF/EC/029/05	Letter to PI – IEC Final report review decision

7. RELEVANT SOPs

SOP Code	SOP Title
SOP/EC/014/05	Review of Final reports
SOP/EC/019/05	Archival and Retrieval of documents

GLOSSARY

IEC	Institutional Ethics Committee is an independent body whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection.
Secretariat	An office responsible for the secretarial, clerical, and administrative affairs of NIRT-IEC

Annexure Code: AF/EC/011/05

Ongoing / Completed / Terminated protocol review submission form

S No	Title	Particulars
1	NIRT-IEC Protocol Number	
2	Title of the research proposal	
3	Name of the Principal Investigator (PI) with Qualification and Designation	
4	Name of the Co-PI and Co-Investigator(s) with Qualification and Designation	
5	Duration of the project / trial (yrs)	
6	Source of funding & financial allocation for the project / trial	
7	Name of the Institute where research is being conducted	
8	Month / Year of IEC approval	
9	Number of ongoing review (Not applicable for 'Yet to be initiated' studies)	
10	What are the study objectives?	
11	What is the sample size required?	
12	Has the project implementation begun?	Yes / No Date
13	Has study participant recruitment begun?	Yes / No Date
14	If study participant recruitment has not begun, give reasons and proceed to S No: 23	
15	How many study participants have been screened?	
16	How many study participants have been recruited?	
17	Is study participant recruitment continuing? If no, give reason	Yes / No / Not applicable
18	Are there any 'drop outs'? If yes, give details.	Yes / No / Not applicable
19	Are study participants still receiving active intervention? If no, give reasons.	Yes / No / Not applicable
20	Have there been any **adverse events**? If yes, give details.	Yes / No / Not applicable
21	Have there been any other **unexpected adverse events**? If yes, give details.	Yes / No / Not applicable
22	Have there been any **unanticipated study-related problems**? If yes, give details.	Yes / No / Not applicable
23	Is there any **new risk or benefit** information?	Yes / No

	If yes, give details	
24	Are there any interim changes to the protocol or consent form? If yes, give details, including submission of revised protocol and consent form for approval. a) State/describe the amendment as annexure	Yes / No
	b) Give reason for the amendment	
	c) Any untoward effects to original protocol (ie. Study objective, design, outcome)	
	d) Expected risks to participants due to the amendment	
25	Does the scientific literature indicate changes in knowledge relevant to the conduct of the study? If yes, give details	
26	Is the study Yet to be initiated/ ongoing/ completed / terminated? If completed please provide the date and provide the Study summary (Participant recruitment completed & analysis ongoing) / Final report (Analysis completed) If terminated, please provide the date and details on the management of the enrolled participants (active and follow-up), if applicable	Yet to be initiated/ Ongoing / completed / terminated
27	Presentations / Publications, if any If yes, provide details	Yes / No
28	Do you require extension of the study period? If yes, please provide justification and summary of study findings as annexure	Yes / No
29	List of attachments for review, if any	
30	Remarks, if any	
31	Signature of the Principal Investigator with date	

Annexure code: AF/EC/029/05

Letter to PI - IEC Final report review decision

ICMR - National Institute for Research in Tuberculosis

INSTITUTIONAL ETHICS COMMITTEE

(SIDCER Recognized Ethics Committee in the Asian and Western Pacific Region)

No: 1, Mayor Sathyamoorthy Road, Chetput, Chennai – 600 031, Tamil Nadu, India

No: ……../NIRT-IEC/20….. Date: …….

To

Sir / Madam,

Ref: NIRT-IEC No: ……: "Title: **……..**" – reg.

The NIRT-Institutional Ethics Committee met on …… under the Chairmanship of ……..and reviewed the above referenced project (based on the 'ongoing protocol review submission form' submitted by you).

The Committee hereby acknowledges the submission.

As the study is terminated and the final report is submitted to IEC and approved, the study file will be closed.

Thanking you.

Yours truly,

Member Secretary

cc to:

The Director, National Institute for Research in Tuberculosis

Annexure code AF/EC/042/05

Checklist for documents submitted by PI to NIRT-IEC (To be filled by PI)

NIRT-IEC No:		**Submitted date:**	
Type of Submission:	☐ Initial Review ☐ Resubmission for re-review ☐ Protocol Amendments	☐ Ongoing review ☐ Study completed ☐ Protocol Termination	
Protocol Title:			
Name of Principal Investigator: **Designation:** **Department:**			
Institute:			

☐ **Initial Review Submitted Package**

- Initial Review Submission / re-submission Form
- NIRT- SAC approval
- PI's updated signed short CV and GCP training record.
- Protocol with version no. & date and to include section on Ethical Consideration
- Protocol-Related Documents with version no. & date
  - ☐ Patient Information sheet
  - ☐ Informed consent form (English)
  - ☐ Case report forms (CRF)
  - ☐ Informed consent form (Local vernacular)
  - ☐ Data collection forms
  - ☐ others……
  - ☐ Investigator's Brochure, if applicable

☐ **Resubmission for Re-review Submitted Package**

- IEC Initial Review decision letter
- Initial Review Submission / re-submission Form
- Revised Protocol with version no. & date
- Protocol history page listing the changes made to the documents
- Protocol-Related Documents with version no. & date
  - ☐ Patient Information sheet
  - ☐ Informed consent form (English)
  - ☐ Case report forms (CRF)
  - ☐ Informed consent form (Local vernacular)
  - ☐ Data collection forms
  - ☐ others……
  - ☐ Investigator's Brochure, if applicable

☐ **Protocol Amendment Submitted Package**

- ❑ Letter of request for Amendment by PI
- ❑ Ongoing / completed / terminated protocol Review Submission Form
  - ❑ State/describe the amendment as annexure
  - ❑ Reason for the amendment
  - ❑ Any untoward effects to original protocol (ie. Study objective, design, outcome)
  - ❑ Expected risks to participants due to the amendment
- ❑ Amended Protocol with version no. & date
- ❑ Protocol history page listing the changes made to the documents
- ❑ Protocol-Related Documents with version no. & date
  - ☐ Patient Information sheet
  - ☐ Case report forms (CRF)
  - ☐ Data collection forms
  - ☐ Investigator's Brochure, if applicable
  - ☐ Informed consent form (English)
  - ☐ Informed consent form (Local vernacular)
  - ☐ others……

☐ **Ongoing Review Package**

- ❑ Ongoing / completed / terminated protocol Review Submission Form
- ❑ Protocol amendment if any
- ❑ Study completed / terminated, if applicable

☐ **Study completed Package**

- ❑ Ongoing / completed / terminated protocol Review Submission Form
- ❑ Final report

☐ **Protocol Termination Package**

- ❑ Ongoing / completed / terminated protocol Review Submission Form
- ❑ Reasons for termination
- ❑ Minutes of other committee meetings that were held if any
- ❑ Final report if available

Signature of the Principal Investigator & date	

Receipt of documents from PI (To be filled by NIRT-IEC Secretariat)

NIRT-IEC No:		
Type of Submission:	☐ Initial Review ☐ Resubmission for re-review ☐ Protocol Amendments	☐ Ongoing review ☐ Study completed ☐ Protocol Termination
Protocol Title:		
Received by:		**Date received:**
Pending documents : Nil / Yes, If yes, details: ☐ Patient Information sheet ☐ Case report forms (CRF) ☐ Data collection forms ☐ Investigator's Brochure, if applicable ☐ Informed consent form (English) ☐ Informed consent form (Local vernacular) ☐ others……		
Received by:		**Date received:**

Acknowledgement of awareness of this SOP

S.No	Name	Capacity	Signature	Date
1.	Dr R Sridhar	Chairperson		
2.	Dr R Arun Kumar	Vice-Chairperson		
3.	Dr G Narendran	Member Secretary		
4.	Dr K Lily Therese	Member (Non-Affiliate)		
5.	Dr S Swarnalakshmi	Member (Non-Affiliate)		
6.	Dr Shyamala Nataraj	Member (Non-Affiliate)		
7.	Mrs Rajalakshmi	Member (Non-Affiliate)		
8.	Mrs Renu Lamech	Member (Non-Affiliate)		
9.	Dr V Gowri	Member (Non-Affiliate)		
10.	Mr D Sairamkumar	Member (Non-Affiliate)		
11.	Mrs Pushkala	Member (Non-Affiliate)		
12.	Dr S Chandrasekar	Member (Non-Affiliate)		
13.	Dr P M Ramesh	Member (Non-Affiliate)		
14.	Dr Padma Srikanth	Member (Non-Affiliate)		
15.	Dr Shuba Kumar	Member (Non-Affiliate)		
16.	Dr K R Uma Devi	Member (Affiliate)		
17.	Dr Luke Elizabeth Hanna	Member (Affiliate)		
18.	Dr Bella Devaleenal	Member (Affiliate)		
19.	Dr M Muniyandi	Member (Affiliate)		
20.	Dr P K Bhavani	Member (Affiliate)		
21.	Dr R Balaji	Member (Affiliate)		

SOP Code: SOP/EC/025/05

7.1. Site monitoring visit

Revisions in the Standard Operating Procedures from version 4.0, dated 4 October 2018 to version 5.0, dated 18 May 2022

The following revisions are made in the Standard Operating Procedures from version 4.0, dated 4 October 2018 to Version 5.0, dated 18 May 2022 following the revision in the National Ethical guidelines for Biomedical and Health Research involving human participants, ICMR 2017 and NDCT Guidelines 2019.

Title of Standard Operating Procedure (SOP)	SOP Code	Revisions
Site monitoring visit	**SOP/EC/025/05**	5.1 Selection of study site for monitoring: The following point has been removed: • NIRT-IEC members and the Chair review periodically the database files of the approved study protocols maintained at the IEC secretariat.

SOP Number: SOP/EC/025	Revision Number: 05	
SOP Author: Dr K R Uma Devi Signature	SOP Approver: Dr R Sridhar (Chair IEC) Signature	Effective Date : 18 May 2022
	Dr C Padmapriyadarsini (Director) Signature	Supersedes : (Doc. version & Date) Version 4.0, dated 04 October 2018

1. PURPOSE

The purpose of this SOP is to specify the procedures as to when and how a study site should be visited and monitored for its performance or compliance with GCP.

2. SCOPE

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

3. RESPONSIBILITY

It is the responsibility of the NIRT-IEC to perform or designate some qualified agents to perform on its behalf on-site inspection of the research projects it has approved.

The NIRT-IEC members in consultation with the Chairperson may initiate an on-site evaluation of a study site for a cause or for a routine audit.

4. FLOW CHART

No.	Activity	Responsibility
1	Selection of study sites	NIRT-IEC members and Chair
	↓	
2	Selection of monitors	NIRT –IEC Chairperson with MS IEC
	↓	
3	facilitation of monitor visit	IEC secretariat

4	Procedures during the visit	Monitor
	↓	
5	Report submission	Monitor
	↓	
6	Present the findings to the Full Board	Monitor
	↓	
7	IEC comments	Full board
	↓	
8	Communication to PI	IEC secretariat

5. DETAILED INSTRUCTIONS

5.1 Selection of monitors
One affiliate and one Non-affiliate member will be appropriately nominated by the Chair in consultation with the MS of IEC

5.1 Selection of study site for monitoring

Study sites are selected based on the following criteria:

- Reports of increased frequency of serious adverse events than anticipated
- Number of studies carried out at the study sites is excessive.
- The IEC feels that time allocation by the PI towards a study/ studies is insufficient
- IEC is informed of the non-compliance to protocol.
- PI Frequently fails to submit ongoing reports
- Any other reason which the IEC feels a visit is required

5.2 Before the visit

The NIRT-IEC Secretariat will fix a suitable date in consultation with the monitor and the PI for site visits. The site/PI will be notified one week before the visit.

- Review the NIRT-IEC files for the study and site,
- Make appropriate notes, or
- Copy some parts of the files for comparison with the site files.

5.3 During the visit

- Get a Monitoring visit Checklist. ***(Annexure code AF/EC/047/05)***
- The site monitors will
  - Review the informed consent document to make sure that the site is using the most recent version,
  - Review randomly the participant files to ensure that subjects are signing the correct informed consent,

- Observe the informed consent process, if possible,
- Observe the laboratory and other facilities necessary for the study at the site.
- Ensure that all relevant documents are filed appropriately.
- Collect views of the study participants.
- Debrief the visit report/comments.

5.4 After the visit

The Site monitors will:

- Prepare a report within 1 week describing the findings during the monitoring visit and submit the final report to the NIRT-IEC Secretariat

The NIRT-IEC Secretariat will

- Place a copy of this site visit report in the 'Site monitoring' file for Full Board review and also in the study folder

5.5 Present the inspection results to the Full Board

- The NIRT-IEC secretariat will schedule the presentation of the monitoring reportin the agenda of the forthcoming meeting.
- The site monitors will present the results of on-site inspections to the Full Board.
- The report as well as remedial measures (if any) , suggested by the committee will be communicated to the PI and also recorded in the study file

6. ANNEXURE

Annexure Code	Annexure title
AF/EC/047/05	Site Monitoring visit checklist

GLOSSARY

Full board review	A review process by all the NIRT-IEC members in a full Board meeting for a consensus decision making
IEC	Institutional Ethics Committee is an independent body whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection.
IEC members	Individuals serving as regular and alternate members on the institute's operational boards (i.e., IEC membership). These boards are constituted in accordance with the EC membership requirements set forth in ICMR Ethical guidelines for Biomedical research involving human participants

Monitor	The act of overseeing the progress of a study, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).
Standard Operating Procedure	Detailed, written instructions, in a certain format, describe all activities and actions undertaken by an organization to achieve uniformity in 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.
Secretariat	An office responsible for the secretarial, clerical, and administrative affairs of NIRT-IEC

Annexure Code: AF/EC/047/05

Site Monitoring Visit checklist

NIRT-IEC No:	Date of the Visit:	
Study Title:		
Principal Investigators:		Phone:
Institute:	Address:	
Sponsor:	Address:	
Total number of expected subjects:	Total subjects enrolled:	
Are site facilities appropriate? ☐ Yes ☐ No	Comment:	
Are Informed Consents recent? ☐ Yes ☐ No	Comment:	
Any AE / SAE / Death / Compensation 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 investigating products locked? ☐ Yes ☐ No	Comment:	
How well are participants protected? ☐ Good ☐ Fair ☐ Not good	Comment:	
Any outstanding tasks or results of the visit? ☐ Yes ☐ No	Give details:	
Duration of visit: …….hours	Starting from:	Finish:
Name of IEC/IRB member/ representatives and accompanion:		
Completed by:		Date:

Acknowledgement of awareness of this SOP

S.No	Name	Capacity	Signature	Date
1.	Dr R Sridhar	Chairperson		
2.	Dr R Arun Kumar	Vice-Chairperson		
3.	Dr G Narendran	Member Secretary		
4.	Dr K Lily Therese	Member (Non-Affiliate)		
5.	Dr S Swarnalakshmi	Member (Non-Affiliate)		
6.	Dr Shyamala Nataraj	Member (Non-Affiliate)		
7.	Mrs Rajalakshmi	Member (Non-Affiliate)		
8.	Mrs Renu Lamech	Member (Non-Affiliate)		
9.	Dr V Gowri	Member (Non-Affiliate)		
10.	Mr D Sairamkumar	Member (Non-Affiliate)		
11.	Mrs Pushkala	Member (Non-Affiliate)		
12.	Dr S Chandrasekar	Member (Non-Affiliate)		
13.	Dr P M Ramesh	Member (Non-Affiliate)		
14.	Dr Padma Srikanth	Member (Non-Affiliate)		
15.	Dr Shuba Kumar	Member (Non-Affiliate)		
16.	Dr K R Uma Devi	Member (Affiliate)		
17.	Dr Luke Elizabeth Hanna	Member (Affiliate)		
18.	Dr Bella Devaleenal	Member (Affiliate)		
19.	Dr M Muniyandi	Member (Affiliate)		
20.	Dr P K Bhavani	Member (Affiliate)		
21.	Dr R Balaji	Member (Affiliate)		