NATIONAL TUBERCULOSIS INSTITUTE BENGALURU

Institutional Ethics Committee

STANDARD OPERATING PROCEDURES

Version 1.2

Government of India
NATIONAL TUBERCULOSIS INSTITUTE
(Ministry of Health and Family Welfare)
'Avalon', No.8, Bellary Road, Bengaluru-560 003
INDIA

CHECKLIST FOR SUBMISSION OF APPLICATIONS FOR REGISTRATION OF ETHICS COMMITTEE

#	Documents required to be submitted	Status		Page No.
		Yes	No	
1.	Application for registration in accordance with the requirements as specified in Appendix VIII of Schedule Y			
2.	Name of the Ethics Committee	✓		1
3.	Authority under which the Ethics Committee has been constituted	✓		2
4.	Membership requirements of the Ethics Committee	✓		2
5.	The terms of reference of the committee	✓		3
6.	Documents, if any, proving that the members of the committee are conversant with the provisions of clinical trials as per the provisions of D & C Rules and Good Clinical Practice Guidelines for clinical trials in India.	✓		37-46
7.	Conditions of appointment and the quorum required.	✓		4
8.	Procedure for resignation, replacement or removal of members.	✓		4
9.	Address of the office of the Ethics Committee.	✓		4
10.	Name, address, qualification, organizational title, telephone number, fax number, e-mail, mailing address and brief profile of the Chairman.	✓		5
11.	Names, qualifications, organizational title, telephone number, fax number, e-mail and mailing address of the members of the Ethics Committee. The information shall also include member's specialty (primary, scientific or non-scientific), member's affiliation with institutions and patient group representation, if any.	✓		6-9
12.	Details of the supporting staff.	✓		10
13.	In the case of Ethics Committee existing before 08.02.2013, following should be submitted-	✓		11
	a) Types of clinical research reviewed by the committee (e.g. pharmaceuticals, devices, epidemiological, retrospective, herbals etc.).	✓		11
	b) Documents reviewed for every clinical trial protocol including Informed Consent documents.		✓	
	c) Information in respect of number of meetings of the committee and documentation of the minutes of meetings of these committees concerning clinical trials.		✓	
	d) Information regarding review of serious adverse events reported during the conduct of the trial.		✓	
14.	The standard operating procedures to be followed by the committee in general.	✓		12-26
15.	Standard operating procedures to be followed by the committee for vulnerable population.	✓		27-30
16.	Policy regarding training for new and existing committee members along with standard operating procedures.	✓		30
17.	Policy to monitor or prevent the conflict of interest along with standard operating procedures.	✓		30
18.	If the committee has been audited or inspected before, give details.	✓		31
19.	Undertaking by the committee as per the format Annexed.	✓		32-36

**Sensitization programme on Institutional Ethics Committee Composition Roles & Responsibilities, NTI-IEC Standard Operating Procedures and Good Clinical Practices was conducted at NTI, Bengaluru for Chairman and all the Committee Members in two batches on 13/10/2018 & 27/10/2018. After the training programme, they also underwent online ICH-GCP examination.*

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NATIONAL TUBERCULOSIS INSTITUTE - INSTITUTIONAL ETHICS COMMITTEE (NTI – IEC)

Standard Operating procedures for NTI – IEC
Version 1.2

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Authority under which the Ethics Committee has been constituted

The National Tuberculosis Institute's - Institutional Ethics Committee (NTI-IEC) is a standing ethics committee of the Institution, functioning independently. It is established under the authority of the Director, National Tuberculosis Institute, Bengaluru, Karnataka, India.

Membership requirements

The membership of NTI-IEC includes individuals with varying backgrounds. It is multidisciplinary and multi-sectorial in composition with medical / non-medical, and scientific / non-scientific persons including lay personnel from the community, so as to reflect different perspectives. They include Epidemiologist, Sociologist, Legal expert, Statistician, Clinician, Basic Scientist, and others as relevant. There is adequate representation of age, gender, and lay personnel from the community in the Committee. The composition of members is appropriate to the nature of the projects being reviewed and appropriate to the local culture and customs, in conformity with the ICMR Ethical guidelines for Biomedical and Health research involving Human participants 2017.

The Chair is an eminent person in the society not affiliated to the Institution in order to maintain independence of NTI-IEC. The Member Secretary (MS) is from the Institution, and is responsible for organizing the meetings and preparing the proceedings, conducting the business of the meetings, maintaining records, and communicating with all concerned. The MS is also responsible for preparing the minutes of the meetings and getting it approved by the Chair and the appropriate authority before communicating it to the researchers.

The Committee possesses appropriate professional competence to review the diverse types of protocols received, and execute the same free from any bias and influence that could affect their objectivity.

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Terms of reference of the Ethics Committee

- The Head of the Institution will appoint all the committee members, including the Chairperson.
- The appointment issued will contain
    - Roles and responsibility of the members
    - Duration of Appointment
    - Conditions of Appointment
- All the Members serve for a period of three years, on renewable terms. Members willing to continue after the completion of the term are retained for another term to provide continuity of their contribution of ethical expertise.
- Members to be appointed on the EC should be willing to fulfill the EC requirements as given:
    - provide a recent signed CV and training certificates on human research protection and good clinical practice (GCP) guidelines, if applicable;
    - either be trained in human research protection and/or GCP at the time of induction into the EC, or must undergo training and submit training certificates within 6 months of appointment (or as per institutional policy);
    - be willing to undergo training or update their skills/knowledge during their tenure as an EC member;
    - be aware of relevant guidelines and regulations;
    - read, understand, accept and follow the Conflict of Interest (COI) policy of the NTI-IEC and declare it, if applicable, at the appropriate time;
    - sign a confidentiality and conflict of interest agreement/s;
    - be willing to place her/his full name, profession and affiliation to the EC in the public domain;
    - be committed and understanding to the need for research and for imparting protection to research participants in research.
- All members are appointed on honorary basis with reasonable honorarium.

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Conditions of appointment

The Director of NTI nominates all the Committee Members, based on their competency and integrity.

Quorum required

A minimum of five persons are required to form a quorum for the meeting. One non-scientific lay person from the community or a social scientist will be present from among the members during each meeting.

Procedure for resignation, replacement or removal of members

A Member can tender resignation from the Committee assignment with proper reasons for doing so in writing to the Chairperson and Member Secretary.

A Member will be replaced in the event of death or long-term non-availability or for any other reason after following due process.

Address of the office of the Ethics Committee.

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National Tuberculosis Institute
8, 'AVALON', Bellary Road,
Bengaluru – 560 003.
Karnataka, India.

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Brief profile of the Chairperson

Name	: Shri S. Vijay Shankar,
Title	: Senior Advocate – Designated by the High court of Karnataka Former Advocate General for Karnataka
Qualification:	:B.A. B.L
Official Address	: 4307, 4308 & 4310, Floor 3, High Point 4, Palace Road, Bengaluru– 560001 Phone no. 080-22268276, 22281191, 22374179
Residential Address	: No. 23, Sankey Road Cross, Abshot Layout, Bengaluru – 560001 Phone No. 080-22250930, 48651015
Mobile No.	: 9845596216
Email ID	: vsalaw@yahoo.com, vsalaw4310@gmail.com

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Details of NTI – IEC members

Name	Shri S. Vijay Shankar	Dr. C. Ravichandra	Dr. Omprakash
Qualifications	B.A. B.L.	MBBS	MBBS, MD
Organizational title	Senior Advocate; Former Advocate General for Karnataka	Divisional Head, HRD, National Tuberculosis Institute, Bengaluru	Head of Medicine Department, St. Martha's Hospital Bengaluru
Telephone number	080 22268276	080 233441192 8660374749 (M)	080 22267428(R) 080 22872759(O)
Fax number	080 22281191	080 32440952	
Email	vsalaw@yahoo.com; vslaw4310@gmail.com	ravipassi56@gmail.com nti@ntiindia.org.in	aparanji43@gmail.com
Mailing address	4307, 4308 & 4310, Floor 3, High Point 4, Palace Road, Bengaluru– 560001	National Tuberculosis Institute, No. 8, Bellary Road, Bengaluru - 560003	5/A, Kumara Krupa Road, High Grounds, Bengaluru - 560001
Member's specialty	Senior Advocate	Trainer in RNTCP & Clinician	Internal Medicine
Scientific or non-scientific	Non Scientific	Scientific	Scientific
Member's affiliation with institutions / Patient	Non-Affiliated	Affiliated	Non-Affiliated

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Name	Dr. S. Vijaya	Mrs. Brindha Nandakumar	Dr. Thelma Narayan
Qualifications	PhD	BA, LLB	MBBS, MSc(Epidemiology), PhD (London)
Organizational title	Associate Professor, Department of Microbiology & Cell Biology, Indian Institute of Science, Bengaluru	Advocate	Director - Academics and Health Policy Action, Society for Community Health, Awareness, Research and Action (SOCHARA) 359, 1st Main, 1st Block, Koramangala,
Telephone number	080 22932685 (O) 080 23092685 (R)	080 22867414 (O) 080 22947310 (R)	080 25531518 080 25525372
Fax number			080-25525372
Email	vijayaschidanandam63@gmail.com; vijaya@mcbl.iisc.ernet.in	brindhanandakumar@yahoo.com	thelma@sochara.org;
Mailing address	Department of Microbiology & Cell Biology, Indian Institute of Science, Bengaluru - 560012	14/2, Curly Street, Richmond Town, Bengaluru– 560025	326, 5th Main, 1st Block, Koramanagala, Bengaluru -560034
Member's specialty	Scientist	Advocate (Civil & Criminal Law in Trial courts and High Court)	Public Health Specialist
Scientific or non-scientific	Scientific	Non Scientific	Scientific
Member's affiliation with institutions / Patient	Non-Affiliated	Non-Affiliated	Non-Affiliated

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Name	Dr. Srigiri S. Revadi	Dr Vishnu VardhanKamineni	Ms. Smitha BR
Qualifications	MBBS, MD (TB & RD), DTDC, FCCP	MBBS, MS Int Health, DTMPH	B.E - Civil Engineering
Organizational title	Chief, Department of Pulmonary Medicine Bengaluru Hospital, Bengaluru and Consultant Pulmonologist at Raghav Diagnostic & Research Centre, Jayanagar, Bengaluru.	Senior Public Health Specialist, World Health Organization	SDM Projects Pvt. Ltd, Bengaluru
Telephone number	9448088261	2341 0185 (O)	9663430054
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Email	drsrigirirevadi@gmail.com	vvkamineni@gmail.com	brc.smitha07@gmail.com
Mailing address	619, B-4 Towers, Yamuna Block, National Games Village, Koramangala, Bengaluru - 560047	# 85, I Stage AECS Layout, 16 Cross, 2 Main Sanjaynagar, Bengaluru - 560094	No 628, 1st Main Road, Kempegowda Nagar 8th Mile, T. Dasarahalli, Bengaluru – 560 057
Member's specialty	TB and Chest Specialist	Public Health Specialist,	QS Engineer
Scientific or non-scientific	Scientific	Scientific	Non - Scientific
Member's affiliation with institutions / Patient	Non-Affiliated	Non-Affiliated	Non-Affiliated

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Name	**Dr. Nivedita**
Qualifications	MBBS, MD Pharmacology
Organizational title	Professor & Head , Pharmacology, ESIC-MC & PGIMSR Rajajinagar, Bengaluru
Telephone number	9448454436
Fax number	
Email	niveditha.belavadi@gmail.com
Mailing address	No. 861, 5th Main, 5th Block, HMT Layout, Vidyaranyapura, Bengaluru-560097
Member's specialty	Pharmacologist
Scientific or non-scientific	Scientific
Member's affiliation with institutions / Patient	Non-Affiliated

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Details of supporting staff

Name	Qualification	Organizational title	Telephone number	Fax number	e-mail	Mailing address
Dr. Uma Shankar S	MBBS, MPH	Head of Research & Epidemiology, NTI	08023441192- Extn. 133 9482073644	08023440952	Ushankars.2017@gmail.com nti@nitindia.org.in	Research & Epidemiology Division, NO. 8, 'AVALON', Bellary Road, Bengaluru- 560 003
Shri. Sanjay Singh	M.Sc., PGD Epidemiology, MPH	I/C RDC, NTI	08023441192- Extn. 116 9449109540	08023440952	sanntiblr@gmail.com nti@nitindia.org.in	NO. 8, 'AVALON', Bellary Road, Bengaluru- 560 003
Smt. S.L. Nagarathna	B.Com	Secretarial Assistance	08023441192- Extn. 134 9980876319	08023440952	Nagarathna_sl@rediffmail.com nti@nitindia.org.in	NO. 8, 'AVALON', Bellary Road, Bengaluru- 560 003

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Types of clinical research reviewed by the NTI Ethics Committee:

Types of research		No. of studies from 2008-2012				
		2008	2009	2010	2011	2012
Clinical Research	Clinical trial Drug Vaccine	-	-	-	-	-
	Diagnostic trial	-	-	-	-	-
	Observational studies	-	-	-	-	-
	Clinical pharmacology	-	-	-	-	-
Epidemiological studies	Observational	-	-	4	-	3
	Operational research	-	1	4	-	11
Laboratory research		-	-	-	-	1
Socio-behavioural research	Observational studies	-	1	-	-	-
	Interventional studies	-	-	-	-	-
Total		00	2	8	00	15

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STANDARD OPERATING PROCEDURES FOR NTI- IEC

Objectives & Responsibilities	To ensure that the research proposals received from NTI for ethical clearance by the National Tuberculosis Institute – Institutional Ethics Committee, (NTI-IEC) Bengaluru : ➢ Are sound in design, have statistical validity and are conducted according to the Indian Council of Medical Research's National Ethical Guidelines for Biomedical and Health Research Involving Human Participants and International Conference on Harmonization/Good Clinical Practice guidelines. ➢ Do not compromise rights, safety and benefits of the patients or volunteers/ study participants. ➢ Are conducted under the supervision of trained Medical / Bio-medical persons with the required expertise. ➢ Include solely, patients or participants who have given voluntary and informed consent. ➢ It may be ensured that no research project shall be / can be started unless Ethics Clearance /Approval is obtained and that no retrospective / post facto Ethics Clearance/ Approval can be provided to research projects which were neither submitted nor vetted by the Institutional Ethics Committee.
Current	The NTI - IEC consists of 10 members (List enclosed)

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Composition:	➢ Only member Secretary is from National Tuberculosis Institute, Bengaluru ➢ 9 Members including Chairperson are from outside the National Tuberculosis Institute, Bengaluru ➢ Out of 10 members 5 members are women ➢ Quorum is complete if at least 5 members are present for Ethics clearance/review ➢ One non-scientific lay person from the affected community or a social scientist will be present from among the members during each meeting.
Procedures:	➢ Any research proposal involving human participants is place before the committee for its consideration and mandatory approval. ➢ A quorum is required for all meetings (05 members out of 10 make a quorum). Decision on the project is made by consensus of members present at the meeting. ➢ The projects/proposals are circulated up to two weeks prior to conducting Institutional Ethics Committee meeting. ➢ If a member is unable to attend a meeting his/her opinion on the project may be submitted in writing to the Chairperson of the Committee before the date of the meeting or decision. The decision of the committee is taken by majority vote. ➢ If Chairperson is absent he/she can nominate a person from the Institutional Ethics Committee to chair the meeting. ➢ In case a member is absent from Institutional Ethics

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	Committee meeting, if no objection / comments are obtained from that member on the previously circulated projects/proposals, they are considered to be approved by that member. ➢ All members have to give an undertaking declaring their conflict of interest. Regarding projects, which evoke a Conflict of Interest among members of Institutional Ethics Committee, these members should voluntarily withdraw from the IEC meeting while making a decision on that project. This may be indicated to the Chairperson prior to the review and be recorded so in the minutes. ➢ The chairperson appoints a member to write the minutes of the meetings. Generally, it is the Member-Secretary who writes the minutes. Minutes are circulated to the Chairperson and after his approval, the comment letters to applicants may be dispatched after the signature of Member-Secretary of the Institutional Ethics Committee. ➢ After the IEC meeting, the decisions of the members of the Institutional Ethics Committees on the projects/proposals to be obtained on the same day of the meeting.
Documents required to be submitted by the research investigators for NTI- IEC review	The applicant of a proposal is required to **submit one copy of his / her application letter with these following documents:** 1) Research Protocol 2) Covering letter for Submission 3) Investigator's Brochure *4)* Participant Informed consent form and Participant

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	information sheet in English and the same translated in vernacular language, in a simple layman's language, in a narrative form directed to Participant/Legally Admissible Representative, covering all the points given on the ***Annexure 2&3*** 5) Any other project – specific document 6) Declaration that no work has started 7) Declaration that work will be done as per Indian Council of Medical Research's National Ethical Guidelines for Biomedical and Health Research Involving Human Participants /Good Clinical Practice guidelines 8) Permission to use copyrighted questionnaire and proforma if any 9) Brief Curriculum Vitae of Principal Investigators
The committee expects from the investigators:	➢ A progress report on six monthly basis or more frequently as the committee deems fit in ***Annexure-4*** ➢ All serious adverse events observed during conduct of the study should be reported with all the details to the Institutional Ethics Committee within twenty four hours and should be reported within ten days to The Drugs Controller General (India), Directorate General of Health Services, Central Drugs Standard Control Organization, New Delhi.* ➢ To keep informed of amendments to any study related documents ➢ To keep informed of study discontinuation with reasons.

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	THE GAZETTE OF INDIA : EXTRA ORDINARY PART II – Sec. 30(i) page no. 10
The schedules of submitting the proposal is as follows	The proposals Submitted will be received on all days. Proposals received will be processed in the upcoming Institutional Ethics Committee meeting. All meetings of Institutional Ethics Committee will be held quarterly as far as possible on every 1st Saturday of the month (as per the availability of Chairperson).
The committee will give its opinion on the project in writing in one of the following ways –:	➢ Approved **Annexure-1** ➢ Pending ➢ Revision ➢ Rejected ➢ Discontinuation of previously approved project The Chairperson / Member-Secretary of the committee may provisionally approve without calling a full meeting in case where only administrative amendment has been made / expedited review is required. This decision will be ratified at the next full committee meeting and minuted. All documents pertaining to the Institutional Ethics Committee will be kept in the office of the Member-Secretary of Institutional Ethics Committee. Members shall voluntarily withdraw from the Institutional Ethics Committee meeting while making a decision on an application which evokes a conflict of Interest, which then may be indicated in writing to the Chairperson prior to the review and be recorded in the minutes. All members shall sign a declaration on conflict of interest in ***Annexure -5***. Serious Adverse Reactions should be submitted to Contract Research Organization / Institutional Ethics Committee within twenty-four

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	hours. In order to assist the Institutional Ethics Committee for monitoring of adverse events in clinical trials, a Sub-committee is constituted. Its function includes giving opinion on causality of Serious Adverse Events and decides the amount of compensation to be given to the patients with trial related injury along with monitoring of clinical trials. The sub Committee will convey its recommendation to the Institutional Ethics Committee, which will inform the DCGI its decision about the causality and compensation regarding the serious adverse events.

(Dr. C. Ravichandra)
Member-Secretary
National Tuberculosis Institute - Institutional Ethics Committee

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List of Chairperson and members of the NTI Institutional Ethics Committee

Sl. No	Name	Designation	Official address	Residential address	Post/Area of Expertise
1.	Shri S. Vijay Shankar	Senior Advocate; Former Advocate General for Karnataka	4307, 4308 & 4310, Floor 3, High Point 4, Palace Road Bengaluru – 560 001	23, Sankey Road Cross Abshot Layout Bengaluru – 560 052	Chair Person
2.	Dr. C. Ravichandra	Divisional Head, HRD, National Tuberculosis Institute, Bengaluru	8, Bellary Road Bengaluru – 560 003	No. 10, Ashraya, 1st cross, KPSC Layout, Sampigehalli, Agrahara main Road, Agrahara, Bengaluru 560064	Member Secretary, Ex-officio
3.	Dr Omprakash	Head of Medicine Department	St. Martha's Hospital, Bengaluru	5/A, Kumara Krupa Road, High Grounds, BENGALURU – 560 001	Senior Clinician & Member
4.	Dr S. Vijaya	Associate Professor	Dept of Microbiology & Cell Biology, Indian Institute of Science, BENGALURU – 560 012	C105, Gowri Apartments New BEL Road, Bengaluru 560054	Scientist & Member

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Sl. No	Name	Designation	Official address	Residential address	Post/Area of Expertise
5.	Mrs. Brindha Nandakumar	Advocate (Civil & Criminal Law in Trial courts and High Court)	124, Ist floor, Srinivasa complex, Infantry Road, Bengaluru 560 001	14/2, Curly Street Richmond Town BENGALURU – 560 025	Legal Expert & Member
6.	Dr Thelma Narayan, MBBS, M.Sc (epidemiology) Ph.D (London)	Public Health Consultant,	Centre for Public Health and Equity, Community Health Cell, Society for Community Health, Awareness, Research and Action (SOCHARA), No. 27, 6th Cross (1st Floor) 1st main, 1st block, Koramangala, BENGALURU – 560 034	326, 5th Main 1st Block, Koramanagala, Bengaluru	Sociologist & Member
7.	Dr. Vishnuvardhan Kamineni	Senior Public Health Specialist	WHO	No. 85, 1 stage AECS Layout, 16 cross, 2 main, Sanjaynagar, Bengaluru – 56 009	Public Health Specialist & Member

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Sl. No	Name	Designation	Official address	Residential address	Post/Area of Expertise
8.	Dr. Srigiri S Revadi MD (TB & RD), DTCD, FCCP	Associate Professor	Chief, Department of Pulmonary Medicine Bengaluru Hospital, Bengaluru and Consultant Pulmonologist at Raghav Diagnostic & Research Centre, Jayanagar, Bengaluru.	619, B-4 Towers, Yamuna Block, National Games Village Koramangala Bengaluru – 560 047	Senior Clinician & Member
9	Dr. Niveditha MBBS, MD Pharmaco-logy	Professor and Head	Pharmacology Department, ESCI-Medical College and PGIMR, Rajajinagar, Bengaluru	No. 861, 5th Main, 5th Block, HMT Layout, Vidyaranyapura, Bengaluru-560097	Basic Medical Scientist, Pharmacologist & Member
10	Ms. Smitha BR	QS Engineer	SDM Projects Pvt. Ltd, Bengaluru	No 628, 1st Main Road, Kempegowda Nagar 8th Mile, T.Dasarahalli, Bengaluru – 560 057	Lay Person & Member

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ANNEXURE – 1

National Tuberculosis Institute - Institutional Ethics Committee
'AVALON' No.8, Bellary Road, Bengaluru, Karnataka

File no.

Dated

Communication of the Decision of the Institutional Ethics Committee (IEC)

Protocol title	:	
Principal Investigator	:	
Co-investigators	:	
Name & Address of the Institution	:	
New review	:	
Date of review (DD/M/YY)	:	
Decision of the IEC ❖ Approved ❖ Pending ❖ Revision ❖ Rejected ❖ Discontinuation	:	
Remarks	:	

Please note:

- *Inform IEC immediately in case of any adverse events and serious adverse event.*
- *Inform IEC in case of any amendments to the protocol, change of study procedure, site and investigator and premature termination of study with reasons along with summary.*
- *Final and six monthly reports to be submitted to IEC.*
- *Members of IEC have right to monitor the trial with prior intimation.*
- *A copy of the consent document to be given to the study participant giving the consent.*

Member Secretary - IEC

Chairperson - IEC

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ANNEXURE – 2

PARTICIPANT INFORMATION SHEET (PIS)

The protocol must be accompanied by the Participant Information Sheet addressed to the patient or participant or parent/guardian, in case of minor. While formulating the participant information sheet, investigator must provide the subjects with the following information in **simple understandable layman's language or local language, in English & Hindi, in a narrative form, directed to participant, covering all the points given as under.**

i) Title of the study/project.
ii) Aims and methods of the research.
iii) Expected duration of participation of the subject.
iv) The benefits to be expected from the research to the subject or to others.
v) Any risks to the subject associated with the study.
vi) Maintenance of confidentiality of records.
vii) Provision of free treatment for research related injury.
viii) Compensation to subjects for disability or death resulting from such injury.
ix) Freedom of individual to participate and to withdraw from research at any time without penalty or loss of benefits to which the subject would otherwise be entitled.
x) Amount of blood sample to be taken should be mentioned in PIS as Tea Spoon Full measure.
xi) Costs and source of investigations, disposables, implants and drugs / contrast media must be mentioned in the PIS.
xii) Telephone number/contact number of the candidate and one of the investigators must be mentioned in the PIS.
xiii) In case of drug trials:
    a) The chemical name of the drug, date of its manufacturing and batch number must be mentioned
    b) Initial Bio equivalent study of the drug / references should be provided
xiv) Self certification should be given that translation to vernacular language is accurate.

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ANNEXURE – 3

PARTICIPANT IFORMED CONSET FORM (PICF)

Participant identification number for this trial: _____

Title of project: _____

Name of Principal Investigator: _____ Tel..No(s). _____

The contents of the information sheet dated ..... that was provided have been read carefully by me / explained in detail to me, in a language that I comprehend, and I have fully understood the contents. I confirm that I have had the opportunity to ask questions.

The nature and purpose of the study and its potential risks / benefits and expected duration of the study, and other relevant details of the study have been explained to me in detail. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal right being affected.

I understand that the information collected about me from my participation in this research and sections of any of my medical notes may be looked at by responsible individuals from National Tuberculosis Institute. I give permission for these individuals to have access to my records.

I agree to take part in the above study.

(Signatures / Left Thumb Impression)

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Place:

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ANNEXURE – 3 (cont..)

Name of the Participant: _____
Son / Daughter / Spouse of:_____
Complete postal address: _____

This is to certify that the above consent has been obtained in my presence.

Signatures of the Principal Investigator

Date:
Place:

1) Witness – 1

Signatures

Name:
Address:

2) Witness – 2

Signatures

Name:
Address:

NOTE: Three copies should be made for (1) patient, (2) researcher, (3) Institution.

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ANNEXURE – 4

Six monthly progress of Project

Institutional Ethics Committee of. _____
Study title: _____
Name of the Principal Investigator _____
Designation / Department _____
Duration of Study _____
Date of Starting of the Study _____

Period of Six monthly progress report: from _____ to _____

Progress:

Side Effect if any:

Amendments if any:

Reasons for discontinuation if any:

Remarks:

Signatures of Principal Investigator _____
Date: _____

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Annexure-5

Declaration on Conflict of Interest by NTI-IEC members

I have read the "Policy on Conflict of Interest" applicable to the Committee Member as mentioned in the NTI-IEC Standard Operating Procedure. I do hereby agree to abide by provisions thereof.

- I hereby declare that I have no conflict of interest of any form pertaining to the proposed research proposal.*
- I hereby declare that I have conflict of interest of any form pertaining to the proposed research proposal and I do hereby withdraw myself from the decision-making process.*

* (Tick whichever is applicable)

Name of the Committee Member

(Signature with date)

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Standard Operating Procedures for Vulnerable population

The vulnerable population in our research studies includes children, economically and socially disadvantaged persons. Since our study participants primarily include those suffering from tuberculosis (TB) and HIV, they will not be considered as vulnerable population. Following are some examples of vulnerable populations or groups as specified in the ***ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants – 2017:***

- Economically and socially disadvantaged (unemployed individuals, orphans, abandoned individuals, persons below the poverty line, ethnic minorities, sexual minorities – lesbian/ gay/bisexual and transgender (LGBT), etc.);
- Unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate which may lead them to give consent;
- Children (up to 18 years);
- Women in special situations (pregnant or lactating women, or those who have poor decision-making powers/poor access to healthcare);
- Tribal and marginalized communities;
- Refugees, migrants, homeless, persons or populations in conflict zones, riot areas or disaster situations;
- Afflicted with mental illness and cognitively impaired individuals, differently abled – mentally and physically disabled;
- Terminally ill or are in search of new interventions having exhausted all therapies;
- Suffering from stigmatizing or rare diseases; or
- Have diminished autonomy due to dependency or being under a hierarchical system (students, employees, subordinates, defense services personnel, healthcare workers, institutionalized individuals, under trials and prisoners).

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The NTI-IEC ensures that all the cardinal principles of research ethics viz. Beneficence, Non-maleficence, Respect for individuals, and Justice are addressed in the proposed research project; it looks into the aspects of informed consent process, assess the risks and benefits to human participants, and requirements for appropriate compensations.

The NTI-IEC ensures that the purpose of research is to obtain knowledge relevant to the health needs of the vulnerable population.

The NTI-IEC ensures that the risks to participants are minimized by using procedures that are consistent with sound research design, not unnecessarily exposing participants to risk, and by using procedures that are already being performed on participants for diagnostic or treatment purposes.

The NTI-IEC ensures that the risks to participants is acceptable and reasonable when compared to the anticipated benefits, if any, to participants and/or the importance of the knowledge that may be expected to result.

The NTI-IEC determines the appropriateness of the informed consent process and its documentation in accordance with and to the extent required. In case of children, the committee ensures that parental or legal guardian consent is obtained and assent is obtained from children aged 8 years and above. The Ethics committee ensures that the selection of participants is equitable, taking into account the purpose of the research and the setting in which the research shall be conducted. The committee also ensures that adequate medical and psychological support is provided in settings where the research is conducted.

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The NTI-IEC determines that there are adequate provisions in the research plan, where appropriate, for monitoring the data collection to ensure the safety of the participants. It also ensures that there are adequate provisions to protect privacy of participants and to maintain the confidentiality of data, where appropriate.

Policy regarding training for new and existing committee members

All new members have to complete a core educational program prior to serving on the NTI-IEC (by attending three to four scheduled meetings).

The core training modules consists of,

(i) **'Ethical Guidelines for Biomedical and Health Research on Human Subjects', Indian Council of Medical Research, India, 2017**, or its revisions as and when available

(ii) **Indian 'Good Clinical Practices' guidelines for clinical trials** on pharmacological products or its revisions as and when available

(iii) **'Schedule Y' of the Drugs and Cosmetics (II amendment) Rules 2005,** or its revisions as and when available

(iv) **Standard Operating Procedures of NTI-IEC,** or its revisions as and when available, and

(v) Practical preparation for and observation of three to four scheduled IEC meetings.

After completion of at least three years in NTI- IEC, members who have earlier been trained in research methodology workshop are appointed for guiding new members through hands-on-training in Ethics Committee.

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Training in guidelines will provide the basic foundation in ethics for protecting human participants in research.

Continuing education information is disseminated to all the Members and they are encouraged to attend national and international training programs on research ethics in order to maintain quality in the ethical review process and help the Members be abreast with the latest developments in the area of protection of human research participants.

Policy to monitor or prevent the conflict of interest

The following policy is followed by NTI-IEC to monitor or prevent the conflict of interest:

- Investigators do not select the committee members.
- No individual involved in the conduct of the research project under review participates in the review process, except to provide information.
- No Committee Member participates in the review process of any research project in which the Member has a conflicting interest, except to provide information requested by the Committee.
- Members having conflict of interest disclose the conflict ***(Annexure-5)*** and withdraw themselves from participation during review of that research, except to provide information on request. Such members do not participate in the discussions during the review of that research and in the decision making process.

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Auditing/Inspection of the NTI Ethics Committee

- The NTI-IEC has not been audited or inspected before.
- In the year 2003, ICMR and WHO invited NTI to participate in the survey of Institutional Ethics Committee in India: NTI-IEC participated in the survey and provided all the information as per the template received on 01/09/2003.

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UNDERTAKING BY THE ETHICS COMMITTEE

1. Full name, address and title of the Chairperson

Name :Shri S. Vijay Shankar

Title : Senior Advocate & Former Advocate General for Karnataka

Address : 4307, 4308 & 4310,
Floor 3, High Point
Palace Road,
Bengaluru – 560001

2. Name and address of the office of Ethics Committee

National Tuberculosis Institute- Institutional Ethics Committee
National Tuberculosis Institute,
8, 'AVLON', Bellary Road,
Bengaluru – 560 003.
Karnataka, India.

3. Name, address, qualifications & designation of the other members' of the NTI –IEC.

Sl. No	Name	Address	Qualifications	Professional Designation	Designation
1	Shri S. Vijay Shankar	4307, 4308 & 4310, Floor 3, High Point 4, Palace Road, Bengaluru– 560001	B.A. B.L.	Senior Advocate; Former Advocate General for Karnataka	Chairperson
2	Dr. C. Ravichandra	National Tuberculosis Institute, No. 8, Bellary Road, Bengaluru - 560003	MBBS	Divisional Head, HRD, National Tuberculosis Institute, Bengaluru	Member Secretary, ex-officio

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3	Dr. Omprakash	5/A, Kumara Krupa Road, High Grounds, Bengaluru - 560001	MBBS, MD	Head of Medicine Department, St. Martha's Hospital Bengaluru	Senior Clinician & Member
4	Dr. S. Vijaya	Department of Microbiology & Cell Biology, Indian Institute of Science, Bengaluru - 560012	PhD	Associate Professor, Department of Microbiology & Cell Biology, Indian Institute of Science, Bengaluru	Scientist & Member
5	Mrs. Brindha Nandakumar	14/2, Curly Street, Richmond Town, Bengaluru– 560025	BA, LLB	Advocate	Legal Expert & Member
6	Dr. Thelma Narayan	326, 5th Main, 1st Block, Koramanagala, Bengaluru -560034	MBBS, MSc (Epidemiology), PhD (London)	Director - Academics and Health Policy Action, Society for Community Health, Awareness, Research and Action (SOCHARA) Bengaluru	Sociologist & Member
7	Dr Vishnuvardhan Kamineni	# 85, I Stage AECS Layout, 16 Cross, 2 Main Sanjaynagar, Bengaluru-560094	MBBS, MS Int Health, DTMPH	Public Health Specialist	Public Health Specialist & Member
8	Dr. Srigiri S. Revadi	"619, B-4 Towers, Yamuna Block, National Games Village, Koramangala, Bengaluru-560047	MBBS, MD (TB and RD),DTDC, FCCP	TB and Chest Specialist	Senior Clinician, Member
9	Dr. Niveditha	ESIC-Medical College & PGIMR, Rajajinagar, Bengaluru	MBBS, MD (Pharmacology)	Professor and Head, Pharmacology, ESIC-Medical College & PGIMR, Rajajinagar, Bengaluru	Basic Medical Scientist, Pharmacologist & Member

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10	Ms. Smitha BR	No 628, 1st Main Road, Kempegowda Nagar 8th Mile, T.Dasarahalli, Bengaluru – 560 057	B.E - Civil Engineering	QS Engineer	Lay Person & Member

4. Commitments:

(i) The Committee shall review and accord its approval to a clinical trial and also carry ongoing review of the trial at appropriate intervals, as specified in Schedule Y and Good Clinical Practice Guidelines for Clinical Trials in India and other applicable regulatory requirements for safeguarding the rights, safety and well- being of the trial subjects.

(ii) In the case of any serious adverse event occurring to the clinical trial subjects during clinical trial, the Committee shall analyze and forward its opinion as per the procedures specified under APPENDIX XII of Schedule Y.

(iii) The Committee shall allow inspectors or officials authorized by the Central Drugs Standard Control Organization to enter its premises to inspect any record, data or any document related to clinical trial and provide adequate replies to any query

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(iv) We agree to maintain adequate and accurate records after the completion or termination of the study for not less than five years from the date of completion or termination of the trial (Both in hard and soft copies).

(Shri S. Vijay Shankar)
Chairman
NTI-IEC, NTI, Bengaluru

Date: 02-01-2019

(Dr. C. Ravichandra)
Member Secretary
NTI-IEC, NTI, Bengaluru

Date: 02-01-2019

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The **NTI-IEC Standard Operating Procedure** ***Version 1.2,*** *dated 02.01.2019* is the updated Version of **NTI-IEC Standard Operating Procedure** ***Version 1.1*** *dated 27.10.2018*.The following amendments are incorporated in the current ***Version 1.2***:

1. Page No. 9: Inclusion of Dr. Nivedita as a new member in the NTI-IEC Member's list.
2. Page No. 12-13: updated the number of NTI IEC members to 10
3. Page No. 15: serial no. 6 and 7 word 'certificate' is replaced with 'declaration' in the proposal submission requirements
4. Page No. 18-20: Updated the list of Members and their area of expertise in NTI-IEC
5. Page No. 32-34: Updated the members details in the declaration form