National Tuberculosis Institute - Institutional Ethics Committee (NTI-IEC)

Standard Operating Procedures
Version: 2.0

Government of India
National Tuberculosis Institute
(Ministry of Health and Family Welfare)
'Avalon', No. 8, Ballari Road, Bengaluru -560003
Karnataka, India

GOVERNMENT OF INDIA
NATIONAL TUBERCULOSIS INSTITUTE
Institutional Ethics Committee
'AVALON' NO.8, BELLARY ROAD, BENGALURU 560 003

NTI-IEC STANDARD OPERATING PROCEDURES
Version 2.0, dated 12.05.2022
(Revised as per the New Drugs and Clinical Trials Rules, 2019)

SOP Number: NTI-IEC, Version 2.0, dated 12.05.2022		
SOP Author: **Dr. C. Ravichandra** **(Member Secretary NTI-IEC)** **Signature**	**SOP Approver:** **Dr. Srigiri S. Revadi** **(Chairman, NTI IEC)** **Signature**	**Effective Date :** 12.05.2022
	Dr. N. Somashekar **(Director)** **Signature**	**Revision of:** NTI-IEC, SOPs Version 1.2, 02.01.2019

Institutional Ethics Committee
Government of India
National TB Institute, Bangalore

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1.0 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.

2.0 Membership requirements

The membership of NTI-IEC includes individuals with varying backgrounds and with compliance to NDCT Rule 2019. It is multidisciplinary and multi-sectorial in composition with medical / non-medical, and scientific / non-scientific persons including lay personnel from the community, One Women member, One Legal Expert and one independent member from any other related field such as social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian 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. As per sub rule 1 the 50 % members are from out the institute. 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 Chairman 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 Chairman 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.

3.0 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.

4.0 Conditions of appointment

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

5.0 Quorum required

A minimum of five persons are required to form a quorum for the meeting. No clinical trial or bioavailability or bioequivalence protocol and related documents shall be reviewed by an Ethics Committee unless at least five of its members are available. One, medical scientist (preferably a pharmacologist); One clinician; one legal expert; One social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian or a similar person and one lay person.

6.0 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.

7.0 Maintenance of records by Ethics Committee for clinical trial as per Rule-13, Chapter III of New Drugs and Clinical Trials Rules, 2019.

Maintenance of records by Ethics Committee for clinical trial—

(1) The Ethics Committee will maintain data, records, registers and other documents related to the functioning and review of clinical trial or

bioavailability study or bioequivalence study, as the case may be, for a period of five years after completion of clinical trial.

(2) In particular and without prejudice to the generality of the sub-rule (1), the Ethics Committee will maintain the following records for a period of five years after completion of every clinical trial or bioavailability study or bioequivalence study, namely:-

(i) The constitution and composition of the Ethics Committee;

(ii) Standard operating procedures followed by the Ethics Committee;

(iii) National and International guidelines followed by the Ethics Committee;

(iv) The curriculum vitae of all members of the Ethics Committee;

(v) All Ethics Committee meetings agenda and minutes of all Ethics Committee meetings with signature of the Chairperson;

(vi) All correspondence with committee members and investigators regarding application, decision and follow up;

(vii) Copies of the protocol, data collection formats, case report forms, investigators brochures, informed consent forms, etc., submitted for review;

(viii) Copies of decisions communicated to applicants;

(ix) Records relating to any order issued for premature termination of study with a summary of the reasons thereof;

(x) Final report of the study including microfilms, compact disks or video recordings;

(xi) Maintain the records relating to the serious adverse event, medical management of trial subjects and compensation paid.

(xii) Records related to determination of compensation, recommendation given by Ethics Committee;

(3) The Ethics Committee will furnish the information maintained under sub-rule (1) and sub-rule (2), as and when required by the Central Licensing Authority or any other officer authorized on its behalf.

8.0 Address of the office of the Ethics Committee.

National Tuberculosis Institute- Institutional Ethics Committee

National Tuberculosis Institute

8, 'AVALON', Bellary Road,

Bengaluru – 560 003.

Karnataka, India.

9.0 Brief profile of the Chairperson

Name	: **Dr. Srigiri S. Revadi**
Title	: Senior Chest Physician
Qualification:	**:** MBBS, MD (TB & RD), DTDC, FCCP
Official Address	: Chief, Department of Pulmonary Medicine, The Bangalore Hospital, Bengaluru and as Consultant Pulmonologist at Raghav Diagnostic & Research Centre, Jayanagar, Bengaluru. Phone no. +91 9448088261
Residential Address	: 619, B-4 Towers, Yamuna Block, National Games Village, Koramangala, Bangalore – 560047
Mobile No.	**:** +91 9448088261
Email ID	: drsrigirirevadi@gmail.com
Experience	**:**32 years in Karnataka Health Services in various Capacities and retired as senior Pulmonologist and Unit Chief at Rajiv Gandhi Institute of Chest Diseases, Bangalore. Worked as Lecturer in M R Medical College, Gulbarga in 1978 to 1980 after DTCD in 1978. Worked as Associate Professor of Pulmonary Medicine at Kempegowda Institute of Medical Sciences, Bengaluru for 4 years from 2013 to 2017 Presently working as Chief, Department of Pulmonary Medicine, The Bangalore Hospital, Bengaluru and as Consultant Pulmonologist at Raghav Diagnostic & Research Centre, Jayanagar, Bengaluru.
Membership	**:** Member of Indian Chest Society Member of European Respiratory Society Member of American Thoracic Society Member of Asia Specific Society of Respirology

10.0 Details of NTI – IEC members

Name	**Dr. Srigiri S. Revadi**	**Dr. C. Ravichandra**	**Dr. Omprakash**
Qualifications	MBBS, MD (TB & RD), DTDC, FCCP	MBBS	MBBS, MD
Organizational title	Chief, Department of Pulmonary Medicine Bengaluru Hospital, Bengaluru and Consultant Pulmonologist at Raghav Diagnostic & Research Centre, Jayanagar, Bengaluru.	Divisional Head, HRD, National Tuberculosis Institute, Bengaluru	Head of Medicine Department, St. Martha's Hospital Bengaluru
Telephone number	9448088261	080 233441192 8660374749 (M)	080 22267428(R) 080 22872759(O)
Fax number		080 32440952	
Email	drsrigirirevadi@gmail.com	ravipassi56@gmail.com nti@ntiindia.org.in	aparanji43@gmail.com
Mailing address	619, B-4 Towers, Yamuna Block, National Games Village, Koramangala, Bengaluru - 560047	National Tuberculosis Institute, No. 8, Bellary Road, Bengaluru – 560003	5/A, Kumara Krupa Road, High Grounds, Bengaluru - 560001
Member's specialty	TB and Chest Specialist	Trainer in RNTCP & Clinician	Internal Medicine
Scientific or non-scientific	Scientific	Scientific	Scientific
Member's affiliation with institutions / Patient	Non-Affiliated	Affiliated	Non-Affiliated

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

Name	**Dr. Vineet Kumar Chadha**	**Dr Vishnu VardhanKamineni**	**Mrs. Smitha BR**
Qualifications	MBBS, MD(PSM)	MBBS, MS Int Health, DTMPH	B.E - Civil Engineering
Organizational title	Advisor, National Tuberculosis Institute Bengaluru	Senior Public Health Specialist, World Health Organization	SDM Projects Pvt. Ltd, Bengaluru
Telephone number	080 233441192 9916493109 (M)	2341 0185 (O)	9663430054
Fax number	080 32440952		
Email	vineet2.chadha@gmail.com	vvkamineni@gmail.com	brc.smitha07@gmail.com
Mailing address	National Tuberculosis Institute, No. 8, Bellary Road, Bengaluru – 560003	# 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	Public Health Specialist,	Public Health Specialist,	QS Engineer
Scientific or non-scientific	Scientific	Scientific	Non – Scientific
Member's affiliation with institutions / Patient	Affiliated	Non-Affiliated	Non-Affiliated

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

11.0 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, N0. 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	N0. 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	N0. 8, 'AVALON', Bellary Road, Bengaluru- 560 003

12.0 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-behavioral research	Observational studies	-	1	-	-	-
	Interventional studies	-	-	-	-	-
Total		00	2	8	00	15

13.0 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. ➢ To review and ensure equitable recruitment of subjects in the study
Current Composition:	The NTI - IEC consists of 10 members (List enclosed) ➢ Only 2 members including the Member Secretary are from National Tuberculosis Institute, Bengaluru

	➢ 8 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 Committee meeting, if no objection / comments are obtained from that member on the previously circulated projects/proposals, they are

	considered to be approval/suggestion for revision 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 of the meeting. ➢ 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 letters of approval/disapproval/advise for revision may be dispatched after the signature of Member-Secretary of the Institutional Ethics Committee, to applicants. ➢ 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 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 Subject recruitment procedure (if applicable)
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 (SAE) observed during conduct of the study should be reported with available details within twenty four hours to the Institutional Ethics Committee and The Drugs Controller General (India), Directorate General of Health Services, Central Drugs Standard Control Organization, New Delhi.* ➢ A detailed SAE report with final outcome and causality assessment by the PI to be submitted with

	14 days to the Institutional Ethics Committee and 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. ****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 –:	**Annexure-1** ➢ Approved ➢ 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 Sponsors/Contract Research Organization / Institutional Ethics Committee within twenty-four 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, ***Annexure-6.***

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

14.0 List of Chairperson and members of the NTI Institutional Ethics Committee

Sr. No.	Name	Qualification with Specialization	Current Organization	Telephone number, fax Number, e-mail I . D .and mailing address	Designation/ Role of member in Ethics Committee	Affiliation of member with institute that has constituted the Ethics
1	Dr. Srigiri S Revadi	MBBS, MD (TB&RD), DTCD, FCCP	The Bengaluru Hospital, Bengaluru and Raghav Diagnostic & Research Centre,	619, B-4 Towers, Yamuna Block, National Games Village, Koramangala, Bengaluru – 560047 Phone No. 9448088261	Clinician, Chairperson	No
2	Dr. Om Prakash	MBBS, MD (General Medicine)	St Martha's Hospital, #5, Nrupathunga Road, RBI Colony, Sampangi Rama Nagara, Bengaluru - 560001, Karnataka	D-16, St. John's Medical College Staff Qtrs., Hosur Main Road, Koramangala, Bengaluru 560034 Phone No. 9343692830 Email: aparanji43@gmail.com	Clinician, Member	No
3	Dr. Vineet Kumar Chadha	MBBS, MD (PSM)	National Tuberculosis Institute, 8, Bellary Road, Bengaluru – 560 003	1016, Prestige Kensington Garden Apartments, HMT Factory Main Road, Jallahalli, Bengaluru – 560013, Phone No. 9916493109, Email: vineet2.chadha@gmail.com	Scientific Member	Yes

4	Dr. Thelma Narayan	MBBS, MSc. (Epidemiology), Ph.D. (Health Policy)	SOCHARA (Society for Community Health Awareness, Research and Action), # 359, Srinivasa Nilaya, Jakkasandra 1st Main, 1st Block, Koramangala, Bengaluru–560034, Karnataka	# 326, 5th Main, 1st Block, Koramangala, Bengaluru – 560 034. Karnataka, India. Phone No. 9341257911 Email: thelma@sochara.org	Social Scientist, Member	No
5	Dr. Nivedita Nivedita	MBBS, MD (Pharmacology)	Department of Pharmacology, ESIC-Medical College & PGIMSR, Rajajinagar, Bengaluru, Karnataka	No. 861, 5th Main, 5th Block, HMT Layout, Vidyaranyapura, Bengaluru-560097 Phone No. 9448454436, Email: niveditha.belavadi@gmail.com	Basic Medical Scientist, Member	No
6	Dr. S. Vijaya	BSc, MSc. (Biochemistry), Ph.D. (Biochemistry)	Department of Microbiology and Cell Biology Indian Institute of Science Bengaluru 560012	C105, Gowri Apartments New BEL Road, Bengaluru 560054. Phone No. 9448360798 Email: vijaya@mcbl.iisc.ernet.in	Scientific Member	No
7	Mrs. Brindha Nandakumar	BA, LLB	Bengaluru Mediation Centre, Karnataka High Court, Bengaluru 560001	Flat No. 301, 3rd floor, H M Wimberly Apartments, No. 6 Berlie Street cross, Langford Town,	Legal Expert, Member	No

8	Dr. Vishnu Vardhan Kamineni	MBBS, MSc Int Health, DTMPH	The Global Fund to Fight AIDS, Tuberculosis and Malaria, World Health Organization, Geneva, Switzerland	No. 85, 1 stage AECS Layout, 16 cross, 2 main, Sanjaynagar, Bengaluru – 560094, Phone No. 9900866875, Email : vvkamineni@gmail.com	Scientific Member	No
9	Mrs. Smitha B R	12th, B.E Civil Engineerir	SDM Projects Pvt. Ltd, Bengaluru	No 628, 1stMain Road, Kempegowda Nagar, 8th Mile, T. Dasarahalli, Bengaluru – 560 057, Phone No. 9663430054, Email: brc.smitha07@gmail	Lay Person Member	No
10	Dr. C. Ravichandra	MBBS	National Tuberculosis Institute, 8, Bellary Road, Bengaluru – 560 003	No. 10, Ashraya, 1st cross, KPSC Layout, Sampigehalli, Agrahara main Road, Agrahara, Bengaluru-560064 Phone no. 8660374749, Email: ravipassi56@gmail.com	Member Secretary, Ex-officio	Yes

15.0 Procedure of Informed Consent:

a. In all trials, a freely given, informed, written consent is required to be obtained from each study subject. The Investigator must provide information about the study verbally as well as using a patient information sheet, in vernacular language that is nontechnical and understandable by the study subject.
b. The subject's consent must be obtained in writing using an "Informed Consent Form". Both the patient information sheet as well as the informed consent form should have been approved by the ethics committee and furnished to the Central Licensing Authority. Any changes in the informed consent documents should be approved by the ethics committee and submitted to the Central Licensing Authority before such changes are implemented.
c. Where a subject is not able to give informed consent (e.g. an unconscious person or a minor or those suffering from severe mental illness or disability), the same may be obtained from a legally acceptable representative a legally acceptable representative is a person who is able to give consent for or authorize and intervention in the patient as provided by the law of India).
d. If the trial subject, his or her legally acceptable representative is unable to read or write an impartial witness should be present during the entire informed consent process who must append his or her signature to the consent form.
e. In case of clinical trials on paediatrics, the subjects are legally unable to provide written informed consent, and are dependent on their parent or legal guardian to assume responsibility for their participation in clinical studies. In such case,-
    i) Written informed consent should be obtained from the parent or legal guardian. However, all paediatric participants should be informed to the fullest extent possible about the study in a language and in terms that they are able to understand.
    ii) Where appropriate, paediatric participants should additionally assent to enroll in the study. Mature minors and adolescents should personally sign and date a separately designed written assent form.
    iii) Although a participant's wish to withdraw from a study must be respected, there may be circumstances in therapeutic studies for serious or life-threatening diseases in which, in the opinion of the Investigator and parent or legal guardian, the welfare of a paediatric patient would be jeopardized by his or her failing to participate in

the study. In this situation, continued parental or legal guardian consent should be sufficient to allow participation in the study.

f. A checklist of essential elements to be included in the study subject's informed consent document as well as a format for the informed consent form for trial subject is given in Table 3 of this Schedule.
g. An audio-video recording of the informed consent process in case of vulnerable subjects in clinical trials of New Chemical Entity or New Molecular Entity including procedure of providing information to the subject and his understanding on such consent, shall be maintained by the investigator for record: Provided that in case of clinical trial of anti-HIV and anti-leprosy drugs, only audio recording of the informed consent process of individual subject including the procedure of providing information to the subject and his understanding on such consent shall be maintained by the investigator for record.

16.0 Informed Consent Review Procedure

Informed Consent form should be reviewed by the IEC on the basis of below mentioned essential elements of the form:

a. Statement that the study involves research and explanation of the purpose of the research.
b. Expected duration of the participation of subject.
c. Description of the procedures to be followed, including all invasive procedures.
d. Description of any reasonably foreseeable risks or discomforts to the Subject.
e. Description of any benefits to the Subject or others reasonably expected from research. If no benefit is expected Subject should be made aware of this.
f. Disclosure of specific appropriate alternative procedures or therapies available to the Subject.
g. Statement describing the extent to which confidentiality of records identifying the Subject will be maintained and who will have access to Subject's medical records.
h. Trial treatment schedule and the probability for random assignment to each treatment (for randomized trials).
i. Statement describing the financial compensation and the medical management as under:
    i) In case of an injury occurring to the subject during the clinical trial, free medical management shall be given as long as required or till

such time it is established that the injury is not related to the clinical trial, whichever is earlier.

ii) In the event of a trial related injury or death, the sponsor or his representative or the investigator or centre, as the case may be, in accordance with the rule 39, as the case may be, shall provide financial compensation for the injury or death.

j. An explanation about whom to contact for trial related queries, rights of Subjects and in the event of any injury.

k. The anticipated prorated payments to meet transportation costs/wage loss etc., if any, to the subject for participating in the trial.

l. Responsibilities of subject on participation in the trial.

m. Statement that participation is voluntary, that the subject can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the subject is otherwise entitled.

n. Statement that there is a possibility of failure of investigational product to provide intended therapeutic effect.

o. Statement that in the case of placebo controlled trial, the placebo administered to the subjects shall not have any therapeutic effect. 216 THE GAZETTE OF INDIA : EXTRAORDINARY [PART II—SEC. 3(i)]

p. Any other pertinent information.

q. Additional elements, which may be required:

i) Statement of foreseeable circumstances under which the participation of the subject may be terminated by the Investigator without his or her consent.

ii) Additional costs to the subject that may result from participation in the study.

iii) The consequences of a Subject's decision to withdraw from the research and procedures for orderly termination of participation by Subject.

iv) Statement that the Subject or Subject's representative will be notified in a timely manner if significant new findings develop during the course of the research which may affect the Subject's willingness to continue participation will be provided.

v) A statement that the particular treatment or procedure may involve risks to the Subject (or to the embryo or foetus, if the Subject is or may become pregnant), which are currently unforeseeable.

vi) Approximate number of Subjects to be enrolled in the study

17.0 Condition of Appointment of the IEC Members and Quorum Requirement

Whoever intends to conduct clinical trial or bioavailability study or bioequivalence study shall be required to have approval of an Ethics Committee for clinical trial registered under rule 8. (2) The Ethics Committee shall apply for registration with the Central Licensing Authority under rule 8. 7. Constitution of Ethics Committee for clinical trial.—

a. The Ethics Committee shall have a minimum of seven members from medical, non-medical, scientific and non-scientific areas with at least,—
    i) One lay person
    ii) one woman member
    iii) one legal expert
    iv) one independent member from any other related field such as social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian.
b. The Ethics Committee referred to in sub-rule(1) shall consist of at least fifty percent of its members who are not affiliated with the institute or organization in which such committee is constituted.
c. One member of the Ethics Committee who is not affiliated with the institute or organization shall be the Chairperson, and shall be appointed by such institute or organization.
d. One member who is affiliated with the institute or organization shall be appointed as Member Secretary of the Ethics Committee by such Institute or organization.
e. The committee shall include at least one member whose primary area of interest or specialization is nonscientific and at least one member who is independent of the institution.
f. The members of the Ethics Committee shall follow the provisions of these rules, Good Clinical Practices Guidelines and other regulatory requirements to safeguard the rights, safety and well-being of trial subjects.
g. Every member of the Ethics Committee shall be required to undergo such training and development programmes as may be specified by the Central Licensing Authority from time to time: Provided that any member, who has not successfully completed such training and developmental programmes, shall be disqualified to hold the post of member of the Ethics Committee and shall cease to be a member of such committee.

h. The members representing medical scientists and clinicians shall possess at least post graduate qualification in their respective area of specialization, adequate experience in the respective fields and requisite knowledge and clarity about their role and responsibility as committee members.
i. As far as possible, based on the requirement of research area such as Human Immunodeficiency Virus (HIV) or genetic disorder, specific patient group may also be represented in the Ethics Committee.
j. No member of an Ethics Committee, having a conflict of interest, shall be involved in the decision process and in the oversight of the clinical trial or bioavailability or bioequivalence study protocol being reviewed by it and all members shall sign a declaration to the effect that there is no conflict of interest.
k. While considering an application which involves a conflict of interest of any member of the Ethics Committee, such member may voluntarily withdraw from the Ethics Committee review meeting, by expressing the same in writing, to the Chairperson.
l. The details in respect of the conflict of interest of the member shall be duly recorded in the minutes of the meetings of the Ethics Committee.

18.0 Roles and responsibilities of the Ethics Committee

The responsibilities of Ethics Committee are:

a. To protect the safety, dignity, rights and wellbeing of the potential research participants.
b. To ensure inclusion of only those patients who have given informed consent for participation in the research.
c. To ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customs.
d. To review recruitment procedure of subjects in the study.
e. To ensure that the research is conducted under the supervision of the medical persons or scientists with required experience and expertise.
f. To assist in the development and the education of a research community responsive to local health care requirements

19.0 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).

The NTI-IEC ensures that all the cardinal principles of research ethics viz. Beneficence, Non-maleficence, Autonomy, 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, 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.

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.

20.0 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) New Drug Clinical Trial Rule 2019**,** 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.

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.

21.0 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.

22.0 Auditing/Inspection of the NTI Ethics Committee

- 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.
- The NTI-IEC has not been audited or inspected before.

23.0 Procedures for review and monitoring of approved/ongoing Clinical Trials

1. Review of on-going studies

a) The NTI-IEC will make, at appropriate intervals, an ongoing review of the trials as per approved protocol. The NTI-IEC will review the ongoing clinical trials and such a review may be based on the periodic study progress reports or the SAE reports furnished by the investigators, or review of internal audit reports furnished by the sponsor or visiting the study sites as per requirements of the ongoing study.

b) The periodic review of protocols is done by the NTI-IEC once in six months for the clinical trials, and once in a year for the academic studies.

c) The decision regarding whether the project needs to be reviewed more frequently will be taken during the NTI-IEC meeting in which the project is finally approved and will be recorded in the minutes. A fresh decision to increase the frequency of review may be taken if required based on the SAE reports, monitoring reports, or safety concerns.

d) The NTI-IEC will review the progress made in the protocol (number of patients recruited, dropped out, reasons for drop-out), the occurrence of unexpected events or problems, and compliance of the investigator regarding IEC communication.

e) If the PI fails to submit documents for continuing review within the stipulated date, the Member Secretary will send a reminder notice asking

the PI to submit the documents within 7 days. Further, non-response or failure to submit documents will be discussed in the full board meeting of the NTI-IEC. One more reminder and asking the PI to give an explanation for the failure to submit documents / withdrawing the ethical approval granted and asking the PI not to continue the study/ any other action which is deemed appropriate. The head of the institution will be informed of the decision of the NTI-IEC. Action could be one of the following: one more reminder and asking the PI to give an explanation for the failure to submit documents / withdrawing the ethical approval granted and asking the PI not to continue the study/ any other action which is deemed appropriate. The head of the institution will be informed of the decision of the NTI-IEC.

2. Serious adverse events Review/ Reporting and recommendation for payments of compensation as per chapter VI of New Drugs and Clinical Trials Rules 2019

a) Any serious adverse events (SAE)should be notified to the NTI-IEC within 24 hours by the PI. Serious adverse events during clinical trial shall be reported in accordance with the New Drugs and Clinical Trials Rules, 2019. Any report of the serious adverse event, after due analysis shall be forwarded by the PI/sponsor to the Central Licensing Authority, the Chairperson of the NTI-IEC and the head of the institution where the trial has been conducted, within fourteen days of knowledge of occurrence of the serious adverse event as specified in Schedule 3 of New Drugs and Clinical Trials Rules, 2019.

b) The NTI-IEC Secretariat will receive the following documents within the specified time frame if an SAE is experienced by any research participant:
   - Initial SAE report to be submitted by the Principal Investigator (PI) within 24 hours of knowledge of occurrence of the SAE.
   - Due analysis report should be submitted by the PI within 14 days of knowledge of occurrence of the SAE.

- Due analysis report will also be submitted to the sponsor within 14 days of knowledge of occurrence of the SAE.

c) The NTI-IEC Secretariat will verify that the report is complete in all respects and that it has been received at the NTI-IEC office within the specified timelines. If the report has been received beyond the specified time, it will be considered as a protocol deviation and action should be taken as described in SOP for protocol deviations. The NTI-IEC Secretariat will sign and write the date on which the report is received. The Secretariat will forward these reports to the NTI-IEC SAE Subcommittee.

d) The NTI-IEC SAE subcommittee (4 members from NTI-IEC comprising a senior pharmacologist, public health specialist, consultant pulmonologist and advocate) will review the reports/ case history with a special focus on relatedness of the serious adverse event to the clinical trial, medical management and financial compensation to be given to the research participants. The applicable formulae and guidelines from the regulatory authority will be used during this discussion. The SAE subcommittee will hold the meeting with investigators and site visits as required. If deemed necessary, the SAE subcommittee may refer the issue to the NTI-IEC full board. The report of SAE subcommittee will be presented during the regular NTI-IEC full board meeting. An emergency meeting of NTI-IEC may be held for this purpose.

e) The PI will be requested to reply to the query letter on the SAE report within 7 working days. The NTI-IEC shall forward its report or order on the event, after due analysis, along with its opinion on the financial compensation, if any, to be paid by the sponsor or her / his representative or institution or Centre, as the case may be, in accordance with Chapter VI of New Drugs and Clinical Trials Rules, 2019.

f) The opinion regarding relatedness, medical management and compensation for research related injury will be communicated by the NTI-IEC to the Licensing authority (DCGI) within 30 calendar days of the initial

reporting of occurrence of the SAE in case of regulatory clinical trials as per the new NDCT Rule 2019 as per stated text "Compensation in case of injury or death in clinical trial or bioavailability or bioequivalence study of new drug or investigational new drug.— (1) Where any death of a trial subject occurs during a clinical trial or bioavailability or bioequivalence study, the legal heir of the trial subject shall be provided financial compensation by the sponsor or its representative, who has obtained permission to conduct the clinical trial or bioavailability or bioequivalence study, in accordance with the procedure specified in rule 42".

3. On Site monitoring

- **Time and Site of Visit**: The decision letter issued to the PI during approval of the protocol will have the statement on on-site monitoring of the study.
  - The routine monitoring of the protocols will be done at least once in a year.
- Two minimum visits are done for a study from initiation till completion.
  - **Visit -1**: During the progress of the study.
  - After the PI submits the first progress report (six months after initiation of the study).
  - **Visit-2**: one visit before the completion of the study.
- **"For-cause monitoring"** will be performed at sites for reasons identified by any member of the NTI-IEC, after approval by the Chairperson. The reasons for identifying a particular site for "for-cause monitoring" could include any one or more of the following:
  - Large number of Serious Adverse Events (SAE) reports/ scientific misconduct/ large number of Protocol deviations/ Complaints received from subjects, head of the institution or any other person (anonymous complaints received shall be entertained if they affect subject safety)
- **During the Visit:**
  - The Monitoring team consisting of a smaller group of IEC members (NTI-IEC sub-committee) will monitor the trial site to check the

following for compliance with the protocol and the New Drugs and Clinical Trials Rules, 2019:

1) Check the log of delegation of responsibilities of study team
2) Check if the site is using latest NTI-IEC approved current versions of the protocol, informed consent documents, case record forms, diaries, advertisements, etc.
3) Observe the informed consent process, if possible
4) Review randomly selected participants files to ensure that participants are signing the correct informed consent,
5) Check investigational product accountability is adequately controlled and documented throughout the product flow at the study site (arrival, dispensing, use, return from the subject and return/destruction after the study),
6) Check for storage times, conditions and expiry dates to be acceptable and sufficient supplies available, wherever applicable,
7) Verify that the investigator follows the approved protocol and all approved amendment(s), if any,
8) Ensure that the investigator and the investigator's trial staff are adequately informed about the trial,
9) Verify that the investigator and the investigator's trial staff are performing the specified study functions, in accordance with the approved protocol and any other written agreement between the sponsor and the investigator/institution, and have not delegated these functions to unauthorized individuals,
10) Verify that the investigator is enrolling only eligible subjects,
11) Determine whether all SAEs are appropriately reported within the time frame as per the applicable regulatory requirement(s). Case record forms would be checked to review the safety data i.e. Adverse Events (AEs) and SAEs for the volume or severity of adverse events,
12) Review the project files of the study to ensure that documentation is filed appropriately.

13) Review the source documents for their completeness,

14) Collect views of the study participants, if possible.

4. Decision taken by the NTI-IEC Sub-Committee will be brought to the notice of the NTI-IEC members at next regular meeting of the NTI-IEC and their concurrence taken into record.

24.0 Management of protocol non-compliance (applicable in case of protocol deviation/violation)

The NTI-IEC Member Secretary and Secretariat are responsible for collecting and recording the protocol non-compliance list (protocol deviation / violation). The NTI-IEC Chairman and members are responsible to discuss and decide action for the protocol non-compliance (protocol deviation / violation)

1. Flow chart

No.	Activity	Responsibility
1	Submission of protocol non-compliance list (protocol deviation / violation) once every calendar month.	The Principal Investigator or Co-Principal Investigator
	↓	
2	Collecting and recording the protocol non-compliance list (protocol deviation / violation).	NTI-IEC Member Secretary & Secretariat
	↓	
3	Committee discussion and decision	NTI-IEC Members and Chairman
	↓	
4	Notify the investigator	NTI-IEC Member Secretary
	↓	
5	Keep records and follow up	NTI-IEC Member Secretary

2. Detailed instructions

2.1 Collecting and recording the list of protocol non-compliance (protocol deviation / violation): The NTI-IEC Member Secretary & secretariat will

- Compile the list of protocol non-compliance (protocol deviation / violation) (***Annexure 7-A***) if reported by the Investigator / Sponsor to the NTI- IEC once every calendar month, separately for each study.

- Ensure that the list of protocol non-compliance (protocol deviation / violation) are included in the agenda of the forthcoming NTI-IEC meeting.

2.2 Committees discussion and decision

The NTI-IEC Chairman and members will

- Discuss the protocol non-compliance (protocol deviation / violation) based on the risks to study participants and compliance with regulatory requirements.(***Annexure 7-B***)
- Decide on
  - continuing the study with frequent monitoring and or on-site monitoring visits
  - suspending or terminating approval of the study

2.3 Notify the investigator

- The Member Secretary records the NTI-IEC's decision.
- Prepare a notification letter. (***Annexure 7-C***)
- The notification letter (***Annexure 7-C***) will be signed by the Chairperson with the date.
- NTI-IEC Secretariat will:
  - Make four copies of the notification letter.
  - Send the original copy of the notification to the investigator.
  - Send the first copy to the sponsor or the sponsor's representative of the study.

2.4 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.
- Keep the last copy in the appropriate study file.
- Follow up the action after a reasonable time.

25.0 UNDERTAKING BY THE ETHICS COMMITTEE

1. Full name, address and title of the Chairman

Name : Dr. Srigiri S. Revadi
Address : 619, B-4 Towers, Yamuna Block, National Games Village, Koramangala, Bengaluru – 560047
Title : Senior Clinician

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. Names, address, qualifications & designation of the other members of the Ethics Committee.*

Sr. No.	Name	Qualification with Specialization	Current Organization	Telephone number, fax Number, e-mail I . D .and mailing address	Designation/ Role of member in Ethics Committee	Affiliation of member with institute that has constituted the Ethics Committee
1	Dr. Srigiri S Revadi	MBBS, MD (TB&RD), DTCD, FCCP	The Bengaluru Hospital, Bengaluru and Raghav Diagnostic & Research Centre, Jayanagar, Bengaluru, Karnataka	619, B-4 Towers, Yamuna Block, National Games Village, Koramangala, Bengaluru – 560047 Phone No. 9448088261 Email: drsrigirirevadi@gmail.com	Clinician, Chairperson	No
2	Dr. Om Prakash	MBBS, MD (General Medicine)	St Martha's Hospital, #5, Nrupathunga Road, RBI Colony, Sampangi Rama Nagara, Bengaluru - 560001, Karnataka	D-16, St. John's Medical College Staff Qtrs., Hosur Main Road, Koramangala, Bengaluru 560034 Phone No. 9343692830 Email: aparanji43@gmail.com	Clinician, Member	No

3	Dr. Vineet Kumar Chadha	MBBS, MD (PSM)	National Tuberculosis Institute, 8, Bellary Road, Bengaluru – 560 003	1016, Prestige Kensington Garden Apartments, HMT Factory Main Road, Jallahalli, Bengaluru – 560013, Phone No. 9916493109, Email: vineet2.chadha@gmail.com	Scientific Member	Yes
4	Dr. Thelma Narayan	MBBS, MSc. (Epidemiology), Ph.D. (Health Policy)	SOCHARA (Society for Community Health Awareness, Research and Action), # 359, Srinivasa Nilaya, Jakkasandra 1st Main, 1st Block, Koramangala, Bengaluru–560034, Karnataka	# 326, 5th Main, 1st Block, Koramangala, Bengaluru – 560 034. Karnataka, India. Phone No. 9341257911 Email: thelma@sochara.org	Social Scientist, Member	No
5	Dr. Nivedita Nivedita	MBBS, MD (Pharmacology)	Department of Pharmacology, ESIC-Medical College & PGIMSR, Rajajinagar, Bengaluru, Karnataka	No. 861, 5th Main, 5th Block, HMT Layout, Vidyaranyapura, Bengaluru-560097 Phone No. 9448454436, Email: niveditha.belavadi@gmail.com	Basic Medical Scientist, Member	No
6	Dr. S. Vijaya	BSc, MSc. (Biochemistry), Ph.D. (Biochemistry)	Department of Microbiology and Cell Biology Indian Institute of Science Bengaluru 560012	C105, Gowri Apartments New BEL Road, Bengaluru 560054. Phone No. 9448360798 Email: vijaya@mcbl.iisc.ernet.in	Scientific Member	No

7	Mrs. Brindha Nandakumar	BA, LLB	Bengaluru Mediation Centre, Karnataka High Court, Bengaluru 560001	Flat No. 301, 3rd floor, H M Wimberly Apartments, No. 6 Berlie Street cross, Langford Town, Bengaluru - 560025 Phone No. 9900510202, Email: brindhanandakumar@yahoo.com	Legal Expert, Member	No
8	Dr. Vishnu Vardhan Kamineni	MBBS, MSc Int Health, DTMPH	The Global Fund to Fight AIDS, Tuberculosis and Malaria, World Health Organization, Geneva, Switzerland	No. 85, 1 stage AECS Layout, 16 cross, 2 main, Sanjaynagar, Bengaluru – 560094, Phone No. 9900866875, Email : vvkamineni@gmail.com	Scientific Member	No
9	Mrs. Smitha B R	12th, B.E. Civil Engineering	SDM Projects Pvt. Ltd, Bengaluru	No 628, 1stMain Road, Kempegowda Nagar, 8th Mile, T. Dasarahalli, Bengaluru – 560 057, Phone No. 9663430054, Email: brc.smitha07@gmail.com	Lay Person Member	No
10	Dr. C. Ravichandra	MBBS	National Tuberculosis Institute, 8, Bellary Road, Bengaluru – 560 003	No. 10, Ashraya, 1st cross, KPSC Layout, Sampigehalli, Agrahara main Road, Agrahara, Bengaluru-560064 Phone no. 8660374749, Email: ravipassi56@gmail.com	Member Secretary, Ex-officio	Yes

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 the 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 the clinical trial, the Committee shall analyze and forward its opinion as per 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 raised by such inspectors or officials, as the case may be, in relation to the conduct of clinical trial.

(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).

Chairman
NTI-IEC

(Signature of the Chairman)
Date:

Member Secretary
NTI-IEC

(Signature of the Member secretary)
Date: 12/05/2022

Institutional Ethics Committee
Government of India
National TB Institute, Bangalore

ANNEXURE – 1

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

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

File no. Dated

IEC Registration Number :
Date:

To,
Dr.

Protocol No./ study no.

Protocol Title:

Dear Dr._____

Please refer to your letter dated……. And the Proposal submitted with it.

The Institutional ethics committee or independent ethics committee (state name of the committee, as appropriate) reviewed and discussed your application to conduct the clinical trial entitled "……. "on…….(date). The following documents were reviewed:

The ethics committee grants approval to the conduct of the study in accordance with the following documents:

Sr.No.	Documents Title	Documents Version & Dated
1.	Study Protocol	
2.	Subject Authorization form	
3.	Trail protocol	
4.	Patients informed sheet (english and vernacular language)	
5.	Informed consent form (english and vernacular language)	
6.	Investigator's Brochure	

7	Principal investigator's current CV	
8.	Insurance policy or compensation for participation and for serious adverse events occurring during the study participation.	
9.	Investigator's agreement with the sponsor.	
10.	Investigator's undertaking	

The Members who were present at the meeting and took part in the deliberations are listed below:

Sr.no	NAME	QUALIFICATION	ROLE/DESIGNATION ETHIC COMMITTEE
1.			
2.			
3.			
4.			
5.			

Type of Review: New Review/ Revised Review/ Expedited Review /Amendment Review

No. of members participated in voting:

Decision of the IEC: Favorable/ Unfavorable/ No Opinion

We approve the trial to be conducted in its presented form.

The ethics committee to be informed about the progress of the study, any Serious Adverse Events (SAE) occurring in the course of the study, any changes in the protocol and patient information or informed consent and to be provided with a copy of the final report.

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.*

Yours sincerely,

Member Secretary - IEC **Chairperson – IEC**

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.**

1. Title of the study/project.
2. Aims and methods of the research.
3. Expected duration of participation of the subject.
4. Statement that the study involves research and explanation of the purpose of the research.
5. Description of the procedures to be followed, including all invasive procedures.
6. Description of any reasonably foreseeable risks or discomforts to the Subject.
7. Description of any benefits to the Subject or others reasonably expected from research. If no benefit is expected Subject should be made aware of this.
8. Disclosure of specific appropriate alternative procedures or therapies available to the Subject.
9. Statement describing the extent to which confidentiality of records identifying the Subject will be maintained and who will have access to Subject's medical records.
10. Trial treatment schedule and the probability for random assignment to each treatment (for randomized trials).
11. Statement describing the financial compensation and the medical management as under:
    a. In case of an injury occurring to the subject during the clinical trial, free medical management shall be given as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier.
    b. In the event of a trial related injury or death, the sponsor or his representative or the investigator or centre, as the case may be, in accordance with the rule 39, as the case may be, shall provide financial compensation for the injury or death.

12. An explanation about whom to contact for trial related queries, rights of Subjects and in the event of any injury.
13. The anticipated prorated payment, if any, to the subject for participating in the trial.
14. Responsibilities of subject on participation in the trial.
15. Statement that participation is voluntary, that the subject can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the subject is otherwise entitled.
16. Statement that there is a possibility of failure of investigational product to provide intended therapeutic effect.
17. Statement that in the case of placebo controlled trial, the placebo administered to the subjects shall not have any therapeutic effect. 216 THE GAZETTE OF INDIA : EXTRAORDINARY [PART II—SEC. 3(i)]
18. Any other pertinent information.
19. Additional elements, which may be required:
    a. Statement of foreseeable circumstances under which the participation of the subject may be terminated by the Investigator without his or her consent.
    b. Additional costs to the subject that may result from participation in the study.
    c. The consequences of a Subject's decision to withdraw from the research and procedures for orderly termination of participation by Subject.
    d. Statement that the Subject or Subject's representative will be notified in a timely manner if significant new findings develop during the course of the research which may affect the Subject's willingness to continue participation will be provided.
    e. A statement that the particular treatment or procedure may involve risks to the Subject (or to the embryo or foetus, if the Subject is or may become pregnant), which are currently unforeseeable.

20. Approximate number of Subjects enrolled in the study
21. Provision of free treatment for research related injury.
22. Compensation to subjects for disability or death resulting from such injury.
23. Amount of blood sample to be taken should be mentioned in PIS as Tea Spoon Full measure.
24. Costs and source of investigations, disposables, implants and drugs / contrast media must be mentioned in the PIS.
25. Telephone number/contact number of the candidate and one of the investigators must be mentioned in the PIS.

26. 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
c. Self certification should be given that translation to vernacular language is accurate.

ANNEXURE – 3:

PARTICIPANT IFORMED CONSET FORM (PICF)

Study Title:			
Subject's Initials:		Subject's Name:	
DOB	[ ] [ ]/ [ ] [ ]/ [ ] [ ] [ ] [ ] d d / m m / y y y y		
Address of the Subject			
Qualification			
Occupation (Please mark as appropriate) Student [ ] Self-Employed [ ] Service [ ] Housewife [ ] Others [ ]			
Annual Income of the subject			
Name of the nominees			
Address of the nominees			
Relation of the nominees to the subject			
Purpose of compensation in case of trial related death to the nominees			

Declaration from the participant's end:

Declaration	Signature (Subject)
I confirm that I have read and understood the information Sheet dated _____ for the above study and have had the opportunity to ask questions.	
I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	
I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and	

the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.	
I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purposes	
I agree to take part in the above study.	

	__ __/ __ __/ __ __ __ __	
Signatory's Name	Date (dd/mm/yyyy)	Signature (or Thumb impression) of the Subject/Legally Acceptable Representative

	__ __/ __ __/ __ __ __ __	
Study Investigator's Name	Date (dd/mm/yyyy)	Signature of the Investigator

	__ __/ __ __/ __ __ __ __	
Name of the Witness	Date (dd/mm/yyyy)	Signature of the Witness

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:_____

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)

***Proposal Reference Code:** _____

Name of the Committee Member: _____

(**Signature with date**)

Annexure 6

Serious Adverse Event Reporting Format

SERIOUS ADVERSE EVENT (SAE) REPORTING FORM					
Is there any Serious Adverse event experienced by the subject? *(If yes, kindly complete the adverse event form)*				Yes ❑ No ❑	
Serious Adverse Event Description				**SAE Number**	
Is this an initial report of follow up report? *(Kindly tick whichever is applicable)*				Initial Report ❑ Follow up report ❑ Follow up report No.*:* [__I__]	
Subject's Details					
Initials			[__I__I__]		
Gender			Male ❑ Female ❑		
Date of Birth (DD-MM-YY)			[__I__]-[__I__]-[__I__]		
Age			[__I__] or [__I__] / [__I__] / [__I__] Years Months / Weeks / Days		
Concomitant conditions:					
Medical history:					
Relevant family history:					
Suspected Drug(s)					
				Route	Duration of Therapy

Name (Brand / or Generic name) with dosage form & strength	Batch / lot no.	Indication (Reason for use or prescribed for)	Daily dose (specify units – e.g., mg, ml, mg/kg) & regimen	Used	Start date	Time	Stop date	Time

Other Treatment(s) (prescription or nonprescription medications/non-drug therapy

Name (Brand / or Generic name) with dosage form & strength	Batch / lot no	Indication (Reason for use or prescribed for)	Daily dose (specify units – e.g., mg, ml, mg/kg) & regimen	Route Used	Duration of Therapy	
					Start date & time	Stop date & time

Details (all available) of the Event(s) reported as Suspected Adverse Drug Reaction(s) / Description

Full description of the reaction/event along with body site/system involved:

Severity of reaction:	Mild ❑	Moderate ❑	Severe ❑

Mild = No interference with usual activities; Moderate = Significant interference with usual activities; Severe = Prevents usual activities

Criteria for reporting the event as an SAE - the adverse event resulted in (please tick as applicable):

❑ Death				
❑ A life threatening experience				
❑ Inpatient hospitalization or prolongation of existing hospitalization *				
❑ A persistent or significant disability/incapacity				
❑ A congenital anomaly/birth defect				
❑ Any other important medical event (Which as per PI opinion can be considered serious				
If patient was hospitalized / hospitalization prolonged, enter dates:	Admitted: [__I__]-[__I__]-[__I__] D D M M Y Y	Discharged: [__I__]-[__I__]-[__I__] D D M M Y Y	Still in hospital: Yes ❑ No ❑	Discharge Summary Attached: Yes ❑ No ❑

Event Start date and time [__I__]-[__I__]-[__I__] [__I__]:[__I__] hrs	**Event Stop date and time** [__I__]-[__I__]-[__I__] [__I__]:[__I__] hrs	**Event ongoing at final contact** Yes ❑ No ❑	
Reaction abated after use stopped or dose reduced	**Yes** ❑	**No** ❑	
	Not applicable ❑		
Reaction reappeared after reintroduction	Yes ❑	No ❑	
	Not applicable ❑		

Relevant diagnostic test results and laboratory data:

Outcome

Resolved with no sequelae ❑	Resolved with sequelae ❑ Please Specify_____
	Date of Resolution: [__I__]-[__I__]-[__I__]

Ongoing at final contact ❑	Death ❑	Unknown ❑

In case of death (please mention cause of death)

a. Immediate cause or condition resulting in death:

_____

b. Other conditions if any leading to cause listed on 'a' line:

_____

Autopsy report (if any)

_____

Causal relationship to the drug	**Certain ❑**	**Probable/ Likely ❑**	**Possible ❑**
	Unlikely ❑	**Conditional/ ❑ Unclassified**	**Unassessible/ Unclassifiable ❑**

Certain: *A clinical event, including laboratory test abnormality, occurring in a plausible time relationship to drug administration, and which cannot be explained by concurrent disease or other drugs or chemicals. The response to withdrawal of the drug (dechallenge) should be clinically plausible. The event must be definitive pharmacologically or phenomenologically, using a satisfactory rechallenge procedure if necessary.*

Probable/likely: *A clinical event, including laboratory test abnormality, with a reasonable time sequence to administration of the drug, unlikely to be attributed to concurrent disease or other drugs or chemicals, and which follows a clinically reasonable response on withdrawal (dechallenge). Rechallenge information is not required to fulfil this definition.*

Possible: *A clinical event, including laboratory test abnormality, with a reasonable time sequence to administration of the drug, but which could also be explained by concurrent disease or other drugs or chemicals. Information on drug withdrawal may be lacking or unclear.*

Unlikely: *A clinical event, including laboratory test abnormality, with a temporal relationship to drug administration which makes a causal relationship improbable, and in which other drugs, chemicals or underlying disease provide plausible explanations.*

Conditional / Unclassified: *A clinical event, including laboratory test abnormality, reported as an adverse reaction, about which more data is essential for a proper assessment or the additional data are under examination.*

Unassessible / unclassifiable: *A report suggesting an adverse reaction which cannot be judged because information is insufficient or contradictory, and which cannot be supplemented or verified.*

Any other relevant information to facilitate the assessment of the case:	
Details about the Investigator	
Name:	Profession (specialty)
Address:	Contact No.
Date of reporting of event to the Ethics Committee overseeing the site: [__I__]-[__I__]-[__I__] Date of reporting of event to the Sponsor: [__I__]-[__I__]-[__I__] Date of reporting of event to the Licensing Authority: [__I__]-[__I__]-[__I__] (*Please report the Serious Adverse Event to the Institution Review Board, sponsor and Licensing Authority within 24 hours of occurrence of SAE.)*	

Annexure: 7-A

PROTOCOL DEVIATION/VIOLATION NOTIFICATION TO NTI IEC BY PRINCIPAL INVESTIGATOR

NTI-IEC Reference Code:	Date:……
Study Title:	
Principal Investigator:	Contact No.:
Sponsor:	Contact No.:

□ Protocol deviation	□ Protocol violation
Description:	
Impact on the participant's risk / benefit:	
Details of corrective actions, if any:	
Details of preventive actions, if any:	
Reported by:…… Date:……	
Signature of PI …… Date: ……	

Annexure: 7-B

PROTOCOL DEVIATION/VIOLATION NTI-IEC REVIEW REPORT

DATE OF NTI-IEC MEETING:	
NTI-IEC Reference Code:	
Study Title:	
Principal Investigator:	
Sponsor:	
□ Protocol deviation	□ Protocol violation
NTI-IEC Discussion	
NTI-IEC Decision: ➢ continuing the study with training of the 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: 7-C

LETTER TO PI – NOTIFICATION OF PROTOCOL DEVIATION/NON-COMPLIANCE/VIOLATION

Members Non-Affiliated)

Dr.

Chairperson

Dr.

Member Secretary

Members (Affiliated)

File No…… Date: …….

To

…….
…….
…….

Sir / Madam,

Sub: NTI IEC Reference Code: …….

"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 NTI-IEC meeting dated --.

The NTI-IEC decision is ----------

Chairman

To : Principal Investigator of the study
cc to : The Director, National Tuberculosis Institute, Bengaluru