GOVERNMENT OF INDIA
NATIONAL TUBERCULOSIS INSTITUTE
Institutional Ethics Committee
(CDSCO Registration No. ECR/1194/Inst/KA/2019)
'AVALON' NO.8, BELLARY ROAD, BENGALURU 560 003

ADDENDUM DATED 06/10/2020 : NTI-IEC STANDARD OPERATING PROCEDURES
Version 1.2, dated 02.01.2019

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

SOP Number: NTI-IEC, Version 1.2, 02.01.2019	**Revision Number: 01**	
SOP Author: **Dr. C. Ravichandra** **(Member Secretary NTI-IEC)** **Signature**	**SOP Approver:** **Shri S. Vijay Shankar** **(Chairman, NTI IEC)** **Signature**	**Effective Date :** **06 October 2020**
	Dr. N. Somashekar **(Director)** **Signature**	**Addendum:** **NTI-IEC, SOPs Version 1.2, 02.01.2019**

1. PURPOSE

To provide instructions for taking actions and maintaining records that identify investigators/institutes who fail to follow the procedures written in the protocol approved by NTI-IEC or to comply with regulatory guidelines for the conduct of research on human participants or fail to respond to the NTI-IECs requests.

2. SCOPE

This SOP applies to all NTI-IEC approved research protocols involving human participants.

3. RESPONSIBILITY

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)

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4. 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

5. DETAILED INSTRUCTIONS

5.1 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 6-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.

5.2 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 6-B)***
- Decide on
  - continuing the study with frequent monitoring and or on-site monitoring visits
  - suspending or terminating approval of the study

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5.3 Notify the investigator

- The Member Secretary records the NTI-IEC's decision.
- Prepare a notification letter. ***(Annexure 6-C)***
- The notification letter ***(Annexure 6-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.

5.4 Keep records and follow up

- Keep the second copy of the notification letter in the "non-compliance" file.
- Store the file in the shelf with an appropriate label.
- Keep the last copy in the appropriate study file.
- Follow up the action after a reasonable time.

6. ANNEXURE

Annexure Code	Annexure title
6-A	Protocol Deviation / Violation notification to NTI-IEC by Principal Investigator
6-B	Letter to Principal Investigator – Notification of Protocol Deviation / Violation
6-C	Protocol Deviation / Violation NTI-IEC review report

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7. GLOSSARY

Protocol deviation	Accidental or unintentional changes to, or non-compliance with the research protocol that does not increase risk or decrease benefit or; does not have a significant effect on the subject's rights, safety or welfare; and/or on the integrity of the data. A deviation may be due to the research subject's non- adherence, or an unintentional change to or non-compliance with the approved research protocol on the part of a researcher. ***Examples of a deviation include***: - *A missed follow-up visit* - *A rescheduled study visit* - *Failure to collect an ancillary self-report questionnaire* - *Subject's refusal to complete scheduled research activities*
Protocol violation	Accidental or unintentional change to or non-compliance with the IEC approved protocol without a prior sponsor and IEC approval. Violations generally increase risk or decrease benefit, affects the subject's rights, safety, or welfare, or the integrity of the data. ***Examples of protocol violations:*** - *Failure to obtain valid informed consent (e.g., obtained informed consent on a non-date stamped form)* - *Loss of laptop computer that contained identifiable, private information about subjects* - *Accidental distribution of incorrect study medication or dose* - *Not following inclusion/exclusion criteria*

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Annexure: 6-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:	

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Annexure: 6-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:

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Annexure: 6-C

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

Shri.
Chairperson

Dr.
Member Secretary

Members (Non-Affiliated)

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 ----------

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Chairman

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