



(Annexure 3)

Continuing Review/Annual Report Format

**North Eastern Indira Gandhi Regional Institute of Health & Medical Sciences (An Autonomous Institute, Ministry of Health and Family Welfare, Government of**

**India)**

**Mawdiangdiang, Shillong (Meghalaya) – 793018 India (**[**www.neigrihms.gov.in**](http://www.neigrihms.gov.in/)**) Email id:** [iec.neigrihms@gmail.com](mailto:iec.neigrihms@gmail.com)**; EC Ref. No**.:(for office use)

***\*The annual report must be duly submitted no later than 30 days before the annual year's completion.***

Title of study:

Principal Investigator (Name, Designation and Affiliation):

1. IEC Reference No : (Project No.)
2. Date of EC Approval: Duration of Approval(months/year):
3. Date of Start of study: Proposed date of Completion: Period of Continuing Report: To
4. Does the study involve recruitment of participants? (Yes/No):
   1. If yes, Total number expected:

No. Screened: No. Enrolled:

* 1. Enrolment status(ongoing/completed/stopped):
  2. Report of DSMB16 (Yes/No/NA):
  3. Any other remark:
  4. Have any participants withdrawn from this study since the last approval? (Yes/No/NA): If yes, total number withdrawn and reasons:

1. Is the study likely to extend beyond the stated period?17 (Yes/No): If yes, please provide reasons for the extension:
2. Have there been any amendments in the search protocol/informed consent document (ICD) during the past approval period? (Yes/No):

If No, skip to item no. 6

* 1. If yes, date of approval for protocol and ICD:
  2. In case of amendments in the research protocol/ICD, was re-consent sought from participants? (Yes/No):

If yes, when/how:

\*Please delete whichever is not applicable.

Version 2.001

*16In case there is a Data Safety Monitoring Board (DSMB)for the study provide a copy of the report from the DSMB. If not write NA.*

*17Problems encountered since the last continuing review application with respect to implementation of the protocol as cleared by the EC*

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1. Is there any new information available that changes the benefits-risk analysis of human participants involved in this study? (Yes/No):

If yes, discuss in details:

1. Have any ethical concerns occurred during this period? (Yes/No)

If yes, give details:

1. a) Have any adverse events been noted since the last review? (Yes/No):

Described in brief:

b)Have any SAEs occurred since last review? (Yes/No): If yes, number of SAEs: Type of SAEs:

c) Is the SAE related to the study? (Yes/No):

Have you reported the SAE to EC? (Yes/No):

If no, state reasons:

1. Has there been any protocol deviations/violations that occurred during this period? (Yes/No):

If yes, number of deviations:

Have you reported the deviations to EC? (Yes/No):

If no, state reasons:

1. In case of multicentric trials, whether reports of off-site SAEs have been submitted to the EC (Yes/No/NA):
2. Are there any publications or presentations during this period? (Yes/No): If yes, give details:
3. Brief summary of the study (up to 500 words) (to briefly described the status, findings, activities undertaken, any deviations or changes, special mentions etc.):

Version 2.002

Signature of PI: Date:

Version 2.003

(Annexure 7)

Premature Termination/Suspension/Discontinuation Report Format

**North Eastern Indira Gandhi Regional Institute of Health & Medical Sciences**

**(An Autonomous Institute, Ministry of Health and Family Welfare, Government of India) Mawdiangdiang, Shillong (Meghalaya) – 793018 India (**[**www.neigrihms.gov.in**](http://www.neigrihms.gov.in/)**)**

**Email id:** [iec.neigrihms@gmail.com](mailto:iec.neigrihms@gmail.com)**; EC Ref. No**.:(for office use)

Title of the study:

Principal Investigator (Name, Designation and Affiliation):

1. Date of IEC Approval: Date of start of study:
2. Date of Last Progress Report Submitted to EC:
3. Date of Termination/suspension/discontinuation:
4. Select the appropriate: - PrematureTermination(yes/No/NA):

Suspension (yes/ No/NA) : Discontinuation:(Yes/No/NA):

Reason for Termination/Suspension/Discontinuation:

Action taken post Termination/ Suspension/ Discontinuation:

1. Plans for post study follow up/withdrawal**21**(if any):
2. Details of study participants:

Total participants to be recruited: Screened: Screen failures: Enrolled:

Consent Withdrawn:

Reason (Give details):

Withdrawn by PI:

Reason(Give details):

Active on treatment: Completed treatment:

Participants on Follow-up: Participants lost follow up:

Any other: No. of drop outs:

Reasons for each drop-out:

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1. Total Number of SAEs reported till date in the study:

Have any unexpected adverse events or outcomes observed in the study been reported to the EC? (yes/No)

1. Have there been participant complaints or feedback about the study? (Yes/No): If yes, provide details:

*21Describe post termination/suspension/discontinuation follow up plans if any. Also described any withdrawal plans for the study.*

1. Have there been any suggestions from the SAE Sub Committee? :(Yes/No) If yes, have you implemented that suggestion? (Yes/No)
2. Do the procedures for withdrawal of enrolled participants take into account their rights and welfare? (e.g., making arrangements for medical care of research participants) (Yes/No/NA):

If yes, provide details:

Summary of Results (if any):

Signature of PI: Date:

Version 2.002

(Annexure 12)

Study completion/Final report format

**North Eastern Indira Gandhi Regional Institute of Health & Medical Sciences**

**(An Autonomous Institute, Ministry of Health and Family Welfare,Government of India) Mawdiangdiang, Shillong (Meghalaya) – 793018 India (**[**www.neigrihms.gov.in**](http://www.neigrihms.gov.in/)**)**

**Email id:** [iec.neigrihms@gmail.com](mailto:iec.neigrihms@gmail.com)**; EC Ref. No**.:(for office use)

Title of the study:

Principal Investigator (Name, Designation and Affiliation):

1. IEC reference No :(Project No)
2. Date of IEC Approval:
3. Date of Start of Study: Date of study completion:

Date of Start of Study: Date of study completion:

1. Provide details of:
   1. Total no. of study participants approved by the EC for recruitment:
   2. Total no. of study participants recruited:
   3. Total no of participants withdrawn from the study (if any): Provide the reason for withdrawal of participants23:
2. Describe in brief the publication/presentation/dissemination plans of the study findings: (Also, mention if both positive and negative results will be shared):
3. Describe the main Ethical issue encountered in the study (if any):
4. State the number (if any) of Deviations/violations/Amendments made to the study protocol during the study period

Deviations: Violation: Amendments:

1. Describe in brief plans for archival of records/Record Retention:
2. Is there a plan for post study follow -up (Yes/No):

If yes, describe in brief:

1. Do you have plans for ensuring that the data from the study can be shared /accessed easily? (Yes/No): If yes, describe in brief:
2. Is there a plan for post study benefit sharing with the study participants? (Yes/No): If yes, describe in brief:
3. Describe results (summary) with Conclusion24:
4. Number of SAEs that occurred in the study:
5. Have all SAEs been intimated to the EC? (Yes/No):
6. Is medical management or compensation for SAE provided to the participants? (Yes/No): If yes, provide details:

Signature of PI: Date