Continuing Review / Annual report

**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)**)**

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Title of Study:

Principal Investigator (Name, Designation and Affiliation):

|  |  |
| --- | --- |
| **1.** Date of EC Approval: | Validity of approval: |
|  |  |
| **2.** Date of Start of study: | Proposed date of Completion: |
|  |  |
| Period of Continuing Report: | to |
| **3.** Does the study involve recruitment of participants? | Yes/No: |

1. If yes, Total number expected: Number Screened: Number Enrolled:

Number Completed: Number on follow up:

1. Enrolment status – ongoing / completed/ stopped
2. Report of DSMB Yes/No/NA:

(d) Any other remark:

(e) Have any participants withdrawn from this study since the last approval? Yes/No:

If yes, total number withdrawn and reasons:

**4.** Is the study likely to extend beyond the stated period? Yes/No:

If yes, please provide reasons for the extension:

**5.** Have there been any amendments in the research protocol/Informed Consent Document (ICD) during the past approval period? Yes/No:

If No, skip to item no. 6

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| --- | --- | --- |
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* 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:
  3. If yes, when/how:

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**6.** Is any new information available that changes the benefit - risk analysis of human participants involved in this study? Yes/No:

If yes, discuss in detail:

**7.** Have any ethical concerns occurred during this period Yes/No:

If yes, give details:

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

Describe in brief:

(b) Have any SAE’s occurred since last review? Yes/No:

If yes, number of SAE’s: Type of SAE’s:

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

Have you reported the SAE to EC? If no, state reasons Yes/No:

**9.** Has there been any protocol deviations/violations that occurred during this period?

If yes, number of deviations

Have you reported the deviations to EC? If no, state reasons Yes/No:

**10.** In case of multicenteric trials, have reports of off-site SAEs been submitted to the EC? Yes/No/NA:

**11.** Are there any publications or presentations during this period? If yes give details Yes/No:

Any other comments:

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| --- | --- | --- |
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Signature of PI:

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