(Annexure 2)

Application Form for Exemption from Review

**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**; EC Ref. No**.:(for office use)

Title of study:

Principal Investigator (Name, Designation and Affiliation):

1. Choose reasons why exemption from ethics review is requested 14?
	1. Research on data in the public domain/ systematic reviews or meta-analyses. (Yes/No):
	2. Observation of public behavior/ information recorded without linked disclosure would not harm the interests of the observed person (Yes/No):
	3. Quality control and quality assurance audits in the institution. (Yes/No):
	4. Comparison among instructional techniques, curricula, or classroom management methods.

(Yes/No):

* 1. Consumer acceptance studies related to taste and food quality (Yes/No):
	2. Public health programmes by government agencies15 (Yes/No):
	3. Any other (please specify in 100 words):

Signature of PI:

Signature of Secretariat:

Signature of Member Secretary:

*14Select the category that applies best to your study and justify why you feel it should be exempted from review. For a detailed understanding of the type of studies that are exempt from review, refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 51 Table 4.2.*

*15Such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers)*

**(Annexure 4)**

Application/Notification Form for Amendments

**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**; EC Ref. No**.:(for office use)

 Title of study:

Principal Investigator (Name, Designation and Affiliation):

1. Date of EC Approval: Date of Start of Study:

2. Details of amendment(s)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Sl. No | Existing Provision | Proposed Amendment | Reason | Location in theprotocol/ICD*18* |
| 1. |  |  |  |  |
| 2. |  |  |  |  |

3. Impact on benefit-risk analysis (Yes/No):

If yes, describe in brief:

4. Is any re-consent necessary? (Yes/No):

If yes, have necessary changes been made in the informed consent? (Yes/No)

5. Type of review requested for amendment:

 Expedited review (No alteration in risk to participants) (Yes/No):

Full review by EC (There is an increased alteration in the risk to participants) (Yes/No):

6. Version number of amended Protocol/Investigator’s brochure/ICD:

Signature of PI: Date:

*18Location implies page number in the ICD/protocol where the amendment is proposed.*

(Annexure 5)

Protocol Violation/Deviation Reporting form (Reporting by case)

**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**; EC Ref. No**.:(for office use)

Title of study:

 Principal Investigator (Name, Designation and Affiliation):

1. Date of EC approval: Date of start of study:
2. Participant ID: Date of occurrence:
3. Total number of deviations /violations reported till date in the study:
4. Deviation/Violation identified by-

Principal Investigator/study team (Yes/No):

Sponsor/Monitor (Yes/No):

SAE Sub Committee/EC (Yes/No):

1. Is the deviation related to (Select options below)-

Consenting (Yes/No): Source documentation (Yes/No):

Enrollment (Yes/No): Staff (Yes/No):

Laboratory assessment (Yes/No): Participant non-compliance (Yes/No):

Investigational Product (Yes/No): Safety Reporting (Yes/No):

Others (specify):

1. Provide details of Deviation/Violation:
2. Corrective action taken by PI/Co-PI:
3. Impact on (if any): Study participant (Yes/No): Quality of Data (Yes/No):
4. Are any changes to the study/protocol required? (Yes/No):

If yes, give details:

Signature of PI: Date:

(Annexure 6)

 Serious Adverse Event Reporting Format (Biomedical Health Research)

**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**; EC Ref. No**.:(for office use)

Title of study:

Principal Investigator (Name, Designation and Affiliation):

1. Participant details:

 Initials and ID: Age at the time of event: Gender: Weight (Kgs):

 Height (cms): Male/Female:

1. Suspected SAE diagnosis:
2. Date of onset of SAE: Describe the event*19*:

 Date of reporting SAE:

1. Details of suspected intervention causing SAE*20*
2. Report type:- Initial (Yes/No): Follow-up (Yes/No): Final (Yes/No):

 If Follow-up report, state date of Initial report:

1. Have any similar SAE occurred previously in this study? (Yes/No):

If yes, please provide details:

1. In case of a multi-centric study, have any of the other study sites reported similar SAEs (Please list number of cases with details if available).
2. Provide whichever is applicable for the SAE: *(Kindly note that this refers to the Intervention being evaluated and NOT disease process)*
3. Expected event (Yes/No): Unexpected event (Yes/No):

*19Duration, setting, site, signs, symptoms, severity, criteria for regarding the event serious*

*20Refers to research intervention including basic, applied and operational research or clinical research, except for investigational new drugs. If it is an academic clinical trial, mention name, indications, dosage, form and strength of the drug(s)*

1. Hospitalization (Yes/No): Increased Hospital stay (Yes/No): Death (Yes/No):

Congenital anomaly/birth defect (Yes/No): Event which poses threat to life (Yes/No):

Persistent or significant disability/incapacity (Yes/No):

Event requiring intervention (surgical or medical) to prevent SAE (Yes/No): Others:

In case of death, state probable cause of death:

1. No permanent/significant functional/cosmetic impairment (Yes/ No):

Permanent/significant functional/cosmetic impairment (Yes/ No):

Not Applicable (Yes/No):

1. Describe the medical management provided for adverse reaction (if any) to the research participants. (include the information on who paid, how much was paid and to whom)
2. Provide details of compensation provided/ to be provided to participants (include the information on who paid, how much was paid and to whom)
3. Outcome of SAE

Fatal (Yes/No): Recovered (Yes/No):

Continuing (Yes/No): Unknown (Yes/No):

Recovering (Yes/No): others (*specify*):

1. Provide any other relevant information to that can facilitate assessment of the case such as medical history:
2. Provide details about PI’s final assessment of SAE relatedness to trial:

Signature of PI: Date:



(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**; EC Ref. No**.:(for office use)

 Title of the study:

 Principal Investigator (Name, Designation and Affiliation):

Date of EC Approval: Date of start of study:

1. Date of Last Progress Report Submitted to EC:
2. Date of Termination/suspension/discontinuation:
3. Select the appropriate: -

Premature Termination (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 to follow up:

Any other: No. of drop outs:

Reasons for each drop-out:

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):

1. 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:

(Annexure 8)

Application form for Clinical Trials

**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**; EC Ref. No**.:(for office use)

 Title of study:

 Principal Investigator (Name, Designation and Affiliation):

1. Type of clinical trials: Regulatory trial (Yes/No): Academic trial (Yes/No):

 CTRI registration number: NABH accreditation number: EC registration number:

1. If regulatory trial, provide status of CDSCO permission letter

Approved and letter attached (Yes/No):

Applied, under process (Yes/No):

Not applied (State reason):

1. Tick all categories that apply to your trial

|  |  |  |  |
| --- | --- | --- | --- |
| Phase - I |  | Phase II |  |
| Phase III |  | Phase IV or Post Marketing Surveillance |  |
| Investigational medicinalproducts |  | Investigational New drug |  |
| Medical devices |  | New innovative procedure |  |
| Drug/device combination |  | Bioavailability/Bioequivalence studies |  |
| Non-drug intervention |  | Repurposing an existing intervention |  |
| Indian system of medicine(AYUSH) |  | Stem cells |  |
| Phytopharmaceutical drug |  | Approved drug for any new indicationor new route of administration |  |
| Others (specify) |  |

1. Trial design of the study (may choose more than one)

I. Randomized (Yes/No): Factorial (Yes/No): Non-randomized (Yes/No):

 Stratified (Yes/No): Parallel (Yes/No): Adaptive (Yes/No):

 Cross-over (Yes/No): Comparison trial (Yes/No): Cluster (Yes/No):

Superiority trial (Yes/No): Matched-pair (Yes/No): Non-inferiority trial (Yes/No):

 Equivalence trial (Yes/No): Others (specify):

* 1. If there is randomization, how will the participants be allocated to the control and study group(s)?
	2. Describe the method of allocation concealment (blinding / masking), if applicable.
1. List the primary / secondary outcomes of the trial.
2. Is there a Contract Research Organization (CRO) /Site Management Organization (SMO) / Any Other

 Agency such as public relation/Human resource? (Yes/No):

 If yes, Name and Contact details:

State how the CRO/SMO/agency will be involved in the conduct of the trial (Select all that apply)

Project management (Yes/No): Clinical and medical monitoring (Yes/No):

Regulatory affairs (Yes/No): Data management (Yes/No):

Statistical support (Yes/No): Medical writing (Yes/No):

Site management (Yes/No): Audits, quality control, quality assurance (Yes/No):

Finance management (Yes/No): Recruitment and training (Yes/No):

Administrative support (Yes/No): Others (specify):

1. Please provide the following details about the intervention being used in the protocol
2. Drug/s, device/s and/or biologics (Yes/No/NA):

 If yes, provide regulatory approval details:

1. Already approved drugs or a combination of two or more drugs with new indications / change in dosage form / route of administration (Yes/No/NA):

If yes, provide details:

1. Provide contact details of who prepared and /or is manufacturing the drug/s, device/s and biologics
2. Provide details of patent of the drug/s, device/s and biologics.
3. Describe in brief any preparatory work or site preparedness for the protocol? (Yes/No/NA):

If yes, (100words)

1. Is there an initial screening/ use of existing database for participant selection? (Yes/No/NA):

Yes, provide details*22*:

1. Are there any anticipated incidence, frequency and duration of adverse events related to the intervention? (Yes/No/NA):

If yes, provide details of arrangements made to address them.

1. Does the study use a placebo? (Yes/No/NA):

If yes, justify the use of the placebo and risks entailed to participants.

1. Will current standard of care be provided to the control arm in the study? (Yes/No/NA):

If no, please justify.

1. Are there any plans to withdraw standard therapy during the study? (Yes/No/NA):

If yes, please justify.

1. Are there any rules to stop the protocol in case of any adverse events? (Yes/No/NA):

 If yes, please specify.

1. Does the study have a Data and Safety Monitoring Plan? (Yes/No/NA):

If no, please justify.

1. Participant Information Sheet (PIS) and Informed Consent Form (ICF)

English (Yes/No):

Local language (Certified that local version (s) is/are true translation of the English version and can be easily understood by the participants) (Yes/No):

Others *(Specify)*:

 List the language in which translations were done:

Justify if translation not done:

*22In order to select participants for your protcol does the protocol require you to screen an initial population or refer to an existing database before shortlisting participants. If yes, provide details on the same*

1. Involvement/consultation of statistician in the study design (Yes/No/NA):
2. Is there any insurance coverage of the trial? (Yes/No/NA):

If yes, provide details.

1. Is the PI registered with Medical Council of India (MCI) or the State Medical Council registration? (Yes/No):

Please provide details:

1. Is the PI trained in GCP in last 3 years? (Yes/No):

 If yes, please enclose certificate.

Signature of PI: Date:

(Annexure 9)

Serious Adverse Event Reporting Format (Clinical trials)

**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**; EC Ref. No**.:(for office use)

 Title of study:

 Principal Investigator (Name, Designation and Affiliation):

1. Participant details:

 Initials and Case No./Subject ID: Age at the time of event: Male/Female:

 Weight (Kgs): Height (cms):

1. Report type- Initial (Yes/No): Follow-up (Yes/No): Final (Yes/No):

If Follow-up report, state date of Initial report:

What was the assessment of relatedness to the trial in the initial report?

By PI- Related/Unrelated:

By sponsor – Related/Unrelated:

By EC – Related/Unrelated:

1. Describe the event and specify suspected SAE diagnosis:

4. Date of onset of SAE: Date of reporting:

5. Onset lag time after administration of intervention: Location of SAE (Clinic/Ward/Home/Other):

6. Details of suspected study drug/device/investigational procedure causing SAE:

* 1. Suspect study drug (include generic name) device/intervention:
	2. Indication(s) for which suspect study drug was prescribed or tested:
	3. Route(s) of administration, daily dose and regimen, dosage form and strength:
	4. Therapy start date: Stop date:

7. Was study intervention discontinued due to event? (Yes/No):

8. Did the reaction decline after stopping or reducing the dosage of the study drug / procedure? (Yes/No/NA):

If yes, provide details about the reduced dose.

9. Did the reaction reappear after reintroducing the study drug / procedure? (Yes/No/NA):

If yes, provide details about the dose.

10. Concomitant study drugs history and lab investigations:

* 1. Concomitant study drug (s) and date of administration:
	2. Relevant test/laboratory data with dates:
	3. Patient relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc)

11. Have any similar SAE occurred previously in this study? If yes, please provide details. (Yes/No)

12. Seriousness of the SAE:

Death (Yes/No): Congenital (Yes/No):

 Life threatening (Yes/No):

Required intervention to prevent Permanent impairment/damage (Yes/No):

 Hospitalization-initial or prolonged Disability (yes/No)

 Others(specify):

13. Describe the medical management provided for adverse reaction (if any) to the research participant. (Include information on who paid, how much was paid and to whom).

14. Outcome of SAE:

Fatal (Yes/No): Recovered (Yes/No):

Continuing (Yes/No): Unknown (Yes/No)

Recovering (Yes/No): Other (specify):

15. Was the research subject continued on the trial? (Yes/No/NA):

16. Provide the details about PI final assessment of SAE relatedness to trial.

17. Has this information been communicated to sponsor/CRO/regulatory agencies? (Yes/No/NA):

Provide details if communicated (including date)

1. Does this report require any alteration in trial protocol? (Yes/No):
2. Provide details of compensation provided/ to be provided the participants (include information on who pays, how much, and to whom):

 Signature of PI: Date:

(Annexure 10)

Application Form for Human Genetics Testing Research

**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**; EC Ref. No**.:(for office use)

Title of study:

Principal Investigator (Name, Designation and Affiliation):

1. Describe the nature of genetic testing research being conducted.

(e.g.- screening/gene therapy/newer technologies/human embryos/foetal autopsy)

2. Does the study involve pretest and post-test counseling? (Yes/No/NA):

 If yes, please describe.

3. Explain the additional safeguards provided to maintain confidentiality of data generated.

1. If there is a need to share the participants’ information/investigations with family/community, is it

addressed in the informed consent? (Yes/No/NA):

If findings are to be disclosed, describe the disclosure procedures (e.g. genetic counseling)

1. Is there involvement of secondary participants? (Yes/No/NA)

If yes, will informed consent be obtained? State reasons if not.

1. What measures are taken to minimize/ mitigate/eliminate conflict of interest?
2. Is there plan for future use of stored sample for research? (Yes/No)

If yes, has this been addressed in the informed consent. (Yes/No)

Signature of PI: Date:

(Annexure 11)

Application Form for Socio-Behavioural and Public Health Research

**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**; EC Ref. No**.:(for office use)

Title of study:

 Principal Investigator (Name, Designation and Affiliation):

1. Data collection method used in the study

Focus group (Yes/No): Questionnaire/survey (Yes/No): Observation (Yes/No):

Interviews (Yes/No): Documents and records (Yes/No):

Ethnographies/oral history/case study (Yes/No):

Others (specify):

If it is an interview, will there be audio-video recording of participants’ interview? (Yes/No):

If yes, justify the reasons and storage strategies.

1. Type of informed consent is used in the study?

Individual consent (Yes/No): Gate-keeper consent (Yes/No): Community consent (Yes/No):

Others (specify):

1. Provide details of safeguards to ensure privacy and confidentiality of participants in the event of data sharing?

(Yes/No):

1. Describe strategies to manage if any patterns of behavior of self-harm or harm to the society are identified (e.g.: Suicide or infanticide) (Yes/No/NA):
2. Are cultural norms and/or social considerations/sensitivities taken into account while designing the study and participant recruitment? (Yes/No):
3. Is there a use of an interpreter? (Yes/No/NA):

If yes, describe the selection process.

1. Describe any preparatory work or site preparedness for the study. (Yes/No/NA):
2. i. Type of risk related to procedures involved in the study

Invasive (Yes/No): Potentially harmful (Yes/No): Emotionally disturbing (Yes/No):

Involving disclosure (Yes/No):

Describe the risk minimization strategies

ii. Justify reasons if individual harm is overriding societal benefit. (Yes/No/NA):

 iii. Describe how do societal benefits outweigh individual harm.

9. Does the study use incomplete disclosure or active deception or authorized deception? (Yes/No)

 If yes, provide details and rationale for deception.

10. Describe the debriefing process that will be used to make participants aware of the incomplete disclosure or deception, including their right to withdraw any record of their participation.

Signature of PI: Date:



(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**; EC Ref. No**.:(for office use)

 Title of the study:

 Principal Investigator (Name, Designation and Affiliation):

1. Date of EC Approval:
2. Date of Start of Study: Date of study completion:
3. Provide details of:
4. Total no. of study participants approved by the EC for recruitment:
5. Total no. of study participants recruited:
6. Total no of participants withdrawn from the study (if any):

Provide the reason for withdrawal of participants23:

1. Describe in brief the publication/presentation/dissemination plans of the study findings: (Also, mention if both positive and negative results will be shared):
2. Describe the main Ethical issue encountered in the study (if any):
3. 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:

1. Is there a plan for post study benefit sharing with the study participants? (Yes/No):

If yes, describe in brief:

1. Describe results (summary) with Conclusion24
2. Number of SAEs that occurred in the study:
3. Have all SAEs been intimated to the EC? (Yes/No):
4. Is medical management or compensation for SAE provided to the participants? (Yes/No):

If yes, provide details:

 Signature of PI: Date:

(Annexure 13)

Format for Curriculum Vitae for Investigators

**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**; EC Ref. No**.:(for office use)

|  |
| --- |
| **Name:** |
| **Present affiliation** *(Job title, department, and organization)***:** |
| **Address** *(Full work address)***:** |
| **Telephone number:** | **Email address:** |
| **Qualifications:** |
| **Professional registration** *(Name of body, registration number and date of registration)***:** |
| **Previous and other affiliations** *(Include previous affiliations in the last 5 years and other current affiliations)***:** |
| **Projects undertaken in the last 5 years:** |

|  |
| --- |
| **Relevant research training/experience in the area25:** |
| **Relevant publications** *(Give references to all relevant publications in the last five years)***:** |
| **Signature** | **Date:**  |

*25Details of any relevant training in the design or conduct of research, for example in the Ethics Training, Human participants’ protection courses, Clinical Trials Regulations, Good Clinical Practice, consent, research ethics training or other training appropriate to non-clinical research. Give the date of the training*

(Annexure 14)

Project Extension Form

**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**; EC Ref. No**.:(for office use)

|  |
| --- |
| ***\*The project extension must be duly submitted no later than 30 days before the approval expires.*** |
| Title of study:Principal Investigator (Name, Designation and Affiliation) |

|  |  |  |
| --- | --- | --- |
| 14 | EC Reference No: |  |
| 15 | Date of EC Approval:  | Duration of Approval months/ years |
| 16 | Date of Start of study:  | Date of Completion: *(As per the first approval granted)* |
| Duration of Extension sought: (months/ years) |  |
| Period of Extension sought from:  | To:  |
| 17 | Have there been any modifications in the budget for the extension sought? (Yes/No):If yes, discuss in detail:**If No, skip to item no.5** |
| 18 | Does the study involve recruitment of participants? (Yes/No): 1. If yes, Total number for study:
2. Screened: Enrolled:
3. Number Completed: No. on follow up:
4. Enrolment status – ongoing / completed/ stopped:
5. If ongoing, Expected No.
6. Report of DSMB (Yes/No/NA):

*\* In 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.*(l) Any other remark |

|  |  |
| --- | --- |
|  | (m) . Have any participants withdrawn from this study since the last approval? (Yes/No/NA) If yes, total number withdrawn and reasons: |
| 19 | Have there been any amendments in the research protocol/informed consent document (ICD) for theextension sought? (Yes/No): **If No, skip to item no.7** |
| 1. If yes, discuss in detail:
 |
|  | 1. In case of amendments in the research protocol/ICD, will re-consent be sought from participants? (Yes/No):

If yes, when / how:  |

1. 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:

1. Have any ethical concerns occurred during the study? (Yes/No):

 If yes, give details

1. (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 :

1. Is the SAE related to the study? (Yes/No):
2. Have you reported the SAE to EC? (Yes/No):

If no, state reasons:

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

 If yes, number of deviations:

Have you reported the deviations to EC If no, state reasons

1. In case of multicentric trials, whether reports of off-site SAEs have been submitted to the EC:
2. Are there any publications or presentations during this period? (Yes/No):

 If yes give details.

1. Briefly explain the reason for the extension sought (up to 500 words) (Please attach the relevant documents in support of the extension.)

Signature of PI: Date: