NKTIREC FORM 4.3: CONTINUING REVIEW REPORT

DIRECTIONS FOR SUBMITTING A CONTINUING REVIEW FORM

- This form must be submitted 30 calendar days before the expiration date of the approval of the protocol.
- Request for continuation of a current approved research protocol will be reviewed at a regularly convened full board meeting of the REC, unless the criteria for expedited review are met.
- Studies that are expired or lapsed from the REC approval date is considered non-compliance. **NKTIREC FORM 4.5: PROTOCOL NON-COMPLIANCE/ VIOLATION/DEVIATION SUMMARY REPORT** must be submitted along with **NKTIREC FORM 4.3: CONTINUING REVIEW REPORT**
- Please ensure that the PI and all key personnel have completed the GCP within the last 3 years. Please submit updated GCP Certificate, if applicable.
- Once the study is approved, it is the PI's responsibility to apply for continuing review at the interval set by the REC for your study as well as to close the study by submitting a site study closure or an end of study report using **NKTIREC FORM 4.4: FINAL REPORT**.
- For clarifications or questions, you may contact us at NKTI REC Secretariat at (02) 8981-0300 loc. 2158

- **WHAT TO SUBMIT**

  All required documents must be submitted 30 calendar days prior to the expiration date
  - Submit copy of the **NKTIREC Form 4.3: CONTINUING REVIEW REPORT** with signature
  - Submit informed consent/assent/information sheet currently in use (If applicable)
  - Submit copy of the completed and signed **Investigator's Progress Report(s)**.
  - Submit copy of the most recently approved **Informed Consent/Assent Form.** If using an addendum consent form for currently enrolled participants, send copy for review. If the study is closed for enrollment, no need to submit the informed consent form.
  - Submit copy of summary report of all approved amendments/revisions since their last renewal.
  - Submit copy of any progress report/s submitted to the sponsoring/funding agency since last renewal, if applicable.

ACTION REQUESTED:

☐ Renew - New participant/subject accrual to continue

☐ Renew - Enrolled participant follow up only

☐ Terminate - Protocol discontinued

PRINCIPAL INVESTIGATOR (PI)

Name of PI			
PI's Signature		Specialization	
Mobile no.		Email.	
Has any potential and/or financial conflict of interest arisen since the last REC review? If yes, a "Financial Conflict of Interest Detailed Disclosure Form" must be submitted to the REC annually or when a change occurs.		☐ Yes ☐ No	

STUDY INFORMATION

NKTIREC Protocol No.:		Sponsor Protocol No.: (If applicable)	
Sponsor/CRO			
Protocol Title			
a) Original Approval Date		Expiration Date	
b) Date of Submission			
c) Is the submission date after or on the expiration date?	☐ Yes If **yes**, please answer below ☐ No		
If **yes**, your study has a lapse in REC approval. Please indicate whether or not any research activities have taken place during the lapse in REC approval.	☐ Yes, I did conduct research activities during the lapse in approval. ☐ No research activities occurred during the lapse		
Note: *If your protocol does not receive approval prior to the expiration date, no participants can be enrolled, no data can be collected or used for research if collected during the period of lapse approval. Repeat lapses of REC approval is deemed non-compliance.*			

STATUS OF PROJECT

Any amendment since the last review? (Describe briefly.)	☐ Yes	☐ No	☐ N/A
Any change in participant population, recruitment, or selection criteria since the last review? (Explain the changes.)	☐ Yes	☐ No	☐ N/A
Any change in the Informed Consent process or documentation since the last review? (Please explain.)	☐ Yes	☐ No	☐ N/A

Is there any new information in recent literature or similar research that may change the risk/ benefit ratio for participants in this study? (Discuss and attach a narrative.)	☐ Yes	☐ No	☐ N/A
Is there any new information in recent literature or similar research that may change the risk/ benefit ratio for participants in this study? (Discuss and attach a narrative.)	☐ Yes	☐ No	☐ N/A
Any complaints about the research from subjects enrolled at the local site since the last REC review?	☐ Yes	☐ No	☐ N/A
Any unexpected complication or side effect noted since the last review? (Discuss and attach a narrative.)	☐ Yes	☐ No	☐ N/A
Did any participant withdraw from this study since the last approval? (Reasons for withdrawal)	☐ Yes	☐ No	☐ N/A
Any new investigator that has been added to or removed from the research team since the last review? (Please identify them and submit the CVs of new investigators.)	☐ Yes	☐ No	☐ N/A
Summary of protocol participants: ☐ Accrual ceiling set by REC ☐ New participants/subjects accrued since last review ☐ Total participants/subjects accrued since protocol began			
Accrual Exclusions: ☐ None ☐ Male ☐ Female ☐ Others (Specify)_____			
Are there any new collaborating sites that have been added or deleted since the last review? Please identify the sites and note the addition or deletion.	☐ Yes	☐ No	☐ N/A
Impaired Participants: ☐ None ☐ Physically ☐ Cognitively ☐ Both			

Received by:

_____
Signature over Printed Name / Date

To be filled out by REC

Recommendations:

Changes to the protocol: Comments:	☐ Yes	☐ No	☐ N/A
Changes to the informed consent form: Comments:	☐ Yes	☐ No	☐ N/A

Recommendations:	**Type of Review:**
☐ Approve ☐ Request an amendment to the protocol or informed consent form ☐ Request further information ☐ Suspend or terminate the study ☐ Others: _____	☐ Expedited review ☐ Full board review Date of Meeting: _____

Primary Reviewer	Certified by REC Chair
_____ *Signature over Printed Name / Date*	_____ *Signature over Printed Name / Date*

Date of NKTI REC Approval validity:	