NKTIREC FORM 4.5: PROTOCOL NON-COMPLIANCE /VIOLATION/DEVIATION SUMMARY REPORT

GENERAL INFORMATION:

NKTIREC Protocol No.		Sponsor Protocol No.	
Protocol Title:			
Protocol Version no. and Date		Research Site:	
Person Completing Form:		Designation:	
Name of Principal Investigator (PI):		Phone Number:	
Patient ID#	Age:	Gender: ☐ Male ☐ Female	
Protocol violation identified by:	☐ PI ☐ Study Coordinator ☐ Monitor ☐ Other: _____		

☐ PI Deviation from protocol ☐ Participant Non-Compliance

☐ Major ☐ Minor

I. This deviation/violation adversely affects: *(check all that apply)*

YES	NO	
[ ]	[ ]	rights/welfare of subject(s)
[ ]	[ ]	safety of subject(s)
[ ]	[ ]	integrity of research data
[ ]	[ ]	subject's willingness to continue study participation

II. Characterization:

The deviation/violation involves:

[ ] Enrollment process *(inclusion/exclusion criteria, ascertainment/recruitment, etc.)*

[ ] Consent process *(oral or written)*

[ ] Drug/Device Administration *(dosage, schedule, route of administration, formulation, etc.)*

[ ] Other Protocol Activities (*research activities, data analysis, reporting, etc.)*

[ ] Complaint from research subject

[ ] Audit finding that requires corrective action

[ ] Others, please specify _____

III. Description:

1. Date(s) of the deviation/violation:

Note: If there is a delay in reporting protocol non-compliance/violation/deviation, explain the reason for the delay.

2. Please describe in detail the specific deviation/violation:

3. If the purpose of this deviation report is a lapse in REC approval, please describe all study activities, including enrollment, interventions, data analysis, that have occurred during the lapse:

4. Please explain how/why the non-compliance/violation/deviation occurred:

5. Please describe how the non-compliance/violation/deviation affected the:

(i) Risk/benefit ratio for the subject(s):

(ii) Integrity of the research data:

(iii) Subject's willingness to continue study participation:

6. Does this protocol non-compliance/violation/deviation require revision of the protocol and/or informed consent form?
   [ ] Yes *(if yes, please submit a completed Amendment form and revised documents with changes marked)*
   [ ] No

7. Please describe: (i) corrective actions, if applicable, and (ii) a plan for preventing the recurrence of the non-compliance/violation/deviation:

By signing below, I declare that the above is an accurate and complete description of the protocol non-compliance/ violation/deviation and that, upon receipt of the REC review, I will fully and immediately implement any corrective actions required by the REC.

_____ _____
Name and Signature of PI *Date*

For REC Use Only

REC Chairman/Designee Review of Problem Report:

I have reviewed this reported protocol non-compliance/violation/deviation and determined that: *(check all that apply)*

[ ] No further action is required.
[ ] PI must complete the prompt reporting.
[ ] The corrective action described in this form below is acceptable. PI must issue a statement to the REC that he/she has implemented the corrective action plan as described.
[ ] PI must submit an interim report to the REC on *<specify date of submission>* **describing his/her progress in implementing the corrective action described below.**
[ ] The attached corrective actions must be implemented.
[ ] The non-compliance/violation/deviation reported appears to represent serious or a continuing non-compliance. Review of the protocol is required.
[ ] Others, please specify:

_____ _____
Name and Signature Primary Reviewer *Date*

_____ _____
Name and Signature of REC Chair *Date*