NKI/RPC IRB INTERNAL ADVERSE EVENT FORM

INTERNAL ADVERSE EVENTS INVOLVING NKI, RPC, RCPC, OR MPC SUBJECTS

INSTRUCTIONS:

PRIOR TO SUBMISSION PLEASE CALL ERNA OSTROM AT 845-398-5493 FOR AN INTERNAL AE #.

1. ***All internal adverse events****, whether serious or nonserious, anticipated or unanticipated, or related to study participation or not,* ***must be reported****. Guidance:* ***Clinically routine events related to a pre-existing condition and not resulting in a change in intensity or frequency need not be reported.***
2. ***Forward to IRB Office*** *by email, erna@nki.rfmh.org and roth@nki.rfmh.org, immediately upon completion and include adverse event # in email subject line. Also email a copy to Elizabeth Falco at rpqalcf@omh.state.ny.us with adverse event # in subject line, and if RPC patient, patient name and C #. For RPC patients only, also fax a copy to Dr. Robert Sobel, including patient name and C # (fax 845-680-5516).*

DEFINITIONS:

- ***Serious adverse events*** *include any event that results in death, life-threatening experiences, hospitalizations, or prolongation of hospitalization, disability, or incapacitation, incorrect dosing of study medication, congenital anomalies or other serious events that may jeopardize the subjects or require medical or surgical intervention to prevent any of the outcomes listed above.*
- ***An unanticipated adverse event*** *is one that is not expected as a risk in the IRB approved protocol, consent form, or investigator's brochure, or occurs at a greater frequency or intensity than expected or results in a pre-existing condition occurring at a greater frequency or intensity than expected.*

Principal Investigator: _____ NKI IRB Protocol #: _____

Study title: _____ Date of report: _____

Date of event: _____

PI Telephone: (___) ___-____ IRB AE #: _____

Report type: ☐ *Initial* ☐ *Follow-Up #:* __ ☐ *Final*

Subject initials: _____ Subject study #: _____

Type of setting: ☐ *Inpatient* ☐ *Outpatient*

1. Type of event: a) ☐ *Nonserious* ☐ *Serious*
   b) ☐ *Anticipated* ☐ *Unanticipated*

2. Brief description of event, including name of study drug, if applicable, or description of study procedure and date of event onset:

   _____

3. Details, History, and Background of Event: *(Include sex, age, and ethnicity/race of subject, diagnosis, pertinent history, history of study participation, medical specialist comments)*

   _____

3a. Concomitant medications: *(Attach additional page if needed)*

Drug	Dose	Added within 30 days prior to event		Dose changed within 7 days prior to event	
_____	_____	☐ *Yes*	☐ *No*	☐ *Yes*	☐ *No*
_____	_____	☐ *Yes*	☐ *No*	☐ *Yes*	☐ *No*
_____	_____	☐ *Yes*	☐ *No*	☐ *Yes*	☐ *No*
_____	_____	☐ *Yes*	☐ *No*	☐ *Yes*	☐ *No*
_____	_____	☐ *Yes*	☐ *No*	☐ *Yes*	☐ *No*
_____	_____	☐ *Yes*	☐ *No*	☐ *Yes*	☐ *No*
_____	_____	☐ *Yes*	☐ *No*	☐ *Yes*	☐ *No*
_____	_____	☐ *Yes*	☐ *No*	☐ *Yes*	☐ *No*
_____	_____	☐ *Yes*	☐ *No*	☐ *Yes*	☐ *No*
_____	_____	☐ *Yes*	☐ *No*	☐ *Yes*	☐ *No*

4. If this is a follow-up report, clearly identify new or revised information:

_____

5. In your opinion, is the adverse event related to research participation? *(Check one)*

☐ *Definitely* ☐ *Probably* ☐ *Possibly* ☐ *Probably not* ☐ *Definitely not*

5a. Please explain the reasoning for your opinion:

_____

6. Have any events similar to the one you are reporting previously occurred in this study or related studies: *(Include external reports)*

☐ *Yes (Explain below)*
☐ *No*

6a. If Yes, please provide information on this recurring event: *(i.e., frequency, number of participants affected, etc)*

_____

7. Did this adverse event involve a clinically significant injury or a clinically significant risk to the subject or to others?

☐ *Yes*
☐ *No*

7a. Please explain the reasoning for your opinion:

_____

8. Does this event change your opinion of the risks and benefits of the study?

☐ *Yes*

☐ *No*

[IF YES, COMPLETE QUESTION 9, BELOW. IF NO, SKIP TO QUESTION 10.]

9. Are any changes to the protocol or informed consent process or document required?

☐ *Yes (Please submit revised protocol and consent forms as appropriate)*

☐ *No (Explain below)*

9a. If No, please explain:

____

10. Should other subjects currently or previously taking the study drug or having the procedure in this study, or other NKI studies involving the same study drug or procedure, be notified or examined?

☐ *Yes (Explain below)*

☐ *No*

10a. If Yes, please explain:

____

11. Describe any actions taken by you thus far, including reports to the sponsor, FDA, etc and plans for follow-up in terms of lab studies, clinical care and reporting:

____

If the adverse event is serious and definitely, probably, or possibly related to the research study, please provide full answers to the following additional questions:

12a. Is the adverse event listed in the Investigator's Brochure or drug labeling? If yes, please provide the reference.

____

12b. Is this event known to occur because of the underlying illness or the population under study, e.g., an age related condition?

____

12c. Is the event a known consequence of treatment that this subject is receiving outside the research context?

____

13. Other comments:

____

Signature of Principal Investigator: _____ Date: ____

Prepared by: ____

IN CASE OF EMERGENCY, NOTIFY TREATING TEAM IMMEDIATELY.

For Administrative Use Only

Noted: _____ Date: ____
Signature of Adverse Event Subcommittee Chair

Noted: Follow-Up Information Requested:
____

Noted: _____ Date: ____
Signature of Adverse Event Subcommittee Chair

Noted: Action Required, Specify:
____

Noted: _____ Date: ____
Signature of Adverse Event Subcommittee Chair