## NKI/RPC IRB Continuing Review Form

**Note: Please submit this annual report (unless the IRB has specified a shorter time frame) to the IRB office at least one month prior to the due date to insure ongoing IRB approval. You will be reminded by the IRB office of the due date. If the report is not received on time, the IRB approval is required to be suspended and all research conducted in connection with the protocol must be discontinued until such time as a report is submitted and approved by the** **IRB.**

**Date:**

**Principal Investigator:**

**Title of Protocol:**

**IRB Number:**

**Clinical Trial Registration: NCT#** **Identity of Responsible Party** **(Please provide this information for all controlled clinical trials, other than Phase I, of a product subject to FDA regulation, including IND-exempt trials.)**

**The time period to cover in the report is from the initial review date to the present date.**

**1. Provide a lay summary of protocol and give current status of project: ongoing, awaiting funding, withdrawn, completed, etc.:**

**2. Describe all revisions, amendments, changes in the protocol since its approval date:**

**3. Describe any changes in staff working on the project:**

 **4. Number of research subjects enrolled in the project:**

1. **total number of subjects approved by the IRB for enrollment**
2. **number of subjects screened**
3. **number of subjects entered**
4. **number of subjects ongoing**
5. **number of subjects completed**
6. **number of subjects dropped and reasons**

**.**

**5. If tissue samples are collected and stored for genetic testing as part of this project, please state how many samples have been collected to date and indicate where they are stored. Please provide a description of the testing that has been done on the samples or is planned to be done. Provide any available results or findings from the testing in your response to question 10 below on findings to date:**

1. **number of samples collected**
2. **location of samples**
3. **description of testing performed or planned to be performed:**

**6. Describe the anticipated activity during the next coming year:**

**7. Summary of information on adverse events in study subjects. Provide a full discussion on any pattern of adverse events or any serious adverse events occurring during the renewal period. These should include both internal and serious external events. Provide a summary of any new information about risks associated with the research:**

**8. Anticipated date of conclusion:**

**9. Provide the number of consents submitted/reviewed by the IRB monitor:**

**10. Describe any findings to date:**

**11. Provide any relevant comments on methodology:**

**12. Conflict of Interest: In order for the IRB to determine whether financial interests pose a potential for bias that might affect the rights and welfare of human subjects or the credibility of the research, please briefly describe any financial relationship the principal investigator or other researchers on this project may currently or in the future have with the study sponsor (other than funding this project) or any financial interest in the product being tested**: \_\_\_\_\_\_\_\_