**FORM 4.4A CONTINUING REVIEW REPORT/RENEWAL REQUEST**

**(This report should be no more than 4 pages)**

1. Protocol Title:
2. Protocol version and date:
3. Expiry date of current approval:
4. Period covered by this report: **(provide dates)**
5. **BRIEF OUTLINE OF THE RATIONALE FOR THE STUDY**

*Provide an outline of the rationale, methods of study, and general plan of investigation as described in the currently approved version of the proposal.*

1. **RESEARCH OBJECTIVES:**

*State the objectives of the research*

1. **NUMBER OF PARTICIPANTS ENROLLED:**

*State the number of participants that was originally approved, how many have been enrolled into the study, and how many withdrawn/terminated. If any participants withdrew/were withdrawn, state how many and why.*

*Also, if modifications have been approved increasing the sample size, please state this and provide dates of approval.*

|  |  |  |
| --- | --- | --- |
| Category | Total Number thisReporting Period | Cumulative Total |
| **Number of Participants approved to enroll:** |  |  |
| **Number Enrolled:** |  |  |
| **Number Lost (deaths, other) and reason for each:****Deaths** |  |  |
| **Number Withdrawn by Investigator and reason for withdrawal(s) of each:** |  |  |
| **Number Withdrawn (drop outs – participant withdrew him/herself) and reason for withdrawal(s) for each:** |  |  |
| **Number of Active Participants:** |  |  |
| **Number completed all study activities:** |  |  |

1. **CURRENT LITERATURE:**

If there have been any publications, provide a brief summary and any relevance it may have to your research. If there has been no literature, include a statement indicating that a search of the literature revealed no new information of this participant matter.

1. **SUMMARY OF ADVERSE EVENTS/ SIDE EFFECTS:**

Give a brief description of all the side effects observed and their severity. Did any adverse effects occur, and were they expected or unexpected? If any unexpected side effects occurred, state what they are, whether they were reported as required, and if a protocol modification has been/will be submitted to add the side effects to the consent form for future participants.

1. **SUMMARY OF RESULTS TO DATE:**

In 1-2 paragraphs provide an account results that have accrued from the study. If there have been no results, indicate so. If any deviations from the protocol occurred, indicate so. A copy of the original report describing the deviation from the protocol should be attached

1. **FUTURE PLANS/ ACTIVITIES:**

What activities are planned for the protocol during the coming year? Continuedcollection of data? Analysis of data? Completion of the protocol? Submission of a modification to the current protocol to expand on results? Any proposed modifications should be mentioned, but the request to modify the protocol should be submitted separately for approval.

1. **DECLARATION & SIGNTURE:**

By signing this form, the Principal Investigator certifies that he/she has disclosed to the IDI REC all relevant information concerning adverse events or other issues that might affect the risk-to-benefit analysis of this study.

**Signature of PI: Date:**