ADVERSE EVENT REPORTING FORM

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Submission Instructions:
Submit all documents including application electronically. No handwritten applications or materials will be accepted. Please refer to Investigator's manual for Adverse Event reporting guidelines.

1. IRB Protocol ID: - -
2. Title of Study:
3. Principal Investigator (PI):
4. Internal Event (subject enrolled at this study site) ☐ External Event (for multi-centered studies) ☐
5. Initial Report: ☐ Follow-Up Report: ☐
6. Date of Report to the IRB: / / (MM/DD/YYYY) Date Received notification of adverse event: / /
7. Sponsor:
8. Manufacturer Report number (if applicable):
9. Date and location of Adverse Event: / / Location:
10. Was the adverse event unexpected? Yes☐ No ☐ Either way, please explain:

    (Specificity and severity of event is not consistent with the current Investigator's brochure or with other current risk information)

11. Was the adverse event serious? Yes ☐ No ☐ Either way, please explain:

    - Results in death, or
    - Is life-threatening, or
    - Requires inpatient hospitalization or prolongation of existing hospitalization, or
    - Results in persistent or significant disability or incapability, or
    - Results in a congenital anomaly or birth defect.

12. Describe the Adverse Event:
13. Subject Identifier:
14. List all drugs (investigational and otherwise) listed in this protocol:
15. On-site Investigator's Assessment of Causality:
    ☐ possibly related ☐ probably related ☐ unlikely related ☐ related
    ☐ not related ☐ unknown
16. Sponsor's assessment of causality:
    ☐ possibly related ☐ probably related ☐ unlikely related ☐ related
    ☐ not related ☐ unknown

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17. What treatment for the adverse event was provided to the subject?

18. Date of treatment for adverse event? / /

19. Describe the subject's prognosis:

20. Is the study closed to enrollment? Yes ☐ No ☐

21. Are subjects still on drug? Yes ☐ No ☐

22. Have similar adverse events been reported previously? Yes ☐ No ☐ If yes, provide a brief description of events:

23. In your judgment, is the overall risk-benefit relationship of the research still acceptable in light of the information concerning this adverse event report? Yes ☐ No ☐

24. In your judgment, is a change in protocol necessary to reduce or eliminate risk? Yes ☐ No ☐

25. Are any changes required in the informed consent documents(s) to better inform and protect the rights and welfare of subjects? Yes ☐ No ☐ (if yes, you must submit an amendment.)

26. It is necessary to re-consent this subject? Yes ☐ No ☐ Either way, please explain:

Principal Investigator Certification

Your signature here certifies that you have assessed the information concerning the adverse event and that in your judgment the risks of this research are minimized to the greatest extent possible and continue to be outweighed or balanced by the potential benefits.

_____ _____

Principal Investigator Date