Continuing Review Form

For Human Subjects Research Studies that Require Continuing Review by the Institutional Review Board

Study Title:

Principal Investigator:

IRB Protocol Number:

1) What is the status of your project? [Select one and see note at end of this form.]
   - ☐ Active (still enrolling subjects)
   - ☐ Closed to subject enrollment, but subjects still involved with procedures
   - ☐ All research interventions completed, but research open for follow-up of subjects
   - ☐ All research interventions completed, but research open for data analysis

2) Have the procedures, informed consent document, or recruiting materials been modified in any way since the last IRB review?
   - ☐ No.
   - ☐ Yes. If so, please summarize the changes that were made and date they were approved by the IRB.

3) Have all personnel changes been reviewed/approved by the IRB?
   - ☐ No.
   - ☐ Yes. If so, please summarize the changes that were made and date they were approved by the IRB.

4) Provide the following information about subject enrollment:
   - Number of subjects approved for enrollment by the IRB
   - Number of subjects who provided informed consent to participate in the study since initial approval
   - Number of subjects who provided informed consent to participate in the study during the most recent approval period
   - Number of subjects terminated form study (lost to follow-up, terminated by PI, withdrew consent, etc.)
   - Number of subjects that have completed all study procedures and follow-up visits
   - Number of subjects currently participating in study-related activities

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5) Please include a statement indicating whether any complaints were received about the research study (if none, enter NONE):

6) Provide a list of all study-related adverse events and summarize any study-related adverse events that resulted in changes to the protocol or informed consent documents.

7) Describe any other unanticipated problems involving risks to subjects, withdrawal of subjects from the research due to non-compliance, or any issues with recruitment, enrollment and/or retention of subjects.

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8) Please provide a succinct narrative (no more than 2 paragraphs) about the interim study results and preliminary findings.

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9) Has any new relevant literature been published during the most recent approval period that may impact the validity/reliability of the study procedures, the level of risk to study subjects, or research questions?
   ☐ No.
   ☐ Yes. If so, please provide a brief summary of the literature with appropriate references.

10) Has any data from this study been disseminated by the investigator in a peer-reviewed forum (e.g., conference, abstract, publication, etc.)?
   ☐ No.
   ☐ Yes. If so, please provide an appropriate citation of the work.

Name of PI: _____ Signature:_____ Date: _____

NOTE:

If your study status is listed as: Active (still enrolling subjects); Closed to subject enrollment, but subjects still involved with research intervention; or, All research interventions completed, but research open for follow-up of subjects, you must include with this form:

1. A new, unstamped copy of your Informed Consent document(s) so it can be stamped as approved with the new date. The stamped approval on an Informed Consent document is valid only for one calendar year.
2. If applicable, a copy of new approval from the IRB at the site where the research is being conducted.

If your study status is listed as: All research interventions completed, but research open for data analysis, there are no additional document requirements to include with this submission.