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| 1. **Contact Information** | | | | | | | | | |
| Title of Study: | |  | | | | | | | |
| IRB ID: | |  | | | | |  | | |
| Principal Investigator (PI): | |  | | | | | | | |
|  | | |  | |  |
| 1. **Current Study Status** (Indicate YES or NO for activities involving this research at this institution/site.) | | | | | | | | | |
| **2.1** Participants have been enrolled (consented). Note: A participant is enrolled if they, or their representative, gave consent (verbal or written) to participate in the research. | | | | | | | | | Yes  No |
| * 1. The research is permanently closed to enrollment of new participants. (If YES, answer items 2.3 through 2.7.)   (If NO, SKIP to Item #3: Accrual of Participants.) | | | | | | | | | Yes  No |
| **2.3** All participants have completed all research-related interventions1 and interactions2, including those related to long-term follow-up. | | | | | | | | | Yes  No |
| **2.4** All collection of both private3 and identifiable4 information about the participants is complete. | | | | | | | | | Yes  No |
| **2.5** All analyses of private3 and identifiable4 information are complete. | | | | | | | | | Yes  No |
| **2.6** The remaining activities are limited to analysis of coded data or data that is not private or identifiable. | | | | | | | | | Yes  No |
| **2.7** Will you follow-up with any participants ***OR*** contact participants about this research study in the future? | | | | | | | | | Yes  No |
| **1***Interaction* means communication or interpersonal contact between investigator and participant.  **2***Intervention* means physical procedures by which data are gathered and manipulations of the participant or the participant’s environment that are performed for research purposes.  **3***Private* means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.  **4***Identifiable* means the identity of the participant is or may readily be ascertained by the investigator or readily associated with the information by the investigator. | | | | | | | | | |
| **3. Accrual of Participants** | | | | | | | **Number** | |
| **3.1** Total number of participants enrolled (consented) in the study. | | | | | | | |  | |
| **3.2** How many participants left the study (withdrew) before they completed all research procedures? | | | | | | | |  | |
| * 1. How many participants completed allresearch procedures? | | | | | | | |  | |
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| **4. Information Relative to All Sites Involved in the Study (**Include information since the last IRB continuing review**.)** | | | | | | | | |
| **4.1** Is there any new risk or benefit information related to the study not previously reported to the IRB?  (If yes, outline new information in item #5.) | | | | | | | Yes  No | |
| **4.2** Have you received any complaints from participants about the study?  (If yes, outline the complaints in item #5.) | | | | | | | Yes  No | |
| **4.3** Were there any unanticipated problems involving risks to participants or others not previously reported to this IRB? (If yes, outline the unanticipated problems in item #5.) | | | | | | | Yes  No | |
| **4.4** Have there been any problems listed not yet reported to the IRB?  (If yes, outline the unreported problems in item #5.) | | | | | | | Yes  No | |
| **4.5** Have there been any changes to the protocol, consent, or participant materials not previously reported to the IRB? (If yes, outline the changes in item #5.) | | | | | | | Yes  No | |

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| **5. Brief Substantive Summary of the Progress of the Research** (A summary is required whether or not you have answered “yes” to any question in Section 4.) |
| Enter summary here. |

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| **Submission Requirements** |
| Submit the following documents with this application when they exist or are applicable:   * + Sponsor’s progress report or annual report   + Investigator's annual report to FDA |
| **Investigator Certification** |
| **By submitting this form, investigator acknowledges and confirms compliance with "INVESTIGATOR GUIDANCE: Investigator Obligations (HRP-800)" throughout the conduct of the study.** |