|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 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 information about the participants that is both private3 and identifiable4 is complete. | | | | | | | | | | Yes  No | |
| **2.5** The remaining activities are limited to long-term follow-up of participants. | | | | | | | | | | Yes  No | |
| **2.6** All analyses of private3 and identifiable4 information are complete.  (If YES, SKIP to Item #4: Accrual of Participants.) | | | | | | | | | | Yes  No | |
| **2.7** The remaining activities are limited to analysis of coded data or data that is not private3 or identifiable4. | | | | | | | | | | Yes  No | |
| **1***Interaction* means communication or interpersonal contact between investigator and subject.  **2***Intervention* means physical procedures by which data are gathered and manipulations of the subject or the subject’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 subject is or may readily be ascertained by the investigator or readily associated with the information by the investigator. | | | | | | | | | | | |
| 1. **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? | | | | | | | | |  | | |
|  | | | | | | | | |  | | |
| 1. **Current consent document** | | | | | | | | | |
| Listthe approval dates of currently used consent documents/scripts: | | | | |  | | | | |
|  | | |
| 1. **Relative to all sites involved in the study, s*ince* the last IRB continuing review:** | | | | | | | | | |
| **5.1** Is there any **new** risk or benefit information related to this study that was **not previously reported** to the IRB? (If YES, outline new information in item #6 below.) | | | | | | | | Yes  No | |
| **5.2** Are you aware of any scientific publications, safety monitoring reports, interim findings, multi-center trial reports, or any similar reports relevant to the risks or potential benefits of this study? | | | | | | | | Yes  No | |
| **5.3** Have you received any complaints from participants about the study? (If YES, outline participant complaint in item #6 below.) | | | | | | | | Yes  No | |
| **5.4** Have there been any unanticipated problems involving risks to participants or others not previously reported to this IRB? | | | | | | | | Yes  No | |
| **5.5** Have there been any changes to the protocol, consent, or materials seen by participants not previously reported to this IRB? | | | | | | | | Yes  No | |
| **5.6** Have there been any problems listed in "INVESTIGATOR GUIDANCE: Prompt Reporting Requirements (HRP-801)" not yet reported to the IRB? | | | | | | | | Yes  No | |
| **5.7** Do any personnel involved in the design, conduct, or reporting of the research have a "Related Financial Interest" not previously reported? | | | | | | | | Yes  No | |
|  | | | | | | | | | |
| 1. **Brief substantive summary of the progress of the research** (A summary is required whether or not you have answered “yes” to any questions in Section 5.) | | | | | | | | | |
| Enter summary here. | | | | | | | | | |
| **Submission Requirements** | | | | | | | | | |
| Provide the following documents with this application:   * **Current "FORM: Research Personnel (HRP-201)" for this study.** * The following documents if applicable:   + Progress report or annual report submitted to sponsor/funding agency if funded from external sources   + 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.** | | | | | | | | | |