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| --- |
| **Use for both continuing review and as a final report to close a protocol.****If modifications are being requested, submit a separate request for a modification.** |
| **IRB Number:** |       |
| **Study Title:** |       |
| **Short Title:** |       |
| **Investigator:** |       |
| **Primary Contact:** |       |
| **Enrollment Status** |
| **Number of subjects enrolled:** | Total | Since last approval |  |  |  |
| At this investigator’s site(s): |       |       |  |  |  |
| Study wide: |       |  |
| **Current Protocol Status[[1]](#footnote-1)***Check all that are true or not applicable* |
|[ ]  The protocol is permanently closed to enrollment at this institution. |
|[ ]  All subjects enrolled at this institution have completed all protocol related interventions and interactions, including interventions and interactions related to collection of long-term follow-up data. |
|[ ]  No additional identifiable private information about the subjects is being obtained by this institution’s investigator. |
|[ ]  Analysis of private identifiable information at this institution is completed. *(This can be checked even if a statistical center at another institution will analyze private identifiable from subjects enrolled at this institution.)* |
| **If all above are checked, this will be the last continuing review of this protocol.** |
|[ ]  The remaining protocol activities are limited to data analysis. |
|[ ]  The protocol remains active only for long-term follow-up of subjects. |
| **Financial Interest Declaration** |
| * + See “SOP: Definitions (HRP-001) for definitions of Immediate Family and a financial interest Related to the Research.
 |
| [ ]  Yes [ ]  No | Do any personnel (or an immediate family member of personnel) involved in the design, conduct, or reporting of the protocol have a financial interest Related to the Research? **If yes, provide the institution’s evaluation of the financial interest.** |
| **Check if true** | **Relative to all sites involved in the protocol, since the last IRB continuing review:** |
|[ ]  NO subjects have experienced unexpected harm. |
|[ ]  Anticipated Adverse Events have NOT taken place with greater frequency or severity than expected. |
|[ ]  NO subjects have withdrawn from the protocol. |
|[ ]  There have been NO unanticipated problems involving risks to subjects or others. |
|[ ]  There have been NO complaints about the protocol. |
|[ ]  There have been NO publications in the literature relevant to risks or potential benefits. |
|[ ]  There have been NO interim findings. |
|[ ]  There have been NO one or more multi-center trial reports. |
|[ ]  There have been NO data safety monitoring reports. |
|[ ]  There have been NO modifications to the protocol that have not been submitted to and approved by the IRB. |
|[ ]  There have been NO regulatory actions that could affect safety and risk assessments. |
|[ ]  There has been NO other relevant information regarding this protocol, such as information about risks. |
|[ ]  In the opinion of the principal investigator, the risks or potential benefits are unchanged. |
|[ ]  All problems that require prompt reporting to the IRB have been submitted. |
| **Attach a summary explanation or description for each unchecked statement.** |
| Provide one copy of the following documents:* Brief summary of the progress of the protocol.
* Explanation of any “Yes” responses to items in above sections
* Clean copies of all consent documents *(Not required if protocol is permanently closed to enrollment.)*
* Copy of sponsor’s progress report or annual report, if available
* Point-by-point response *(When in response to modifications to secure approval, deferral, or disapproval)*
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| **Investigator Acknowledgement** |
| I will conduct this protocol in accordance with requirements in the INVESTIGATOR MANUAL (HRP-103).  |
| Investigator signature | Date |
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1. This refers to the status of the protocol under the supervision of the investigator, not the status of the protocol at all centers. [↑](#footnote-ref-1)