|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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)* | | | | | | | | | | |
| **Investigator Acknowledgement** | | | | | | | | | | |
| I will conduct this protocol in accordance with requirements in the INVESTIGATOR MANUAL (HRP-103). | | | | | | | | | | |
| Investigator signature | | | | | | | | | Date | |
|  | | | | | | | | |  | |

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)