|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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.** | | | | | | | | |
| **HSPP (IRBNet) Number:** | | | |  | | | | |
| **Protocol Name:** | | | |  | | | | |
| **Principal Investigator:** | | | |  | | | | |
| **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* | | | | | | | | |
|  | The protocol is permanently closed to enrollment. | | | | | | | |
|  | All subjects enrolled 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 organization’s investigator(s). | | | | | | | |
|  | Analysis of private identifiable information at this organization is completed. *(This can be checked even if a statistical center at another organization will analyze private identifiable from subjects enrolled at this organization.)* | | | | | | | |
| **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** | | | | | | | | |
| * “Immediate Family” means spouse, domestic partner, children, and dependents. * “Related Financial Interest” means any of the following interests in the sponsor, product or service being tested, or competitor of the sponsor held by the individual or the individual’s immediate family:   + Ownership interest of any value including, but not limited to stocks and options, exclusive of interests in publicly-traded, diversified mutual funds.   + Compensation of any amount including, but not limited to honoraria, consultant fees, royalties, or other income.   + Proprietary interest of any value including, but not limited to patents, trademarks, copyrights, and licensing agreements.   + Board or executive relationship, regardless of compensation.   + Reimbursed or sponsored travel by an entity other than a federal, state, or local government agency, higher education institution or affiliated research institute, academic teaching hospital, or medical center. | | | | | | | | |
| **Yes  No** | | | **Do any personnel involved in the design, conduct, or reporting of the protocol have a Related Financial Interest?**  If yes, provide the organization’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, including the addition of new investigators, 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 a brief summary of the progress of the protocol** *:* | | | | | | | | |
| **Include the following documents in your submission when they exist or are applicable:**   * Clean copies of all approved consent documents *(provide in MS Word format)*    + Note: Consent documents are NOT required if protocol is permanently closed to enrollment. * Explanation of any unchecked responses to items in above section * Evaluation of any Related Financial Interest. * Copy of sponsor’s progress report or annual report | | | | | | | | |
| **Principal Investigator Acknowledgement** | | | | | | | | | |
| **I will conduct this protocol in accordance with requirements in the INVESTIGATOR MANUAL (HRP-103).** | | | | | | | | | |
| Principal Investigator (signature or typed name) | | | | | | | | 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)