|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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.** | | | | | | | | | | |
| **Study ID Number**  (HSC # or RAMP ID)**:** | | | |  | | | | | | |
| **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)**  *Select all that apply* | | | | | | | | | | |
|  | The protocol is permanently closed to enrollment OR was never open for enrollment. | | | | | | | | | |
|  | All subjects have completed all study-related interventions, OR not applicable (i.e., the study did not include interventions). | | | | | | | | | |
|  | Collection of study subjects’ identifiable private information is complete OR not applicable (i.e., the study did not include collection of subjects’ identifiable private information). | | | | | | | | | |
|  | Analysis of identifiable private information is complete OR not applicable (i.e., the study did not include collection of subjects’ identifiable private information). | | | | | | | | | |
| **Important! If all above are checked, the study will be closed to further IRB oversight. If you plan to make any subsequent modification to the study that might change your response to the above items, contact the OHSP/IRB to see whether you must re-open the study for IRB review and approval.** | | | | | | | | | | |
|  | The remaining study activities are limited to data analysis. | | | | | | | | | |
|  | The study 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***[[2]](#footnote-2)***:** | | | | | | | | |
|  | | NO subjects have experienced unexpected harm. IF any subject has experienced unexpected harm, submit a Reportable New Information (RNI) in RAMP IRB; if an RNI was already submitted, provide the RNI ID: | | | | | | | | |
|  | | Anticipated Adverse Events have NOT taken place with greater frequency or severity than expected. IF such events have taken place with greater frequency or severity than previously expected, submit a Reportable New Information (RNI) in RAMP IRB; if an RNI was already submitted, provide the RNI ID: | | | | | | | | |
|  | | NO subjects have withdrawn from the protocol. IF subjects have withdrawn, indicate how many:  Also provide a summary of the reasons for these withdrawals: | | | | | | | | |
|  | | There have been NO unanticipated problems involving risks to subjects or others. IF there have been such problems, submit a Reportable New Information (RNI) in RAMP IRB; if an RNI was already submitted, provide the RNI ID: | | | | | | | | |
|  | | There have been NO complaints about the protocol. IF there have been complaints, submit a Reportable New Information (RNI) in RAMP IRB; if an RNI was already submitted, provide the RNI ID: | | | | | | | | |
|  | | There have been NO publications in the literature relevant to risks or potential benefits. IF there have been such publications, provide a summary of these publications: | | | | | | | | |
|  | | There have been NO interim findings. IF there have been interim findings, provide a summary of these findings: | | | | | | | | |
|  | | There have been NO multi-center trial reports. IF there have been such reports, upload the reports as additional or supporting documents in your RAMP IRB continuing review submission. | | | | | | | | |
|  | | There have been NO data safety monitoring reports. IF there have been such reports, upload the reports as additional or supporting documents in your RAMP IRB continuing review submission. | | | | | | | | |
|  | | There have been NO modifications to the protocol that have not been submitted to and approved by the IRB. Submit a modification in RAMP IRB if any changes are needed. IF ANY change to the study was made without IRB approval, explain:  Also, submit a Reportable New Information (RNI) in RAMP IRB for making any change to the study without IRB approval; if an RNI was already submitted, provide the RNI ID: | | | | | | | | |
|  | | There have been NO regulatory actions that could affect safety and risk assessments. IF there have been such actions, submit a Reportable New Information (RNI) in RAMP IRB; if an RNI was already submitted, provide the RNI ID: | | | | | | | | |
|  | | There has been NO other relevant information regarding this protocol, such as information about risks. IF there is other such relevant information, describe: | | | | | | | | |
|  | | In the opinion of the principal investigator, the risks or potential benefits are unchanged. If the risks or potential benefits are changed, explain: | | | | | | | | |
|  | | All problems that require prompt reporting to the IRB have been submitted.  IF ANY such problems have not been submitted, explain:  Also, submit a Reportable New Information (RNI) in RAMP IRB to report the problem; if an RNI was already submitted, provide the RNI ID: | | | | | | | | |
| **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)
2. For any item that is NOT checked, follow the related instructions for that item. [↑](#footnote-ref-2)