|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Use for both continuing review and as a final report to close the study at a site.**  **If modifications are being requested, submit a separate request for a modification.**  *(Make copies of pages as needed)* | | | | | |
| **Study IRB Number:** (if known) | |  | | | |
| **Study Title:** | |  | | | |
| **Short Title:** | |  | | | |
| **Site Investigator:** | |  | | | |
| **Site Primary Contact:** | |  | | | |
| **Site Enrollment Status** | | | | | |
| Number of subjects enrolled at my site: | | | Total: | Since last approval: | |
| **Check if true** | **For your site, since the last IRB reviewing 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|  | NO subjects have withdrawn from the protocol.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. | | | | |
| **Site Information** | | | | | |
| Provide one copy of the following documents:   * Point-by-point response. *(For a response to modifications to secure approval, deferral, or disapproval.)* * Evaluation of any Related Financial Interest. * Explanation of any items above which you check as being true. * Brief summary of the progress of the protocol. * Clean copies of all consent documents. *(Not required if protocol is permanently closed to enrollment.)* | | | | | |
| **Investigator Acknowledgement** | | | | | |
| I will conduct this protocol in accordance with requirements this IRB’s requirements and any relevant local requirements. | | | | | |
| Investigator signature | | | | | Date |
|  | | | | |  |