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| **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|[ ]  NO subjects have withdrawn from the protocol.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.)*
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| **Investigator Acknowledgement** |
| I will conduct this protocol in accordance with requirements this IRB’s requirements and any relevant local requirements. |
| Investigator signature | Date |
|       |  |