HRP-812 | 1/1/2024

FORM: Site Continuing Review

Use for both continuing review and as a final report to close a protocol.[[1]](#endnote-2) If modifications are being requested, submit a separate request for a modification.

basic information

|  |  |
| --- | --- |
| **Basic Study Information** | **Study Details** |
| **IRB Number (if known):** | Click or tap here to enter text. |
| **Study Title:**  | Click or tap here to enter text. |
| **Short Title:** | Click or tap here to enter text. |
| **Site Investigator:**  | Click or tap here to enter text.  |
| **Site Primary Contact:** | Click or tap here to enter text. |

Site Enrollment Status

|  |  |
| --- | --- |
| **Enrollment Status** | **Site Enrollment Details** |
| Number of subjects enrolled at this site in total: | Click or tap here to enter text. |
| Number of subjects enrolled at this site since last approval: | Click or tap here to enter text. |

Current SITE Status[[2]](#endnote-3)

**Check all that are true or not applicable.**

[ ]  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[ ]  NO subjects have withdrawn from the protocol.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 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 did not 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 this IRB’s requirements and any relevant local requirements.

Investigator Signature

Date of Signature: Click or tap here to enter text.

1. This document satisfies AAHRPP elements I-9, II.3.A, II.3.C, III.1.B [↑](#endnote-ref-2)
2. This refers to the status of the protocol under the supervision of the investigator, not the status of the protocol at all centers. [↑](#endnote-ref-3)