HRP-812 | 7/24/2024

FORM: Site Continuing Review

The UMN study team can use this form to collect information from a pSite for continuing review.[[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 participants enrolled at this site in total: | Click or tap here to enter text. |
| Number of participants 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 participants have experienced unexpected harm.

[ ]  Anticipated Adverse Events have NOT taken place with greater frequency or severity than expected.

[ ]  NO participants have withdrawn from the protocol.

[ ]  There have been NO unanticipated problems involving risks to participants 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.

[ ]  pSite investigator and study personnel do not have a conflict of interest. If yes, please contact relyirb@umn.edu as soon as possible as the University of Minnesota IRB may not be able to continue to serve as the IRB of record for this site (see pSite Manual (HRP-103p)).

Site information

Provide one copy of the following documents or explain below:

* Point-by-point response. *(For a response to modifications to secure approval, deferral, or disapproval)*
* Explanation of any items above which you did not check as being true:

Click or tap here to enter text.

* Brief summary of the progress of the protocol.

Click or tap here to enter text.

Investigator Acknowledgement

I will conduct this protocol in accordance with requirements this IRB’s requirements and any relevant local requirements (pSite Manual (HRP-103p) and Investigator Manual (HRP-103)).

Investigator Signature

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

1. This document satisfies AAHRPP elements I.6.B, I-9, II.2.E-II.2.E.2, II.2.F-II.2.F.3, II.3.A, II.3.C-II.3.C.1, 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)