HRP-212 | 2/2/2024

FORM: Continuing Review

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

BASIC INFORMATION

Basic 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.
Investigator:	Click or tap here to enter text.
Primary Contact:	Click or tap here to enter text.

ENROLLMENT STATUS

Enrollment Status	Study Enrollment Details
Number of subjects enrolled at this investigator's site(s) in total:	Click or tap here to enter text.
Number of subjects enrolled at this investigator's site(s) since last approval:	Click or tap here to enter text.
Number of subjects enrolled study-wide in total (if multi-site or collaborative study):	Click or tap here to enter text.

CURRENT PROTOCOL STATUS[2]

Check all that are true or not applicable

☐ The protocol is permanently closed to enrollment at this institution.

☐ All subjects enrolled at this institution have completed all protocol related interventions and interactions, including interventions and interactions related to collection of long-term follow-up data.

☐ No additional identifiable private information about the subjects is being obtained by this institution's investigator.

[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

[2] This refers to the status of the protocol under the supervision of the investigator, not the status of the protocol at all centers.

☐ Analysis of private identifiable information at this institution is completed. *(This can be checked even if a statistical center at another institution will analyze private identifiable from subjects enrolled at this institution.)*

If all the above are checked, this will be the last continuing review of this protocol.

☐ The remaining protocol activities are limited to data analysis.

☐ The protocol remains active only for long-term follow-up of subjects.

Financial interest Declaration

See HRP-001 - SOP - Definitions for definitions of Immediate Family and a financial interest Related to the Research.

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.**

☐ Yes ☐ No

Additional information

Check the items that are true since the last IRB approval for all sites involved in the study:

☐ 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.

Attach a summary explanation or description for each unchecked statement.

Attachments

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 HRP-103 - INVESTIGATOR MANUAL.

Investigator Signature

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

X_____