HRP-213 | 2/2/2024

FORM: Modification

Use to request a modification to previously approved activity[1]

BASIC INFORMATION

Basic Study Information	Study Details
IRB Number:	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.

CURRENT PROTOCOL STATUS[2]

Check all that are true or not applicable:

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

☐ All subjects enrolled at this organization 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 organization's investigator.

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

If all above are checked, submit a continuing review to close this protocol.

NOTIFICATION OF SUBJECTS

☐ Subjects are currently enrolled.

☐ Current subjects will be notified of these changes.

☐ Former subjects will be notified of these changes.

If either is checked, ensure that the submitted documents describe how current or former subjects will be notified): Click or tap here to enter text.

SUMMARY

[1] This document satisfies AAHRPP elements II.2.I, II.3.A, II.3.C-II.3.C.1

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

Summarize the modifications. Write only a brief overview of the study modifications here, then update the protocol and other study documents and change all applicable details of the existing study in the appropriate places.

Click or tap here to enter text.

Attachments

Provide the following documents when they have changed:

- Investigator Protocol *(See HRP-503 - TEMPLATE PROTOCOL for instructions)*
- Point-by-point response *(For a response to modifications to secure approval, deferral, or disapproval)*
- Evaluation of any Related Financial Interest
- Appendix A of this form: External Site Approvals
- Appendix B of this form: Drugs and Device *(include associated attachments, such as package insert, investigator brochure, or labeling, verification of IND/ IDE number)* [3]
- Written materials to be provided to or meant to be seen or heard by subjects
  - Evaluation instruments and surveys[4]
  - Advertisements *(printed, audio, and video)*
  - Recruitment materials and scripts
  - Consent documents *(The IRB does not require an informed consent document for HUD use.)*
  - If consent will not be documented in writing, a script of information to be provided orally to subjects
  - Foreign language versions of the above
- Complete sponsor protocol[5]
- Grant application
- DHHS protocol and DHHS-approved sample consent document[6]
- For Department of Energy (DOE) research, a completed "Checklist for IRBs to Use in Verifying that HS Research Protocols are In Compliance with Department of Energy (DOE) Requirements"

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_____

[3] Omit this item if this is the activation of a previously approved protocol at a new site or sites that will be overseen by a principal investigator who will take separate and full responsibility for that site or those sites.
[4] Ibid
[5] Ibid
[6] Ibid