HRP-813 | 1/1/2024

FORM: Site Modification

Use to request a modification to previously approved site activities.[[1]](#endnote-2)

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

Site Enrollment Status

**Check all that are true:**

[ ]  No subjects have been enrolled to date.

[ ]  Subjects are currently enrolled.

[ ]  The study is permanently closed to enrollment at my site.

[ ]  All subjects enrolled at my site have completed all study 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 me.

Notification of subjects

[ ]  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.

Site information

Provide the following documents when they exist or are applicable and have been modified:

* Point-by-point response *(For a response to modifications to secure approval, deferral, or disapproval)*
* Evaluation of any Related Financial Interest.
* Written materials to be provided to or meant to be seen or heard by subjects at your site
	+ Evaluation instruments and surveys
	+ 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
* Site supplement to the main protocol

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)