HRP-816 | 1/1/2024

FORM: External IRB Study Update

Use to notify local IRB of study changes approved by the external IRB of record[[1]](#endnote-2)

basic information

|  |  |
| --- | --- |
| **Basic Study Information** | **Study Details** |
| **Study 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. |

Study Update Information

**Summarize the updates:** 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 at my site.

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 external IRB approval letter for the change(s) and any of the following documents if they have been modified:

* Study Protocol
* Drug and device information (if applicable)
* 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
	+ If consent will not be documented in writing, a script of information to be provided orally to subjects
	+ Foreign language versions of the above
* Grant application/funding information

SITE Investigator Acknowledgement

I will conduct this protocol in accordance with the external IRB’s requirements and any relevant local requirements.

SITE Investigator signature

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

1. This document satisfies AAHRPP element I-9. [↑](#endnote-ref-2)