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| **Use to request a modification to previously approved site activities[[1]](#footnote-1)***(Make copies of pages as needed)* |
| **Study IRB Number:** (if known) |       |
| **Study Title:** |       |
| **Short Title:** |       |
|  **Site Investigator:** |       |
| **Site Primary Contact:** |       |
| **Study Update Information** |
| **Summarize the updates:**       |
| **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. | *If either is checked, ensure that the submitted documents describe how current or former subjects will be notified.* |
|[ ]  Former subjects will be notified of these changes. |  |
| **Site Information** |
| Provide the following documents when they exist or are applicable and have been modified:* Investigator Protocol *(See HRP-503 - TEMPLATE - PROTOCOL for instructions)*
* 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)* [[2]](#footnote-2)
* Written materials to be provided to or meant to be seen or heard by subjects
	+ Evaluation instruments and surveys1
	+ 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 1
* Grant application
* DHHS protocol and DHHS-approved sample consent document 1
* 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 this IRB’s requirements and any relevant local requirements. |
| Investigator signature | Date |
|       |  |

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