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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)