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| **Use to request a modification to previously approved research** |
| **IRB Number:** |       |
| **Protocol Name:** |       |
| **Investigator:** |       |
| **Primary Contact:** |       |
| **Current Protocol Status** *Check all that are true* |
| [ ]  | Subjects are currently enrolled. |
| [ ]  | The protocol is permanently closed to enrollment. |
| [ ]  | All subjects have completed all protocol-related interventions. |
| [ ]  | Collection of private identifiable information is completed. |
| [ ]  | 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. |

Provide the following documents as applicable:

* A summary of the modifications
* A description of how current or former subjects will be notified
* For any financial interest related to the research, Conflict of Interest Committee’s determination.
* FORM: Application for Initial Review (HRP-211), including as applicable:
	+ Appendix A: External Site Approvals
	+ Appendix B: Drugs and Device (include associated attachments, such as package insert, investigator brochure, or labeling, verification of IND/ IDE number)\*
* Investigator Protocol **with Version Date** (See TEMPLATE PROTOCOL (HRP-503) for instructions)
* Clean and tracked changes versions of written material to be provided to or meant to be seen or heard by subjects
	+ 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
* Complete sponsor protocol including DHHS-approved protocol, if any\*
* DHHS-approved sample consent document, if any \*
* Grant application, if any\*
* If the research is conducted or funded by the Department of Energy (DOE), a completed “Checklist for IRBs to Use in Verifying that HS Research Protocols are In Compliance with Department of Energy (DOE) Requirements”
* Addition of new personnel to the protocol, submit for each individual;
	+ Completed HRP-201 Contact Information, Financial Conflict of Interest Disclosure Form, Summary memo describing the roles the new personnel will have on the protocol
* Removal of personnel is to be described in the modification summary memo

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| **Investigator Acknowledgement** |
| I agree to conduct this Human Research in accordance with applicable regulations and the organization’s policies and procedures. |
| Investigator signature | Date |
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