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| --- | --- | --- | --- | --- |
| **Use to request a modification to previously approved activity** | | | | |
| **HSPP (IRBNet) Number:** | |  | | |
| **Protocol Name:** | |  | | |
| **Principal Investigator:** | |  | | |
| **Current Protocol Status[[1]](#footnote-1)**  *Check all that are true* | | | | |
|  | The protocol is permanently closed to enrollment. | | | |
|  | All subjects enrolled have completed all protocol 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 this organization’s investigator(s). | | | |
|  | Analysis of private identifiable information at this organization is completed. *(This can be checked even if a statistical center at another organization will analyze private identifiable from subjects enrolled at this organization.)* | | | |
| **If all above are checked, submit a continuing review to close this protocol.** | | | | |
|  | Subjects are currently enrolled | | | |
|  | 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 a point-by-point description of your proposed modifications:** | | | | |
| **Include the following in your submission when they have changed or are new:**  *(Use “track-changes” or otherwise highlight revisions.)*   * Investigator Protocol *(ensure that you are modifying only the latest approved version of your protocol)* * HRP-211 Initial Review Form *(to add/change study personnel, external study sites or funding sources)* * Materials to be provided to or meant to be seen, read, or heard by subjects *(or potential subjects)*   + Recruitment materials and scripts, advertisements *(printed, audio, and video)*   + Consent documents: consent forms, written consent statements, or verbal scripts *(provide in MS Word format)*   + Study instruments and data collection forms *(e.g., surveys, questionnaires, interview or focus group questions, demographics, observation guides, assessments, etc.)*   + Foreign language versions of the above * Evaluation of any Related Financial Interest. * Grant application * Complete sponsor protocol, DHHS protocol, and/or DHHS-approved sample consent document * Appendices B or C *(include associated attachments, such as package insert, investigator brochure, or labeling, verification of IND/ IDE number)* [[2]](#footnote-2) * 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” | | | | |
| **Principal Investigator Acknowledgement** | | | | | |
| **I will conduct this protocol in accordance with requirements in the INVESTIGATOR MANUAL (HRP-103).** | | | | | |
| Principal Investigator (signature or typed name) | | | | Date | |
|  | | | |  | |

1. This refers to the status of the protocol under the supervision of the investigator, not the status of the protocol at all centers. [↑](#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)