|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Use for new proposals**  *(Make copies of pages as needed)* | | | | | | | | | |
| **IRB Number:** (if known) |  | | | | | | | | |
| **Study Title:** |  | | | | | | | | |
| **Short Title:** |  | | | | | | | | |
| **Investigator:** |  | | | | | | | | |
| **Primary Contact:** |  | | | | | | | | |
| **Brief Description** |  | | | | | | | | |
| **IRB Oversight** | | | | | | | | | |
| Which IRB at this institution should oversee this study? | | |  | | | | | | |
| Will this institution’s IRB act as the IRB of record for other participating sites? | | | ☐ Yes ☐ No | | | | | | |
| Will an external IRB act as the IRB of record? | | | ☐ Yes ☐ No | | | | | | |
| What kind of study is this? | | | Multi-Site Study or Collaborative Study  Single-Site Study | | | | | | |
| **Funding Sources** | | | | | | | | | |
| **Name of Funding Source** | | | | | **Funding Source ID** | | | **Grant Office ID** | |
|  | | | | |  | | |  | |
|  | | | | |  | | |  | |
|  | | | | |  | | |  | |
| **Financial Interest Declaration** | | | | | | | | | |
| * See “SOP: Definitions (HRP-001)” for definitions of Immediate Family and a financial interest Related to the Research. | | | | | | | | | |
| Do any personnel (or an immediate family member of personnel) involved in the design, conduct, or reporting of the research have a financial interest Related to the Research? **If yes, provide the institution’s evaluation of the financial interest below.** | | | | | | | | | Yes  No |
| Name | | Role | | Involved in consent? | | | Evaluation (You may attach a separate page describing the outcome of the evaluation.) | | |
|  | |  | |  | | |  | | |
|  | |  | |  | | |  | | |
|  | |  | |  | | |  | | |
| **Protocol Information** | | | | | | | | | |
| Provide an Investigator Protocol (See TEMPLATE PROTOCOL (HRP-503) for instructions)  Provide the following documents when they exist or are applicable:   * Point-by-point response *(For a response to modifications to secure approval, deferral, or disapproval)* * Evaluation of any Related Financial Interest. * Appendix A: Personnel * Appendix B: Research Locations * Appendix C: External Sites * Appendix D: Drugs, Biologics, Dietary Supplements, and Foods, and Device and associated attachments[[1]](#footnote-2) * Appendix E: Devices and associated attachments * 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 | | | | | | | | | |
| **Investigator Acknowledgement** | | | | | | | | | |
| I will conduct this protocol in accordance with requirements in the INVESTIGATOR MANUAL (HRP-103). | | | | | | | | | |
| Investigator signature | | | | | | Date | | | |
|  | | | | | |  | | | |

|  |  |  |
| --- | --- | --- |
| **Appendix A: Personnel** | | |
| * Name all personnel involved in this protocol’s design, conduct, or reporting. * Include the Principal Investigator named above. | | |
|  | | |
| Name | Role | Involved in consent? |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Appendix B: Research Locations** | | | | | | |
| * Complete for local research location (e.g., an elementary where an investigator for this institution will intervene or interact with students). * Do not include other institutions participating in a Collaborative Study or Multi-Site Study. | | | | | | |
|  | | | | | | |
| **Site name** | **Location/Address and Contact name** | **Contact phone or email** | **Will this location provide a letter of support?** | | | |
|  |  |  | Yes  No | | | |
|  |  |  | Yes  No | | | |
|  |  |  | Yes  No | | | |
|  |  |  | Yes  No | | | |
|  |  |  | Yes  No | | | |
|  |  |  | Yes  No | | | |
|  |  |  | Yes  No | | | |
|  |  |  | Yes  No | | | |
|  |  |  | Yes  No | | | |
|  |  |  | Yes  No | | | |
| **Appendix C: External Sites** | | | | | | |
| * Complete for each external site at which the investigator will conduct or oversee the protocol. | | | | | | |
|  | | | | | | |
| **Site name** | **Contact name** | **Contact phone or email** | **Will site’s IRB review the protocol?** | | **Will site rely on this institution’s IRB?** | |
| **Yes** | **No** | **Yes** | **No** |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Appendix D** | | | | | | |
| **Drugs, Biologics, Dietary Supplements, and Foods** | | | | | | |
| **List all:**   * **Unapproved drugs/biologics being used in the protocol** * **Approved drugs/ biologics whose use is specified in the protocol[[2]](#footnote-3)** * **Foods or dietary supplements whose use is specified in the protocol3** | | | | | | |
| **Generic Name** | | | **Brand Name** | | | **Submit a package insert or investigator brochure for each listed drug** |
|  | | |  | | |
|  | | |  | | |
|  | | |  | | |
|  | | |  | | |
|  | | |  | | |
|  | | |  | | |
|  | | |  | | |
|  | | |  | | |
|  | | |  | | |
|  | | |  | | |
| Protocol is being conducted: |  | Under IND# | | IND#(s) |  | **Submit evidence of IND#(s)[[3]](#footnote-4)** |
|  | Without IND#  What is the basis for determining an IND is not required[[4]](#footnote-5)? | | | | |
| Who holds the IND? |  | Sponsor | | | | |
|  | Investigator | | | | **Submit approved IND application(s) (Form 1571) and FDA approval letter(s)) for IND#(s)** |
|  | Other | | Specify: |  | |
| **Appendix E** | | | | | | |
| **Devices** | | | | | | |
| **List all:**   * **Devices being evaluated for safety or effectiveness** * **Humanitarian Use Devices (HUD)** | | | | | | |
| **Name** | | | | | | **Submit product labeling for each item listed** |
|  | | | | | |
|  | | | | | |
|  | | | | | |
|  | | | | | |
|  | | | | | |
|  | | | | | |
|  | | | | | |
|  | | | | | |
|  | | | | | |
|  | | | | | |
|  | | | | | |
| Protocol is being conducted: |  | Under IDE# | | IDE#(s) or HDE#(s) |  | **Submit evidence of IDE#(s)[[5]](#footnote-6)** |
|  | Under HDE# | |
|  | Under abbreviated IDE requirements | | | | **Submit an explanation of why the device is a non-significant risk** |
|  | None of the above | | | | |
| Who holds the IDE? |  | Sponsor | | | | |
|  | Investigator | | | | **Submit approved IDE application(s) and FDA approval letter(s) for IDE#(s)** |
|  | Other | | Specify: |  | |

1. 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)
2. “Specified in the protocol” means that the protocol requires the one or more subjects to use the drug, biologic, dietary supplement, or food as part of study participation, regardless of whether its use is standard of care. For example, if the protocol indicates that “subjects in group 1 will take 650 mg of aspirin in response to a headache” the use of aspirin is specified by the protocol. If the protocol indicates that “subjects in group 1 may take 650 mg of aspirin in response to a headache” the use of aspirin is not specified by the protocol [↑](#footnote-ref-3)
3. Acceptable evidence includes: Sponsor protocol with the IND#, communication from the sponsor documenting the IND#, or FDA approval letter indicating IND#. [↑](#footnote-ref-4)
4. IRBs should ask the clinical investigator whether the sponsor determined that an IND is or is not required and the basis for the determination.  If the sponsor has determined that an IND is not required, the IRB may request that the investigator provide a copy of any available supporting documentation (e.g., letter from the sponsor or FDA, other basis for that determination). FDA Guidance August 2013, IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is needed. [↑](#footnote-ref-5)
5. Acceptable evidence includes: Sponsor protocol with the IDE#, communication from the sponsor documenting the IDE#, or FDA approval letter indicating IDE# [↑](#footnote-ref-6)