HRP-811 | 02/01/2024

**FORM: Basic Site Information**

Use for new participating site proposals.[[1]](#footnote-1) Participating site investigator must receive a copy of or link to HRP-103p – Investigator Manual pSite with this FORM.

**basic information**

|  |  |
| --- | --- |
| **Basic Study Information** | **Study Details** |
| Study IRB Number (if known): | Click or tap here to enter text. |
| Study Title: | Click or tap here to enter text. |
| Short Title: | Click or tap here to enter text. |
| Site Investigator: | Click or tap here to enter text. |
| Site Primary Contact: | Click or tap here to enter text. |

**Funding Sources**

**Include funding sources only if different than funding for the main study.**

|  |  |  |
| --- | --- | --- |
| **Name of Funding Source** | **Funding Source ID** | **Grant Office ID** |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |

**Financial interest Declaration**

According to your institution’s Conflict of Interest Policy, 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?

☐ Yes ☐ No

**If yes, provide the institution’s evaluation of the financial interest below.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Role** | **Involved in consent?** | **Evaluation (You may attach a separate page describing the outcome of the evaluation.)** |
| Click or tap here to enter text. | Click or tap here to enter text. | ☐ Yes ☐ No | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | ☐ Yes ☐ No | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | ☐ Yes ☐ No | Click or tap here to enter text. |

**Protocol Information**

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
* Written materials to be provided to or meant to be seen or heard by subjects
  + Evaluation instruments and surveys that contain site specific language
  + Advertisements *(printed, audio, and video)*
  + Recruitment materials and scripts
  + Consent documents
  + If consent will not be documented in writing, a script of information to be provided orally to subjects
  + Foreign language versions of the above
* Site Supplement to the main protocol (when site activities differ from or are not described in the main protocol)

**Local Context**

|  |  |
| --- | --- |
| Will the process for identifying and recruiting subjects differ from that described in the multi-site protocol? | ☐ Yes (Explain): Click or tap here to enter text.  ☐ No  ☐ NA |
| Will any other study activities at this site differ from those described in the multi-site protocol? | ☐ Yes (Explain): Click or tap here to enter text.  ☐ No |
| Do local requirements or state law stipulate requirements for enrolling vulnerable populations in this study differ from those described in the multi-site protocol or other study documents? | ☐ Yes (Explain): Click or tap here to enter text.  ☐ No  ☐ NA |
| Do local requirements or state law stipulate requirements for how data will be accessed and/or stored at this site differ from those described in the multi-site protocol? | ☐ Yes (Explain): Click or tap here to enter text.  ☐ No  ☐ NA |
| Are there any additional factors particular to this site (e.g., community attitudes, ethnic diversity, language) that may affect how this study is implemented at this site? | ☐ Yes (Explain): Click or tap here to enter text.  ☐ No  ☐ NA |
| Are there any ancillary committee reviews (i.e., biosafety, radiation safety) at this site that should be taken into consideration by the Reviewing IRB? | ☐ Yes (Explain): Click or tap here to enter text.  ☐ No |
| Will drug and/or device storage by managed centrally by a pharmacy at this site? | ☐ Yes (Explain): Click or tap here to enter text.  ☐ No  ☐ NA |
| Are there any standard of care differences at this site from the multi-site protocol? | ☐ Yes (Explain): Click or tap here to enter text.  ☐ No  ☐ NA |
| Will the consent process at this site be different from the multi-site protocol? | ☐ Yes (Explain): Click or tap here to enter text.  ☐ No  ☐ NA |

**Site Investigator Acknowledgement**

I will conduct this protocol in accordance with requirements in the HRP-103p - INVESTIGATOR MANUAL pSite.

**Site Investigator Signature**

Date of Signature: Click or tap here to enter text.



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