HRP-811 | 2/2/2024

FORM: Basic Site Information

Use for new participating site proposals.[1] Participating site investigator must receive HRP-103p – pSite Manual 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.

[1] This document satisfies AAHRPP elements I-9

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
    - 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 (if 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 pSite 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 - pSite Manual.

Site Investigator Signature

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

X_____