|  |
| --- |
| **BSPH Protocol Information:** |
| **BSPH IRB No.:** |       |
| **Study Title:** |       |
| **BSPH PI:** |       |
| **Reason for Reliance on BSPH IRB:** |       |

|  |
| --- |
| **Relying Site Information:** |
| **Relying Site:** |       |
| **Relying Site PI:** |       |
| **Relying Site PI Contact Info:** |       |
| **Relying Site IRB Contact:** |       |
| **Relying Site FWA No.:** |       |
|  |  |
|  |  |
| **IRB Quality Control:** | [ ]  Indicate the IRB Quality Control mechanism in place at Relying Site:[ ]  AAHRPP[ ]  OHRP Quality Assessment[ ]  Internal Quality Assurance Program (Please describe): Click or tap here to enter text.[ ]  None[ ]  Other (Please describe): Click or tap here to enter text. |
| **Relying Site Monitoring:** | Are there any investigations, audits, or findings (e.g. OHRP, FDA, or local audits) over the past three years that would be relevant to the conduct of new human subjects research proposed at the site? [ ]  No[ ]  Yes (If YES, please explain any investigations, audits, or findings that may be relevant): Click or tap here to enter text. |

**HUMAN SUBJECT’S ETHICS TRAINING:**

*Please check the box, if true.*

|  |
| --- |
|[ ]  Please review the planned list of personnel who will be engaged in human subjects research at your institution and **verify by checking this box** that all of your institutionally-required training for the conduct of the research [including human subjects protections training, GCP training, and HIPAA training, as applicable] has been completed for each individual. |

**CONFLICT OF INTEREST:**

*Please check applicable box.*

|  |
| --- |
|[ ]  An institutional or financial **conflict of interest** has been identified at the relying site, and the **Conflict of Interest Management Plan** is attached. |
|[ ]  An institutional or financial conflict of interest has been identified at the relying site, and the **COI has been eliminated**. |
|[ ]  No institutional or financial conflict of interest at the relying site has been identified or reported. |
|[ ]  The relying institution does not have a COI review process. |

**INSTITUTIONAL ANCILLARY REVIEW:**

*Please check the applicable box(es).*

|  |
| --- |
| Local institutional ancillary review requirements at relying institution: |
|[ ]  Primary grant recipient/grant review |
|[ ]  Radiation safety review |
|[ ]  Biosafety review |
|[ ]  Data Security review |
|[ ]  HIPAA/PHI review |
|[ ]  FERPA review |
|[ ]  Other (Please describe and attach any relevant documentation): Click or tap here to enter text. |
|[ ]  There are no institutionally-required ancillary reviews that apply to this protocol. |

**STATE OR LOCAL LAWS AND REGULATIONS:**

*Please check the applicable box and report the age of majority.*

|  |
| --- |
|[ ]  Relying institution has identified and interpreted requirements of its applicable **state or local laws and regulations** relevant to the study. (Please describe the relevant state laws and regulations and provide a link to any key documents, such as institutional policy for applying state law or link to the statute): Click or tap here to enter text. |
|[ ]  There are no state or local laws or regulations that pertain to this protocol. |
| Age of majority for the state in which the relying site is located: Click or tap here to enter text. |

**INSTITUTIONAL POLICIES:**

*Please check the applicable box.*

|  |
| --- |
|[ ]  Relying institution has identified and interpreted requirements of its applicable institutional policies relevant to the study. (Please describe the relevant institutional policies and provide a link to any key documents or attach relevant documentation): Click or tap here to enter text. |
|[ ]  There are no institutional policies that pertain to this protocol. |

**THE CONDUCT OF THE STUDY AT THE RELYING SITE:**

*Please select the activities that will be performed at your site and/or performed by your site’s employees (select all that apply).*

|  |
| --- |
|[ ]  Funding only |
|[ ]  Recruiting – informing potential participants about the study. (If applicable) Site-specific recruitment materials attached |
|[ ]  Consenting participants |
|[ ]  Accessing/providing identifiable data or biospecimens |
|[ ]  Analyzing identifiable data/specimens |
|[ ]  Performing research intervention |

**CONSENT FORM:**

*Please check the applicable box.*

|  |
| --- |
|[ ]  Site-specific language is necessary for the **template consent form** (including language pertaining to contact information, compensation language, subject injury, HIPAA authorization, local legal/regulatory requirements, and conflict of interest). See attached. |
|[ ]  Please review the protocol and template consent and identify any institutional requirements (e.g., policy or procedural requirements such as recruitment, data security, remuneration) that apply to this study and describe any steps that must be taken to adhere to these requirements. See attached.  |
|[ ]  No site-specific language is required for the template consent form. |

**LOCAL, COMMUNITY, OR CULTURAL CONCERNS:**

*Please check the applicable box.*

|  |
| --- |
|[ ]  Relying institution has identified **local, community, or cultural concerns** specific to the targeted population at the relying site and documentation summarizing this is attached. |
|[ ]  Relying institution confirms that there are no specific local, community, or cultural concerns specific to the targeted population at the relying site. |