Investigators engaged in human subject’s research require oversight by an IRB. Typically, this is the IRB of his or her own institution. However, an IRB authorization agreement (IAA, or “reliance agreement”) can be established in which one institution delegates its IRB review to another institution.

Reliance decisions are made on a case-by-case basis. Please complete each question on this form and email it to lu-ann.kozlowski@stonybrook.edu with the subject line “Reliance Request”.

**MUST READ BEFORE PROCEEDING**

• This form is not required for the following studies:

* Industry Initiated/Funded studies being submitted to Advarra under the Master Service Agreement
* Industry Initiated/Funded studies where WIRB is the central IRB of Record.
* Studies submitted to the National Cancer Institute’s Central IRB (NCI-CIRB) Adult and Pediatrics Initiative.
* For exempt studies

 o SBU IRB will not enter into reliance agreements for studies deemed “exempt”.

• For international studies:

o SBU IRB will not agree to rely on international IRB’s/Ethics Committees, but we may enter into a reliance agreement with a domestic (i.e. US) site in a multisite study, where there are also international sites.

NOTE: PLEASE DO NOT COMMUNICATE TO ANOTHER INSTITUTION THAT SBU IRB IS WILLING TO PURSUE A RELIANCE AGREEMENT UNTIL YOU HAVE SUBMITTED THIS FORM AND RECEIVED CONFIRMATION BACK FROM THE OFFICE OF RESEARCH COMPLIANCE THAT SBU IS WILLING OR ABLE.

**Title of Research Study:**

**Title of Research Study**

Response:

**Stony Brook University (PI) Information:**

|  |
| --- |
| PI Name (first, last):  |
| Title, Department:  |
| Email:  |
| Phone Number:  |

**Overall Research Study Principal Investigator (PI) Information (Lead PI):**

*The Overall PI is the principal investigator who initiates and assumes leadership and has ultimate responsibility for the conduct of, and to ensure the safety and data integrity for, this Research Study.*

[ ]  **Stony Brook University PI is also Overall PI (If checked, skip to next section)**

|  |
| --- |
| **PI Name:**  |
| **Name of Institution**:  |
| **Email Address:**  |
| **Phone Number:** |

**Reviewing IRB Information**

The Overall PI's Home Institution will have the first option of electing to serve as the Reviewing IRB. The Home Institution will consider the proposal of an alternate Reviewing IRB, as appropriate.

[ ]  **Requesting SBU IRB to be the IRB of Record (please choose reason for request and then skip to the next section)**

|  |
| --- |
| IRB Name/Institution: |
| Point of Contact (POC) Name, Title:  |
| POC Email: |
| POC Phone Number:  |

**Has Requested IRB agreed to be IRB of record?**

[ ]  YES

[ ]  No

**Is Requested IRB AAHRPP-accredited?**

[ ]  YES

[ ]  No

**Reason for requesting this institution**

*\* Please check all that apply.*

[ ]  PI Home Institution IRB

[ ]  Sponsor Requirement

[ ]  Conflict of Interest Issues

[ ]  NIH Funded (Single IRB Mandate)

[ ]  IRB Expertise

[ ]  Grant-Holding Institution

[ ]  Location of Research Activities

[ ]  Proposed Reviewing IRB has already reviewed this study or a similar/related study

[ ]  Research Subject Population

[ ]  Student Involvement

[ ]  Feedback from institutional Official, Chair, others, IRB

[ ]  Other clinical research infrastructure considerations

[ ]  Other

* If “Other” chosen, explain here:

**Research Study Information**

**Brief Description of Research Study (5-10 sentences):**

Include the overall aim, procedures involving human subjects or their data, data source, subject population and location.

Response:

**Site Involved in the Research**

**List all sites involved in Research Project**

Response:

**Funding Details (if applicable)**

*Multiple sources may be added.*

[ ]  **NIH or other federally funded study that requires a single IRB (sIRB)**

**Source of Funding**:

**Primary Awardee Institution:**

**Funding Type:**

*Please check only one.*

[ ]  Federal Government

[ ]  State Government

[ ]  Industry

[ ]  Other *Describe*: [Type here]

**If SBU is not Primary Awardee, will it receive a subaward?**

[ ]  YES

[ ]  No

**Research Participant Activities**

**Site Details**

[ ]  SBU is conducting the full protocol attached.

[ ]  SBU is only conducting some of the procedures specified in the protocol.

* Check all that apply (must check at least one)

 [ ]  Enrollment/Consenting of Subjects

 [ ] Access to Identifiable Data (Medical Record Review)

 [ ] Data Analysis

 [ ] Administering Study Interventions

[ ]  Other: [Type here]

*Please provide information on the research activities that will take place at Stony Brook University.*

*check all that apply.*

**Type(s) of Research Participants at this Site**

[ ]  No subjects [ ]  Prisoners

[ ]  Healthy controls [ ]  Persons with impaired decision making

[ ]  Adults (as defined by NYS law) [ ]  Students

[ ]  Newborns, Infants [ ]  Employees/Staff in Dept/Unit/Lab

[ ]  Children [ ]  Other: [Type here]

[ ]  Pregnant Women/Fetuses

**Specimen use at this Site**

[ ]  None [ ]  Collection

[ ]  Analysis [ ]  Creation of Repository

[ ]  Banking

**Data Analysis of Health Information**

[ ]  No data analysis at this site [ ]  De-identified but hold a code

[ ]  Anonymous [ ]  Identifiable

[ ]  De-identified

**Research Data**

[ ]  No research data retained at this site [ ]  Data will be kept at another location

[ ]  All or most research records retained at this site

**Is the study FDA-regulated?**

[ ]  YES

[ ]  No

**Does the study qualify as a clinical trial?**

[ ]  YES

[ ]  No

**Will a study investigator (at SBU or Other Institution) hold an IND or IDE for the study?**

[ ]  YES *Which Institution*: [Type here]

[ ]  No

**Ancillary Services utilized at this site requiring other institutional reviews**

[ ]  None

[ ]  Nursing

[ ]  Biostatistics

[ ]  Pharmacy

[ ]  Biomedical Engineering

[ ]  Radiation Safety (exposure to ionizing radiation or administration of radiopharmaceutical)

[ ]  Other (describe): [Type here]

**Supporting Documents**

*Documents containing protected health information (PHI) as defined by HIPAA should not be submitted.*

Submit via email with request form:

• Research Protocol or Summary (if protocol not complete)

• Consent Template(s) (If applicable)

• Other Supporting Documentation