

Stony Brook University Policy

Reliance on another University's Institutional Review Board (IRB)

("IRB Reliance Policy" v.9.15.16)

I. In order for Stony Brook University (SBU) to rely on another Institution for IRB review (non-SBU IRB), the following requirements of that Institution must be met:

- The non-SBU IRB must have:
 - a human research protection program (HRPP), accredited by a recognized accrediting entity.
 - an active federal-wide assurance (FWA) with OHRP (Office of Human Research Protections).
 - When applicable: the most recent FDA Inspection date and result
- The non-SBU IRB must accept SBU specific SOPs; e.g., minor assent, adults with diminished capacity, incidental findings etc., when applicable to the study in review. These specific SOPs will be communicated to the non-SBU institutional contact before an agreement is signed.
- An inter-institutional Agreement (IIA) signed by the IO's of both parties. The IIA must reference compliance with this IRB Reliance Policy.

II. Responsibilities of the non-SBU IRB include:

- Review and approval, disapproval or modification of the new study;
- Review and approval, disapproval or modification of consent documents or waivers of consent;
- Review and approval, disapproval or modifications to amendments of approved studies;
- Review and approval or disapproval of the investigator(s);
- Review of all DSMB reports, monitoring reports, unanticipated problems involving risks to subjects or others, and serious or continuing noncompliance;
- Maintenance of required IRB records applicable federal regulations;
- Continuing review of research studies appropriate to the degree of risk in such studies, at least annually.
- Prompt notification of IRB decisions to the Principal Investigator (PI)
- Provide PI applicable study related documents including but not limited to approved protocols, consent forms, surveys, and decision letters.
- Notify SBU within 5 working days:
 - if there is ever a suspension or restriction of the IRB's authorization to review studies;
 - of any changes in the non-SBU IRB operating procedures or practices that might affect the SBU's reliance on the non-SBU IRB review;
 - of complaints from human subjects enrolled in studies at SBU;
 - of unanticipated problems involving injury or risks to subjects or others in the study;
 - if the non-SBU IRB determines that serious or continuing non-compliance has occurred, and any steps the non-SBU IRB deems necessary for remediation of non-compliance;
 - of suspension or termination of IRB approval;

- of any communication with the FDA, OHRP or funding agency of matters relevant to human subject protections and relating to the institution's studies;
- of any finding or information (including study results, information discovered during site monitoring visits or by data safety monitoring committees, or other problems of which the non-SBU IRB becomes aware during or after the conduct of the study) that: involves risks to subjects or others, could influence the conduct of the Study, may adversely affect the safety, well-being, or medical care of subjects or others, affects the subjects' willingness to continue their participation in the Study, alters the risk/benefit ratio of the Study, alters the conduct of the Study, or alters the non-SBU IRB's approval to continue the Study; or
- changes in non-SBU IRB Institution's accreditation status

III. Responsibilities of Stony Brook University (SBU) include:

- Ensuring PI with non-SBU IRB determinations, applicable federal and state regulations, sponsor requirements, and the terms of its OHRP-approved FWA.
- Ensuring PI compliance with applicable SBU requirements, such as HRPP training, financial disclosure/conflicts of interest, and ancillary approvals required prior to initiation of an IRB-approved protocol.
- Ensuring the PI has been trained regarding prompt reporting to the non-SBU IRB of proposed changes in a research activity, and ensuring that such changes may not be initiated without prior IRB review and approval except when necessary to eliminate apparent hazards to the subject.
- Providing all information reasonably required by the non-SBU IRB in order to conduct its reviews and facilitate non-SBU IRB access to SBU expertise when needed.
- SBU cannot approve any research study that has been disapproved by the non-SBU IRB. SBU may, however, disapprove any study approved by the non-SBU IRB. .
- Ensuring that investigators and other study personnel at the institution are qualified and have appropriate resources to conduct the research, including but not limited to education
- Ensuring an institutional process exists so complaints can be made by local study participants or others. SBU and non-SBU IRB will provide appropriate contact information in the consent process and documents. Complaints received by either party, that meet criteria as a potential unanticipated problem involving risks to subjects or other or serious or continuing noncompliance, must be promptly reported to the other party within 5 working days.
- Cooperation with non-SBU IRB investigation regarding serious or continuing noncompliance or an unanticipated problem involving risk to subjects or others related to the study at the institution. Nothing in this Agreement shall prevent either party from conducting its own investigation. However, non-SBU IRB shall have primary authority to determine whether serious or continuing noncompliance or unanticipated problems involving risks to subjects or others have occurred.
- SBU will notify the non-SBU IRB:
 - of a suspension or restriction of SBU's authorization or ability to conduct studies;
 - of any changes in institutional operating procedures or practices that might affect the non-SBU IRB's ability to review for SBU;

- of complaints from subjects enrolled in studies reviewed by the non-SBU IRB which involve potential unanticipated problems involving risks to subjects or others;
- of unanticipated problems involving injury or risks to subjects or others in a study
- of serious or continuing non-compliance in a study reviewed by the non-SBU IRB, and any steps SBU deems necessary for remediation of non-compliance;
- of suspension or termination of study approval;
- of any communication with the FDA, OHRP or funding agency relating to the institution's studies being reviewed by the non-SBU IRB;
- of changes in SBU's HRPP accreditation status.

IV. Responsibilities of SBU Investigators include:

- **Create an initial submission package in IRBNet:**
 - Include the following documents:
 - IRBNet Registration Form
 - Application for Approval to Conduct Research at Stony Brook University Hospital (if applicable)
 - Non-SBU IRB-approved Study Protocol
 - Non-SBU IRB-approved Study Consent(s)
 - Non-SBU IRB approval letter
 - The proposed draft reliance agreement to be signed by SBU
 - A statement from an applicable HRPP administrator from the Institution addressing:
 - The Institutions' accreditation status
 - The Institution's OHRP federal-wide assurance (FWA) status
 - The institution's most recent FDA Inspection result
 - Share the package with all co-investigators, and all UH entities as required.
 - Obtain e-certifications (package signatures) from Department Chair, PI, all co-investigators listed on the registration form, and all required UH entities (if applicable).
- **Ensure that these parties understand that their certification means:**
 - **For the Principal Investigator:**
 - The research activity, as approved by the non-SBU IRB, will be conducted in full compliance with federal regulations governing human subject research, as well as applicable SBU policies and procedures.
 - Prompt reporting of any revisions or amendments to the research activity for review and approval by the non-SBU IRB prior to commencement of the revised protocols, with the only exception to this policy being those situations where changes in protocol are required to eliminate apparent, immediate hazards to the subject
 - **Prompt reporting in IRBNet, and to the non-SBU IRB, of**
 - **Protocol deviations or non-compliance**

- **Addition of study team members, and**
 - **Unanticipated problems or serious adverse events affecting risk to subjects or others,**
- Full responsibility for selecting subjects in strict accordance with the inclusion/exclusion criteria outlined in the application materials,
- Ensure that only non-SBU IRB approved consent forms will be used for studies in which consent form(s) have been approved for the research activity, and
- Ensure that all personnel involved with human subjects, or human data and/or biological specimens during the course of this research activity maintain current SBU training certifications, in full accordance with SBU policy on this matter.
- Ensure that no member of the study team will be involved in any aspect of the study for which s/he has not been trained, or conduct any procedure in which s/he has not been certified/licensed.
- **For the Study Team members (i.e., all individuals listed on the registration form):**
 - Are fully cognizant of the details of the protocol, and will conduct all aspects of the study as approved by the non-SBU IRB
 - Will promptly report to the PI any unanticipated problems or serious adverse events affecting risk to subjects or others
 - Will have no involvement in any aspect of the study for which they have not been trained, or conduct any procedure in which they are not certified/licensed.
- **For the Department Chair/Departmental Review Committee:**
 - Has reviewed the application and all supporting documents pertaining to this research protocol and attests to the scientific merit of this study and the competency of the investigator(s) to conduct this project.
 - Scientific merit means:
 - The research uses procedures consistent with sound research design;
 - The research design is sound enough to reasonably expect the research to answer its proposed question;
 - The knowledge expected to result from this research is sufficiently important to justify the risk.
- **Create a continuing review package in IRBNet, at the time of the study's continuing review.**
 - When the PI submits continuing review materials to the non-SBU IRB, the following must also be submitted to SBU via IRBNet:
 - A redacted (subject name/initials/ID# blacked out) copy of the consent form of the latest subject enrolled in the study. If it is a study involving children, upload the parent permission and the minor assent forms, as applicable.
 - A redacted, completed Inclusion/Exclusion checklist for the latest subject enrolled during the prior approval period. Random audits of the I/E backup

(‘source’) documentation will be conducted by SBU to assess compliance with subject eligibility.

- A completed up-to-date registration form

Any questions concerning this reliance policy should be directed to:

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