

PRINCIPAL INVESTIGATOR EXTERNAL IRB APPLICATION REQUIREMENTS

When using an external IRB to review a research activity at Stony Brook University, the Principal Investigator must comply with the policy in the Standard Operating Procedures section 17.16

<https://research.stonybrook.edu/human-subjects-standard-operating-procedures> . The research activity must be registered with the University prior to submission to the external IRB following the procedures outlined below. Post approval requirements for investigators are also summarized below. The External IRB has the same authority as the SBU IRB and all determinations and requirements of the external IRBs are equally binding.

SBU remains responsible for the conduct of the research in which it engages. Research reviewed by external IRBs remain subject to review, approval, oversight, and monitoring by SBU (in cooperation with the reviewing IRB when appropriate) and must adhere to all applicable policies, procedures, and requirements of the University HRPP.

- **Responsibilities of the SBU Investigator When Using an External IRB**

- The SBU Investigator must be familiar with, and comply with the external IRB's policies and procedures for initial and continuing review, record keeping, prompt reporting, and any additional requirements or procedures outlined in the IRB reliance agreement or companion materials (e.g., reliance SOPs)
- Expectations of PI compliance, as detailed in the SOPs, remain in place regardless of the reviewing IRB.
- Even though the External IRB may be reviewing the study, it must not commence at SBU until all HSR training, COI disclosure, and required ancillary reviews and certifications (e.g., Chair endorsement, University Hospital sign-offs, IBC, RDRC etc.) have been satisfied

- **Institutional Registration Requirement:**

Studies that will be reviewed by external IRBs must be registered with SBU via the IRB electronic management system. The Package MUST include:

- **Copy of Reliance Agreement** – Identify if SMART IRB agreement is to be used or a separate contract – provide a copy of the agreement the external site would request SBU to sign.
- **Communication Plan:** Identify and document key communication roles for the study. Provide name, title, email address, and phone number.
 - REVIEWING IRB – Point of Contact (POC)
 - LEAD STUDY TEAM – POC
 - RELYING SITE STUDY TEAM POC
 - Describe how Stony Brook University as a relying site will receive study communication and reportable events promptly. (i.e. exchange platform, email, etc.)
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- **IRB FEE Form** if Industry Sponsored
- **Scientific Merit Review Form (PRC approval letter if Cancer Center study);** The application materials must be endorsed as scientifically meritorious by either the department chair or departmental review committee of all departments impacted by the proposed activity.
 - **Application for Approval to Conduct Research at Stony Brook University Hospital;** this form is necessary to assess impact of the proposed activity on UH patients, services and facilities.

- **The Study Protocol** with Stony Brook Specific activities highlighted
- **Inclusion/exclusion criteria checklist:** (for more than minimal risk studies) this checklist should contain required eligibility ranges where applicable, and a line to write the subject's actual value. Completed and maintained for each subject, along with all source documentation (lab values, x-ray reports, confirmation of diagnosis etc.).
- **SHARE with 'Research Pharmacy' for their endorsement** if the study involves drug/biologics where the services of the Investigational Drug Pharmacy are not used for storage, dispensing, and accounting of the agent, the following must be submitted in a cover letter for Research Pharmacy review: Where are the drugs/biologics being stored? Describe the security of the storage unit/facility. Provide full detail regarding dispensing of the drug(s), how labeled, controlled (accountability, disposition of unused drug at the conclusion of the investigation) and documented (accounting records/logs)
- **SHARE** the package with all study personnel and the department chair (or designee), but only the PI and chair e-signatures are required.
- **Registration Form for Expedited or Full CORIHS Review:** This is a short 'smart' or 'wizard' form that quickly captures critical, searchable data pertaining to your study.

Once the package is received by the IRB office, the Reliance Administrator will conduct the internal review checks to verify the following:

- ✓ Study acceptability for reliance agreement
- ✓ Training completed by all study team members.
- ✓ PI & Chair signatures in place
- ✓ QA check of project documents
- ✓ COI disclosures complete
- ✓ COEUS approved

After all internal checks are complete and the reliance contract is fully executed by both institutions, the PI will be sent an email for final certification of study compliance. Once the PI responds, the study package will be acknowledged.

Post-IRB Approval Requirements: Investigators approved through external IRB review must report local unanticipated problems, complaints, and any noncompliance to the ORC via the IRB electronic management system in addition to reporting to the external IRB. Copies of the report submitted to the external IRB are generally acceptable, but additional information may be requested on an as needed basis. Investigators must also submit copies of continuing review reports, updated protocols, updated consent forms, study closures and corresponding IRB approval or acknowledgment. Changes in PI and the addition of other research team members must be submitted to the ORC via the IRB management system prior to the new PI or research team member assuming any study responsibilities. CITI trainings, COI review, and any other applicable requirements will be verified. Notices about, and reports from, DSMB's, external monitors, auditors, or inspectors must be provided to the ORC via the IRB management system as well. In general, Investigators are reminded that all other University reporting requirements, such as to Compliance, Privacy, and Risk Management, remain applicable in addition to HRPP reporting requirements.