



Initial Submission in myResearch for Studies Relying on an External IRB

V 04.22.26

The initial submission must include the following documentation:

- **Study Information:**
 - Master Consent Templates
 - Protocol
 - Other study documents as applicable
- **Site Information:**
 - [IRB FEE FORM](#) for industry sponsored studies only. Not applicable for federally funded research.
 - [University Hospital Approval Form](#) - This form pertains to all clinical trial studies, including Cancer Center. Please complete this form in its entirety. If the question or section does not apply, please write N/A. Complete the hospital research budget section. Include the Coverage Analysis with the UH form upon submission, if applicable. If you cannot submit a Coverage Analysis, indicate this in the University Hospital Research Budget chart and the reason why one is not included.
 - [Inclusion/Exclusion criteria checklist](#) - 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 backup documentation (lab values, x-ray reports, confirmation of diagnosis etc.), this information will provide definitive proof of your study subjects' eligibility. **This form must include the protocol version and date and a signature line for investigator verification.**
 - [Scientific Merit Review Form \(non-oncology studies\)](#) - 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.
 - [PRMC Approval Letter \(oncology studies only\)](#) - This committee oversees and ensures the scientific merit, priorities and progress of all cancer clinical studies conducted at the Stony Brook Cancer Center.
 - [HIPAA Waiver of Authorization for screening and recruiting activities](#) - When using an external IRB you must apply to the IRB of record to obtain a waiver for recruitment activities. The approved waiver must be uploaded with the approval documents to myResearch IRB.
 - **[EXCEPTION:](#)** NCI-CIRB does not review HIPAA requests (see below)



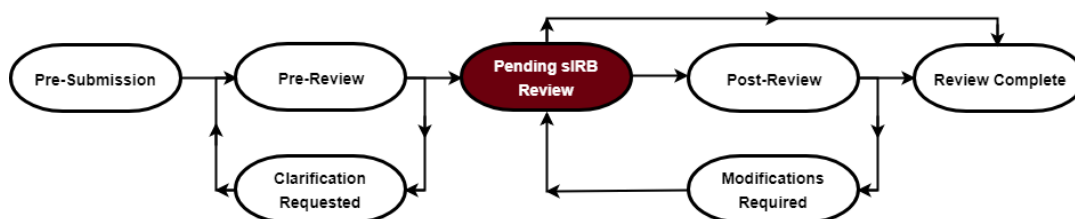
- NCI-CIRB studies ONLY:
 - HIPAA Authorization form - NCI-CIRB does not review HIPAA Authorization and HIPAA language cannot be added to the CIRB consent form. A separate authorization using the Office of Research Compliance approved template must be used.
 - HIPAA Waiver of Authorization for screening and recruitment activities - Complete the Waiver Form, you may use template language provided and must add applicable study specific information. This document must be submitted with the myResearch IRB external IRB application and will undergo review by the SBU IRB for approval.
- Request all relevant ancillary reviews (dept. chair, pharmacy, privacy, etc.).
- When the Department Chair has approved of the research activity, the PI may submit for acknowledgement. If the Department Chair is also the PI or on the study team, the Dean signature is required.

PRE-REVIEW

- Once the package is received by the Office of Research Compliance (ORC), the Reliance Administrator will conduct the internal quality review checks to verify the following:
 - ✓ Study acceptability for reliance agreement
 - ✓ Training completion by all study team members.
 - ✓ Chair approval in place
 - ✓ Other relevant ancillary reviews requested
 - ✓ QA check of project documents
 - ✓ Request review by the COI administrator
 - ✓ NCI-CIRB only – Request IRB review of the HIPAA Waiver of Authorization for screening and recruitment as applicable.



- After the local review is complete the submission will be moved to Pending sIRB review.
- The study team will receive an email confirming that the study may be submitted to the external IRB of record. This email will include any COI that was identified and notes on documents that have been pre-reviewed if applicable. The study team must include this email with the external IRB submission.



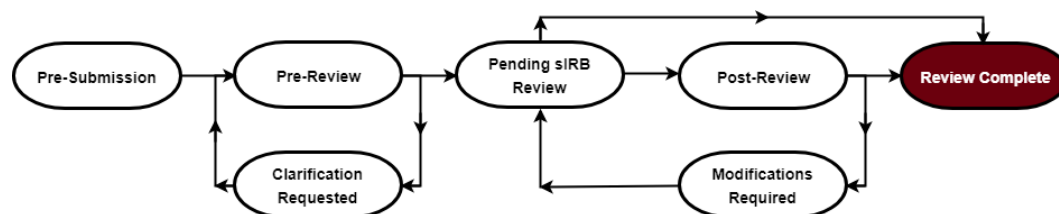
Initial Approval Granted by the External IRB

- When the External IRB has approved the project, please update the submission with the following:
 - **Study Information**
 - Update External IRB information questions 1-12 (upload approval letter in appropriate section).
 - Update other sections as applicable
 - **Site Information**
 - Attach local site approved documents (i.e. HIPAA waivers, approve site consent forms)

IMPORTANT

DO NOT ADD ANY STUDY TEAM MEMBERS WHILE SUBMISSION IS IN THE PENDING sIRB STATE.

Please send an email directly to the assigned IRB Coordinator for review once approval documents have been added. If documents are acceptable the project will be moved to the state of "Review Complete"





Please be reminded that all studies approved through an External IRB must comply with Post-IRB Approval Requirements:

- Investigators approved through external IRB review must report local unanticipated problems, complaints, and any noncompliance to the ORC 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.
 - Incidents, experiences, or outcomes during research that suggests increased risk to participants, unexpected harm, or significant non-compliance must be reported as an RNI.
 - **Batching of Events** - events that do not meet the criteria of serious, unanticipated and related may be batched, summarized and submitted at the time of continuing review.
- 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 prior to the new PI or research team member assuming any study responsibilities. CITI training, 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.
- ❖ **Note: You may not proceed with any aspect of the study until:**
 - All other applicable ancillary reviews have been completed.
 - The sponsor-RF contract is fully executed and the myResearch grants submission is approved by the Office of Sponsored Programs (OSP)
 - If industry sponsored, the consent form injury language has been approved by the OSP.
 - IRB approval is obtained and submitted through myResearch for final acknowledgement. The state will change to "Review Complete"