Human Subjects Research

Stony Brook University Informed Consent and HIPAA Authorization Policy for Studies Under NCI-CIRB Oversight.

1. Purpose

A. Policy for obtaining Informed Consent and HIPAA Authorization for Research Activities under the National Cancer Institute Central Institutional Review Board (NCI CIRB) to ensure compliance with NCI-CIRB standard operating procedures, HIPAA Privacy Rule, and applicable federal regulations.

a. Describe process for addition of local context to the NCI-CIRB approved informed consent form.
b. Describe procedures for obtaining HIPAA Authorization for research under NCI-CIRB oversight.
c. Describe request and documentation process for a HIPAA Waiver of Authorization for screening and recruitment for research activities under NCI-CIRB oversight.

2. Scope

A. This policy applies to all investigators and study personnel conducting human subjects research under NCI CIRB oversight that involves obtaining informed consent and access to Protected Health Information (PHI).

3. NCI-CIRB Policy

A. Informed Consent Form

a. The content of the CIRB approved model consent form cannot be altered, except for incorporation of CIRB approved boilerplate language.

B. HIPAA authorization language or requests for waivers of HIPAA Authorization.

a. Compliance with HIPAA regulations is considered an institutional requirement and remain the purview of the local institution. The CIRB does not permit HIPAA language to be included as boilerplate language. HIPAA requirements must be addressed by the institution in a separate document. The HIPAA documentation cannot be paginated consecutively with the NCI consent. The HIPAA header should not include details of the NCI consent or study. The HIPAA header must reflect details of the HIPAA document and not be a continuation of the NCI consent document header.
(CIRB Operations Office, 2024)

4. Stony Brook University Policy

A. Informed Consent Form

a. CIRB-approved consent forms must be modified in accordance with approved local boilerplate language.
b. No deletions may be made to the consent form.
c. Dosimetry information related to research images or research radiation may be added in the consent document by way of the Study Specific Worksheet if needed. This may not be included if the scans or radiation are all standard of care. Language must be approved through ancillary review by the Research Radiation Consultant Review.
d. Provide the model consent, a track changed version with boilerplate additions, and a clean copy of the final consent form with the myResearch IRB submission.
e. The CIRB makes the determination of assent requirements for any study enrolling children. The assent requirements are documented in the Approval Letter.

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5. HIPAA Authorization and Waivers

A. HIPAA Authorization

a. HIPAA Authorization must be obtained in compliance with the HIPAA Privacy Rule 45 CFR §164.512(i).
b. HIPAA Authorization is to be obtained on a separate Stony Brook Research HIPAA Authorization Form using the template approved by the Office of Research Compliance. Authorization language may not be added to the NCI-CIRB research consent form.

B. HIPAA Waiver of Authorization

a. HIPAA Waiver of Authorization for subject screening and recruitment activities must be requested using the HIPAA Waiver of Authorization Form.
b. HIPAA Waiver of Authorization requests must be submitted in myResearch IRB and will be reviewed by the Stony Brook University Institutional Review Board for approval.