



LOCAL CONTEXT INFORMATION

V.12.17.19

Institution: SUNY Stony Brook – AAHRPP Accredited since September 2010

Research Compliance Address:

W5530 Melville Library
Stony Brook, NY 11794-3368

FWA#: 00000125 **FWA Expiration Date:** 11/18/2021

Institutional Official:

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SUNY Stony Brook Human Subjects Research Standard Operating procedures:

<https://research.stonybrook.edu/human-subjects-standard-operating-procedures>

Institutional Review Board

State University of New York at Stony Brook IRB #3 - Stony Brook University Institutional Review Board

Chair: Dr. Harold Carlson, MD, Professor of Medicine

IRB A Registration #: 00011996

Conflict of Interest: Potential Financial COI is identified in the IRB Registration Form and the Designated Institutional Official will determine if the conflict can be managed.

Training Requirements: Training of study team members will be confirmed by Stony Brook University.

Basic Training: Each study team member must complete the University-required Basic Modules in CITI Course in the Protection of Human Research Subjects.

Additional Training: Study Coordinators on file with the Office of Clinical Trials must satisfy a one-time completion of the CITI course on Clinical Research Coordinators (CRC). NIH-funded investigators and clinical trial site staff who are responsible for the conduct, management and oversight of NIH-funded clinical trials must complete training in GCP (every three years).

Local Policy and State Law Information

Legally Authorized Representative:

NEW YORK STATE: Per the Family Health Care Decisions Act (FHCDA), a person in the highest category on the following surrogate list who is available, willing and competent to make decisions for the incapable patient, and is identified when there is no health care agent:

1. A court-appointed guardian (per NYS Mental Health Law Article 81)
2. An individual designated as a representative/agent through a health care proxy that is appropriately executed. For a health care proxy to be effective, it must have been signed at a time when the subject had decision-making capacity. The subject's wishes, if any, with regard to research as expressed in the health care proxy govern (e.g. prohibiting all research or permitting only research which may provide a direct benefit)
3. The spouse, if not legally separated from the patient, or the domestic partner
4. A son or daughter eighteen years of age or older; 5. A parent; 6. A brother or sister eighteen years of age or older
7. A close friend (meaning a person eighteen (18) years of age or older who has maintained such regular contact with the subject as to be familiar with the subject's activities, health and beliefs).

The age of majority in New York State is 18. All subjects must be re-consented when they reach the age of majority if they remain on study.

Emancipated Minors:

NYS Public Health Law, at section 2504 speaks to who may consent (to medical care in general, but NY state law does not specifically reference who may consent to participation in research) as follows:

1. (Any person) 18 or older, or is the parent of a child or is married may give effective consent for medical, dental health and hospital services for himself or herself and the consent of no other person shall be necessary.
2. Any person who has been married or who has borne a child may give effective consent for medical, dental health and hospital services for his or her child.
3. Any person who is pregnant may give effective consent for medical, dental health and hospital services related to the pregnancy.

Assent of Minors: Each protocol is unique and is reviewed by the IRB accordingly. As such, the IRB's decision regarding assent (and documentation thereof) may necessarily vary from the general parameters below.

Assent will be required for:

1. **Non-therapeutic protocols.** Assent must be documented as follows:

a) For 12-17 year olds: via a 'full' assent form (containing highly simplified 'consent' information - see section below "About Full Assent Form") that the child signs; and

b) For 7-11 year olds: a note in the subject's research record that the assent discussion has occurred and the child's agreement has been obtained.

2. Potentially therapeutic protocols (FDA-approved or investigational) where there are alternatives available outside of the research with similar risk/benefit profiles. Assent must be documented as follows:

a) For 12-17 year olds: via a 'full' assent form (containing highly simplified 'consent' information— see section below "About Full Assent Form") that the child signs; and

b) For 7-11 year olds: via a note in the subject's research record that the assent discussion has occurred and the child's agreement has been obtained.

3. Potentially therapeutic protocol involving FDA- approved drugs, devices, radiation, procedures, etc. used in an experimental way (dosages, scheduling etc). Assent must be documented as follows:

a) For 12-17 year olds: via a 'full' assent form (containing highly simplified 'consent' information— see section below "About Full Assent Form") that the child signs, or alternatively, via an assent 'short form' (see section below 'About the Short assent form'-this latter method must be specifically approved by the IRB for this category of research); and

b) For 7-11 year olds: via a note in the subject's research record that the discussion has occurred and the child's agreement has been obtained.

4. Protocols that do not fit into categories (1), (2), or (3) above, but where assent is none-the-less required by NCI CIRB (for cooperative oncology protocols), or as otherwise required by the IRB. Assent must be documented as follows:

a) For 12-17 year olds: via an assent 'short form' (see section below, 'About the Short assent form'); and

b) For 7-11 year olds: via a note in the subject's research record that the discussion has occurred and the child's agreement has been obtained.

Assent is waived for:

1. Non-therapeutic protocols where results of biological tests are required in order to determine eligibility for potentially therapeutic protocols (certain COG protocols).

2. Potentially therapeutic protocols involving an experimental drug or procedure where there are no standard alternatives available, or where the risk/benefit profile of the standard alternatives that are available are such that participation in the protocol would be important to the health or wellbeing of the children.

3. Studies where the subject population is too young, or the capability of some or all of the children is so limited, that they cannot reasonably be consulted Whether assent is required or waived, no physical or chemical means of restraint may be used on a minor subject unless specifically approved prior to use by the IRB.

Full Assent Form: This document must be an accurate and complete, but highly simplified version of the approved consent form/permission form for the study. It must be understandable to a twelve (12) year old (approximately 7th grade). Investigators should try to draft a form that is age appropriate and study specific, taking into account the typical child's experience and level of understanding, and composing a document that treats the child respectfully and conveys the essential information about the study. The assent form should:

1. Tell why the research is being conducted;
2. Describe what will happen and for how long or how often;
3. Say it's up to the child to participate and that it's okay to say no;
4. Explain if it will hurt and if so for how long and how often;
5. Say what the child's other choices are;
6. Describe any good things that might happen;
7. Say whether there is any compensation for participating; and
8. Ask for questions.

Consent for Cognitively or Decisionally Impaired Adults: : If the reviewing IRB determines that adults who lack capacity to provide consent for themselves are eligible to participate in a particular study, the investigator will obtain consent/permission from the subjects legally authorized representative (as described above).

Non-English Speakers: For subjects whose native language is not English, informed consent must be obtained in a language that is understandable to the subject (or to the subject's legally authorized representative). In accordance with this policy, the IRB requires that informed consent conferences include a reliable translator when the prospective subject does not understand the language of the person who is obtaining consent.

Informed consent on Non-English speaker should be documented by the use of either:

A translated version of the IRB approved 'full' English consent form that embodies the basic and required additional elements of informed consent. An affidavit of accurate translation from the IRB approved English version must be provided from a qualified translator who is unaffiliated with the study.

OR

A "short form" written consent document which states that the elements of informed consent have been presented orally to the subject or the subject's legally authorized representative. Both the short form and the oral presentation must be presented in the language of the subject. The IRB must receive and approve all foreign language versions of the short form document (along with translator affidavit) prior to use.

GENETIC TESTING:

State Law: Genetic Test results may not be provided to research subjects who are New York State residents if the genetic test is not FDA approved and/or New York State validated, and is not being performed in a New York State (NYS) approved laboratory (unless an exemption is obtained, for each subject, from the NYS DOH). The study doctor may refer the research subject to a geneticist or recommend that the test be repeated for non-study purposes in a NYS approved clinical laboratory.

Institutional Policy: If there are hereditary implications, genetic counseling by a genetic counselor or other qualified health care provider is required *prior* to participation in the study. Consent should indicate who will cover the cost of the counseling. • There is an obligation to inform the subject of the test results in a timely manner after they are known. However, the subject should be offered an opt-out option (to not be told). • Consent document must indicate that the results of the research testing must not be used as the basis for clinical decision making, and the subject should seek confirmation of research test results in a certified clinical laboratory.

Ancillary Reviews (As Applicable):

Chair Endorsement
Research Pharmacy
Bio-Safety
Radiation Safety
University Hospital Administration
Privacy Officer
COI Disclosure
Human Subjects Training
Other (as needed)

Indemnification:

Can be left blank

OR

Subject to the availability of lawful appropriations and consistent with Section 8 of the New York State Court of Claims Act, SBU shall hold harmless and indemnify Company for any final judgment against Company of a court of competent jurisdiction arising out of this Agreement to the extent attributable to the negligence of SBU or of its officers or employees when acting within the course and scope of their employment.

STATE LAW:

<https://www.health.ny.gov/professionals/diseases/reporting/communicable/>

Communicable Disease Reporting

Reporting of suspected or confirmed communicable diseases is mandated under the New York State Sanitary Code (*10NYCRR 2.10*). Although physicians have primary responsibility for reporting, school nurses, laboratory directors, infection control practitioners, daycare center directors, health care facilities, state institutions and any other individuals/locations providing health care services are also required to report communicable diseases.

Reports should be made to the local health department in the county in which the patient resides and need to be submitted within 24 hours of diagnosis. However, some diseases warrant prompt action and should be reported immediately to local health departments by phone. A list of diseases and information on properly reporting them can be found under [Communicable Disease Reporting Requirements](#).

SUNY Stony Brook Informed Consent Requirements & Language

Site Specific Logo for Consent Forms and recruitment materials:



Black Text= Instructions for Investigator

Green text = required template language

Blue Text= study-dependent language

In Case of Injury:

IN CASE OF INJURY (applicable if the study involves the potential for injury to subject {psychological, physical, etc., including blood drawing protocols}).

- Standard text:

'If you are injured as a result of being in this study, please contact [Dr. P. Investigator] at telephone # [XXX-XXXX]. The services of Stony Brook University Hospital will be open to you in case of such injury.

Then, if the study is not externally funded, or is investigator-initiated, add this line:

However, you and/or your insurance company will be responsible for payment of any resulting treatment and/or hospital stay'.

Or, if the study is industry funded (e.g., pharmaceutical company):

The sponsor will pay for medical expenses for the hospitalization and/or treatment of a physical injury. The following conditions must be met for this to occur:

- The injury must be reasonably-related to the experimental drug, device or procedure
- The study doctor and staff must have met the conditions of the study

HIPAA/PRIVACY Language:

CONFIDENTIALITY

If you are only obtaining completely anonymous data (no identifiers or codes at all) from your subjects, use this as your first and only paragraph:

All the information we get about you will not be linked to you at all. We will do this by not writing down your name or anything else that could link you in any way to the answers you give us for our study. All the study data that we get from you will be kept locked up. If any papers and talks are given about this research, your name will not be used.

If your research is subject to NIH's Genomic Data Sharing Policy, use this as a first paragraph:

As explained above we are required to send information we obtain about your health and your genes to one of the federal National Institutes of health databases or repositories so it can be used in future research along with similar information from other research participants. Preserving the confidentiality of your information is very important to us, and we will do so by removing any information that can identify you (like your name), and instead, assign a code to your medical information and the information we obtain from your tissue samples before we send that information to one of the National Institutes of health databases or repositories. Stony Brook will keep the master list that links your code number to your identifying information and only certain Stony Brook research staff members will ever have access to this master list.

For all other studies, use this as a first paragraph:

We will take steps to help make sure that all the information we get about you is kept confidential. Your name will not be used wherever possible. We will use a code instead. All the study data that we get from you will be kept locked up. The code will be locked up too. If any papers and talks are given about this research, your name will not be used. If your study involves videotaping or audiotaping subjects, add a statement regarding the disposition of the tapes (deleted after transcription? Stored indefinitely post-transcription? Where?)

Then:

We want to make sure that this study is being done correctly and that your rights and welfare are being protected. For this reason, we will (add the word 'also' for studies subject to NIH Genomic Data Sharing policy) share the data we get from you in this study with the study team, the sponsor of the study (and those who work for them), Stony Brook University's Committee on Research Involving Human Subjects, applicable Institutional officials, and certain federal offices, including the Office for Human Research Protections (OHRP), and, where applicable, the Food and Drug Administration (FDA). However, if you tell us you are going to hurt yourself, hurt someone else, or if we believe the safety of a child is at risk, we will have to report this.

In a lawsuit, a judge can make us give him the information we collected about you.

*****Special 'lawsuit/judge' exception: - If you or the sponsor has obtained a **Certificate of Confidentiality from the NIH**, delete the sentence above that starts 'In a lawsuit...', and add this next section in blue:**

This study requires that we collect very personal information about you. Therefore, we had the National Institutes of Health give us a Certificate of Confidentiality (COC). This piece of paper says that nobody can force the researchers to give out your information, even if a court of law asks for it. This will give you more protection. The only time information about you can be given out is:

- If you are going to hurt yourself,
- If you are going to hurt someone else
- If we believe the safety of a child is at risk.
- (if applicable) If the Department of Health and Human Services, who pays for this study, wants to look over the study.
- (if applicable) If data about the study drug/device needs to be reported to the Food and Drug Administration.

This Certificate doesn't mean you can't talk about this study. If you give written permission, your insurance company, your boss, or your medical doctor can be given the research information too.

For all studies, if you are obtaining or generating data regarding your subjects' mental or physical health, add:

While you are in this study we will get data about your health from your medical record. We will also get health data from the results of the tests you will have done in this study. You have a right to privacy but the data we get about your health in this study can be shared with the people referenced above (the study team, the sponsor of this study, those who work for the sponsor, Stony Brook University's Committee on Research Involving Human Subjects, applicable institutional officials, and federal offices such as OHRP, FDA) as well as (as applicable):

- your insurance company
- your medical doctor
- A board that reviews the safety of the study on an on-going basis.

Your health data are shared to make sure the study is being done correctly, costs are charged correctly, and to make sure your rights and safety are protected. Not all of these people are required by law to protect your health data. They might share it with others without your permission. For example, the sponsor of this study does not have to make the same promise under the law to protect your health data, however, (Add detail here concerning how the sponsor will protect health data; see contract language)

Some of the health information we get from you in this study cannot be shared with you until the end of the study.

You have the right to stop allowing us to use or give out your health data. You can do this at any time by writing to (name of Principal Investigator). If you do this, we will stop collecting any new health data from you, except if we need to keep an eye on a bad side effect you were having in the study. We will use any data we collected before you wrote your letter. When you sign the consent form at the end, it means:

- That you have read this section.
- That you will allow the use and reporting of your health data as described above.
- (If the subject is a patient at UH) You have received a form from the University Hospital. It is called the Notice of Privacy Practices form.

If you are paying your subjects for their participation, add the below statement and assure the appropriate box is checked:

☐ I am a U.S. Citizen or Resident Alien. If paid \$600 or more a year as a research subject, your social security number and amount paid will be reported to those in charge of taxes (IRS) by the Research Foundation and you may have to pay taxes on this money.

☐ I am a Nonresident Alien. For tax purposes, all payments made to you must be done through the Research Foundation and are subject to a 30% tax withholding. All withholdings and payments will be reported to those in charge of taxes (IRS) by the Research Foundation.

The Genetic Information Nondiscrimination Act (GINA) (if this study involves obtaining genetic information, including studies subject to the NIH Genomic Data Sharing Policy, add this section)

You should know that a federal law called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law will generally protect you in the following ways:

§ Health insurance companies and group health plans may not request your genetic information from this research.

§ If health insurance companies and group health plans do somehow receive your genetic information from this research, they may not use it to make decisions about your eligibility or premiums.

§ Employers with 15 or more employees may not use your genetic information from this research when making a decision to hire, promote, or fire you when setting the terms of your employment.

Be aware that this new law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

OTHER Consent Language Required by Institutional Policy:

QUESTIONS ABOUT THE STUDY OR YOUR RIGHTS AS A RESEARCH SUBJECT

- If you have any questions, concerns, or complaints about the study, you may contact [Dr. P. Investigator], at telephone # (631-XXX-XXXX).
- If you have any questions about your rights as a research subject or if you would like to obtain information or offer input, you may contact the Stony Brook University Research Subject Advocate, Ms. Lu-Ann Kozlowski, BSN, RN, (631) 632-9036, OR by e-mail, lu-ann.kozlowski@stonybrook.edu

OTHER Consent Language Required by Law: N/A