Reliance Agreement
for Institutions Utilizing
Stony Brook University's Institutional Review Board(s)

v.9.15.16

Name of Organization Providing IRB Review: Stony Brook University ("**SBU IRB**")

Name of Institution Relying on the SBU IRB ("Institution"):

Latest AAHRPP Accreditation Date (if applicable)	
OHRP Federal Wide Assurance (FWA) #	
Name of Institutional Official	
Street Address	
City	
State (if US)	
Zip/Postal Code	
Country	

Name of Individual Responsible for Administration of this Agreement	
Title of Individual	
Phone Number	
Email address	

1. ***Scope of the Agreement**:*

1.1 The Officials signing below agree that Institution will rely on SBU IRB for review and continuing oversight of human subject research covered by the Institution's FWA, if applicable.

OR

The Officials signing below agree that Institution will rely on SBU IRB for review and continuing oversight of the following human subject research covered by the Institution's FWA:

Title of Research Project	
Name of Principal Investigator	
Name of Sponsor	
Name of Funding Agency	
Award Number, if any	

1.2 This document must be kept on file by all parties and provided to FDA, OHRP, and/or other applicable regulatory agencies upon request. This Agreement may be executed in any number of counterparts, either in original, emailed or faxed form.

1.3 The SBU IRB will follow SBU IRB's policies and procedures pertaining to documentation and review. For the purposes of conducting the IRB review, Institution will identify and provide interpretation to the SBU IRB of local policies and procedures, and requirements of applicable state or local laws, and regulations. Institution and SBU IRB will have the ability to discuss these interpretations to ensure agreement of these requirements.

2. *Responsibilities of the SBU IRB*

2.1 The review performed by SBU IRB will meet the human subject protection requirements of the Common Rule (e.g., 45 CFR 46) and applicable FDA regulations (e.g., 21 CFR Parts 50, 56, 312, 812). SBU IRB will follow written procedures for reporting its findings and actions to the PI, Sponsor, and appropriate officials at the Institution and federal agencies as appropriate. Relevant minutes of IRB meetings may be made available to the Institution by SBU IRB upon request.

2.2 SBU IRB services for the study/studies referenced in Section 1.1. above will include:

- Review and approval, disapproval or modification of the study
- Review and approval, disapproval or modification of consent documents or waivers of informed consent;
- Review and approval, disapproval or modifications to amendments of approved protocols;
- 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 pursuant to applicable federal regulations
- Continuing review of certain new research studies appropriate to the degree of risk in such studies, at least annually.

2.3 SBU IRB will promptly notify the Principal Investigator (PI) of the study as designated on the IRB protocol submission of all IRB decisions and will make available to the PI all applicable study related documents including but not limited to approved protocols, consent forms, surveys, and decision letters.

2.4 SBU IRB will notify the institution within 5 working days:

- if there is ever a suspension or restriction of the IRB's authorization to review studies;
- of any changes in SBU IRB operating procedures or practices that might affect the institution's reliance on SBU IRB reviews;
- of complaints from human subjects enrolled in studies at the institution;
- of unanticipated problems involving injury or risks to subjects or others in the study;

- if the SBU IRB determines that serious or continuing non-compliance has occurred, and any steps the 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 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 SBU IRB's approval to continue the Study; or
- changes in SBU's accreditation status.

3. Responsibilities of the Institution

3.1 The Institution will be proactive in ensuring investigator compliance with IRB determinations, applicable federal and state regulations, sponsor requirements, and if applicable with the terms of its OHRP-approved FWA.

3.2 The Institution will ensure investigator compliance with applicable institutional requirements, such as HRPP training, financial disclosure/conflicts of interest, and ancillary approvals required prior to initiation of an IRB-approved protocol.

3.3 The Institution will ensure that the Principal Investigator has been trained regarding prompt reporting to the SBU IRB of proposed changes in a research activity, and ensuring that such changes in approved research may not be initiated without prior IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

3.4 Institution will provide all information reasonably required by SBU IRB in order to conduct its reviews and will facilitate SBU IRB access to Institution expertise when needed. Institution cannot approve any research study that has been disapproved by the SBU IRB. Institution may, however, disapprove any study approved by the SBU IRB. Institution agrees to abide by the decisions of the SBU IRB and will use its best efforts to ensure that the human subject research performed by Institution will be conducted in accordance with those decisions.

3.5 Institution will ensure 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 and

training in human research protection regulations. The institution will provide documentation of training and education, as requested by the SBU IRB.

3.6 Institution will ensure an institutional process exists by which complaints about the study can be made by local study participants or others. Institution and SBU IRB will address provision for 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 others or serious or continuing noncompliance must be promptly reported to the other party, preferably within 5 working days.

3.7 Institution will cooperate with any 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 will prevent either party from conducting its own investigation. However, SBU IRB will have primary authority to determine whether serious or continuing noncompliance or unanticipated problems involving risks to subjects or others have occurred.

3.8 Institution will notify the SBU IRB within 5 working days:

- if there is ever a suspension or restriction of the Institution's authorization or ability to conduct studies;
- of any changes in institutional operating procedures or practices that might affect the SBU IRB's ability to review for the institution;
- of complaints from human subjects enrolled in studies reviewed by the 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 reviewed by the SBU IRB;
- if the Institution believes that serious or continuing non-compliance has occurred in a study reviewed by the SBU IRB, and any steps the Institution deems necessary for remediation of non-compliance;
- of suspension or termination of Institutional approval;
- of any communication with the FDA, OHRP or funding agency relating to the institution's studies being reviewed by the SBU IRB;
- changes in accreditation status, if applicable.

3.9 ***Federally Funded Studies:*** Institution will maintain a current, approved Federalwide Assurance (FWA) with OHRP for the duration of this Agreement. The Institution will notify the SBU IRB promptly in writing if its FWA is suspended or expires for any reason.

4. Joint Responsibilities

4.1 **Confidentiality** Each party is authorized to exchange information pursuant to this Agreement and agrees to treat such information as confidential (Confidential Information). No Party will disclose Confidential Information received pursuant to this Agreement to any individual or entity other than another Party without prior written approval of all Parties. Notwithstanding the foregoing, nothing in this Agreement will be construed to restrict a Party from disclosing Confidential Information as required by law, subpoena, court order, or other governmental order or request. Institution will cause Principal Investigator and all other research personnel to comply with the terms and conditions of this section in the same manner as such terms and conditions apply to Institution. This section will survive the termination of this Agreement.

4.2 **Protected Health Information (if applicable to the study in question):** The parties will hold in confidence the identity of the participants in any Studies and will comply with applicable laws regarding confidentiality of individually-identifiable subject information and the requirements of any authorization executed by subjects for a given study. Each party will comply with all applicable laws and regulations, including, but not limited to, HIPAA, relating to the use and disclosure and privacy and security of individually identifiable health information of human subjects ("**Subject Health Information**"). Each party will use and disclose Subject Health Information only as authorized by the subject or legally-authorized representative pursuant to subjects' written authorization and informed consent forms. Each party will notify the other party orally and in writing within twenty-four (24) hours of its discovery of any Subject Health Information in its possession, which is improperly used or disclosed in violation of HIPAA or the applicable subject authorization, and serious or continuing noncompliance. The parties will cooperate with each other in taking such steps as are deemed appropriate, to enjoin misuse, regain possession of the data, and otherwise protect each parties' rights and subjects' privacy. It is expressly understood that, by providing review services as described herein, SBU IRB will not be regarded as a "Business Associate" of Institution

4.3 **Record Keeping** SBU IRB and Institution agree to maintain records in compliance with all applicable federal, state, and local regulations regarding record retention and agree to make to records available when and as required by law.

4.4 **Federal Regulatory Agency Review** SBU IRB and Institution agree to notify the other party when a federal regulatory agency has or will conduct an audit or review of a study applicable to this authorization agreement and will notify each party of the outcome of the review.

4.5 **Inspection** SBU IRB or its authorized representatives will be permitted upon request to: (1) examine and inspect Institution's facilities used for the performance of its research, including storage and use

of any investigational products; (2) observe the conduct of the research performed at the Institution, including witnessing of consent processes; (3) inspect and copy all documents relating to its studies, including study records and informed consent documents, investigational product logs, required licenses, certificates and accreditations; and (4) interview all necessary personnel involved in the research conduct of its studies.

Likewise the Institution will be permitted upon request to (1) obtain copies of all applicable IRB correspondence pertaining to activities hereunder; (2) review SBU IRB's policies, procedures, roster and other information pertinent to board functions; and (3) inspect and copy all documents relating to its studies, including but not limited to protocols and informed consent documents, investigational drug brochures, reports, unanticipated problems, reports of noncompliance, required licenses, certificates and accreditations.

4.6 **Reporting to Sponsor, Federal Agencies, or other oversight entities** If the SBU IRB or Institution determines that it must report the findings of an investigation to sponsor, OHRP, the FDA and/or other oversight entities, it will notify the other party in advance. The party making the report will share the report with the other party before it is sent to the sponsor/oversight authority, and will copy the other parties' institutional official(s) and designees. Nothing in this Agreement will be construed to prevent prompt reporting, or an Institution or SBU IRB from making its own report to OHRP, the FDA, in accordance with its written procedures, or from taking additional remediation steps.

4.7 **Conflict of Interest Review** The Institution will perform its own investigator conflict of interest analysis under its relevant policies. Any applicable conflict of interest and associated management plan will be communicated to the SBU IRB. The SBU IRB will apply its standard policies regarding confidentiality of review of information and disclosures submitted to it regarding potential investigator conflicts of interest. SBU IRB will implement investigator and institutional conflict of interest management plans to the extent that they involve human subject protection considerations, such as mandated language in informed consent forms once this information is communicated to the SBU IRB. If the SBU IRB determines the management plan is not acceptable, the SBU IRB will promptly inform the institution's responsible individual.

4.8 **Clinical Trial Agreements and Compensation for Research Related Injury (when applicable):** Institution will ensure that the Clinical Trial Agreement (CTA) and the proposed consent form do not conflict with each other with regard to provisions regarding the availability of compensation for research-related injury regarding the compensation for injury clause. In the event of a conflict between the CTA and the consent form, Institution will notify SBU IRB to withhold approval until the conflict between the two documents is resolved, with revision to the consent form as required.

5. General Terms and Conditions

5.1 ***Term and Termination***[1] The term of this Agreement will commence upon execution of this Agreement by both parties, and will continue until this date: or until such time as either party gives 60 days written notice of termination, whichever comes first. Notwithstanding the foregoing, in the event that either party is in default in the performance of any of its obligations under this Agreement, and the default has not been remedied within days after the date of notice in writing of such default, the party not in default may terminate this Agreement immediately by written notice.

Notwithstanding the immediately preceding paragraph, the parties specifically recognize that 45 CFR 46.109(e) and 21 CFR § 56.109(f) requires that, "An IRB will conduct continuing review of research . . . not less than once per year, and will have authority to observe or have a third party observe the consent process and the research." Therefore, termination of this Agreement will not affect the SBU IRB's obligations of continuing review for studies approved hereunder or Institution's payment responsibilities until such studies are appropriately transferred to a new IRB.

5.2 ***Assignment:*** This Agreement may not be assigned or transferred by either party without the prior written consent of the other party.

5.3 ***Notices:*** All notices relating to this Agreement will be delivered personally, by facsimile, by e-mail, by registered or certified first class mail, or by overnight courier service to the contact addresses set forth below. Notice will be effective upon receipt if personally delivered, delivered by e-mail or delivered by facsimile; upon the third business day following the date of mailing by registered or certified first class mail; or on the first business day following the date of delivery to the overnight courier. All notices hereunder will be directed as follows

If to Institution: [include information here]

If to SBU IRB:

- Judy Matuk, M.S.
  Assistant VP for Research Compliance
  Office of Research Compliance
  Stony Brook University
  Stony Brook, NY 11764-3368
  PH: (631) 632-9036
  FX: (631)-632-9839
  Judy.matuk@stonybrook.edu

5.4 ***Amendment/Modification*** this Agreement will not be subject to any change or modification unless such modification is signed by both parties and specifically states that it is an amendment to this Agreement.

5.5 ***Governing Law*** This agreement is governed under the laws of the State of New York.

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Each party accepts the terms contained within this reliance agreement as evidenced by signatures below.

[Institution]	[SBU IRB]
(Signature of Institutional Official)	(Signature of Institutional Official)
Name:	Name:
Title:	Title:
Date:	Date: