**PROTOCOL TEMPLATE FOR INVESTIGATOR-INITIATED STUDIES**

**INSTRUCTIONS:**

* Sections will expand to fit your responses.
* Keep an electronic copy to modify when making changes either as directed by the IRB, or for amendments/modifications.
* Mark sections “NA” if they are not applicable to your research.
* Please use lay language, avoid professional jargon and define all abbreviations when they first appear.

**PROTOCOL TITLE:**

Response:

**PROTOCOL VERSION/AMENDMENT # AND DATE**

Response:

**PRINCIPAL INVESTIGATOR:**

Response:

**1.0** **Objectives**

1.1 Describe the purpose, specific aims, or objectives of this research. Specifically, explain why it is important to do the study.

Response:

**2.0 Background**

2.1 Provide the scientific or scholarly background, rationale, and significance of the research based on the existing literature and how it will contribute/fill in gaps to existing knowledge.

Response:

2.2 Include complete citations or references:

Response:

**3.0 Study Design**

3.1 Describe and explain the study design (e.g., case-control, cross-sectional, ethnographic, experimental, interventional, longitudinal, and observational). Indicate if there is randomization, blinding, control group, etc. If randomizing, explain how this will be achieved.

Response:

3.2 Include the number of subjects and the power analysis. If applicable, indicate your screen failure rate, i.e., how many subjects you expect to screen to reach your target sample.

Response:

3.3 Indicate the duration of the subject participation including long-term follow-up.

Response:

3.4 Indicate whether you are specifically recruiting or targeting any of the following special populations in your study using the checkboxes below.

Response:

Minors (under 18 years old)

Adults unable to consent

Pregnant women

Prisoners

3.5 Indicate if you will include minorities (American Indians, Alaskan Native, Asian, Native Hawaiian, Pacific Islander, Black [not of Hispanic origin] and Hispanic) as Federal mandates require that you include minorities unless you can justify their exclusion.

Response:

Yes

No, Justify:

3.6 Indicate whether you will include non-English speaking individuals in your study. Provide justification if you will specifically exclude non-English speaking individuals. Review <https://www.stonybrook.edu/research-compliance/Human-Subjects/sops> for the SBU policy on inclusion of non-English speakers (section 17.8). Following approval of the English version, you must submit the translated version of the materials with the attestation of the translation.

Response:

3.7 Describe the data analysis plan, including any statistical procedures.

NOTE: If we are a lead site for a multi-site study include the total number of subjects that will be enrolled or records that will be reviewed across all sites. This section applies to both quantitative and qualitative analysis.

Response:

**4.0 Inclusion and Exclusion Criteria**

NOTE: If your study is more than minimal risk, you must also upload (in the myResearch IRB smartform) a copy of your inclusion/exclusion checklist to be completed at time of enrollment of each subject.

4.1 Describe, in bullet points, the criteria that define who will be included in this study.

Response:

4.2 Describe, in bullet points, the criteria that define who will be excluded from this study.

Response:

4.3 Describe how individuals will be screened for eligibility. Upload all relevant screening documents with your submission (screening protocol, script, questionnaire). Identify who will certify that subjects meet eligibility requirements. (Upload these documents in the myResearch IRB smartform.)

Response:

**5.0 Vulnerable Populations**

5.1 For research that specifically recruits/targets minors (under 18 years), review, complete and upload Supplemental Form F: Minors.

Confirmed

N/A: This research does not involve persons who have not attained the legal age for consent to treatments or procedures (“children”).

5.2 For research that specifically recruits/targets adults who cannot consent for themselves, you will be asked additional information in Section 25 (“Informed Consent”).

Confirmed

N/A: This research does not involve this population.

5.3 For research that specifically recruits/targets pregnant women, review, complete and upload Supplemental Form A: Pregnant Women, Fetuses, Non-Viable Neonates, or Neonates of Uncertain Viability.

Confirmed

N/A: This research does not involve pregnant women.

5.4 For research that specifically recruits/targets neonates of uncertain viability or non-viable neonates, review, complete and upload Supplemental Form A: Pregnant Women, Fetuses, Non-Viable Neonates, or Neonates of Uncertain Viability.

Confirmed

N/A: This research does not involve non-viable neonates or neonates of uncertain viability.

5.5 For research that specifically recruits/targets prisoners, review, complete and upload Supplemental Form B: Prisoners.

Confirmed

N/A: This research does not involve prisoners.

5.6 Consider if other specifically targeted populations such as students, employees of a specific firm, or educationally or economically disadvantaged persons are vulnerable. Provide information regarding their safeguards and protections, including safeguards to eliminate coercion or undue influence.

Safeguards include:

N/A: This research does not involve these populations.

**6.0 Recruitment Methods**

N/A: This is a records review only, and subjects will not be recruited.

NOTE: If you select this option, please make sure that all record review procedures and inclusion/exclusion screening are adequately described in other sections, including date range for records that will be reviewed.

6.1 Describe source of subjects: When, where, and how potential subjects will be recruited. In order to approach patients in the clinic/hospital setting you must have a treatment relationship with these individuals.

NOTE: Recruitment refers to how you are identifying potential participants and introducing them to the study.

Response:

6.2 Describe how you will protect the privacy of prospective subjects during the recruitment process.

NOTE: Examples of appropriate responses may include: “participant only meets with a study coordinator in a private office setting where no one can overhear”, “the participant is reminded that they are free to refuse to answer any questions that they do not feel comfortable answering.”

Response:

**7.0 Research Procedures**

7.1 Provide a detailed description of all research procedures or activities being performed on the research subjects. **This should serve as a blueprint for your study and include enough detail so that another investigator could pick up your protocol and replicate the research.** For studies that have multiple or complex visits or procedures, consider the addition of a schedule of events table in in your response. Be sure to include:

* Procedures being performed to monitor subjects for safety or to minimize risks.
* All drugs and devices used in the research and the purpose of their use, and their regulatory status

Response:

7.2 Describe what data, including long-term follow-up data, will be collected.

NOTE: For studies with multiple data collection points or long-term follow up, consider the addition of a schedule or table in your response.

Response:

7.3 List any instruments or measurement tools used to collect data (e.g., surveys, scripts, questionnaires, interview guides, validated instruments, data collection forms). Upload these materials in the myResearch IRB smartform.

Response:

7.4 Describe any source records that will be used to collect data about subjects (e.g., school records, electronic medical records) and include the date range for records that will be accessed.

Response:

7.5 Indicate whether or not the results for individual subjects, such as results of investigational diagnostic tests, genetic tests, or incidental findings will be shared with subjects or others (e.g., the subject’s primary care physician) and if so, describe how these will be shared.

Response:

**8.0 Research Setting**

8.1 Describe all facilities/sites/locations where you will be screening and conducting research procedures.

Example: “A classroom setting in the Department of Psychology equipped with a computer with relevant survey administration software,” “The angiogram suite at Stony Brook University Hospital, a fully accredited tertiary care institution within New York State with badge access,” etc.

Response:

8.2 For research procedures being conducted internationally), Supplemental Form C must be completed and uploaded.

Response:

N/A: This study is not conducted outside of SBU or its affiliates.

8.3 For research procedures conducted externally to Stony Brook University (e.g. other institutions, schools, other states), attach applicable approval letter(s) in the myResearch IRB smartform.

Response:

**9.0 Resources and Qualifications**

9.1 The Principal Investigator (PI) must confirm, in consultation with Chair and Dean as applicable, that adequate resources are present to conduct and complete the study compliantly and safely. Specifically:

NO YES The proposed subject population(s) are available in sufficient numbers to meet the study requirements.

NO YES Sufficient funds are available to conduct and complete the study compliantly and safely.

NO YES The PI and study team have sufficient time to conduct and complete the study compliantly and safely.

NO YES The PI has determined that the named study team is qualified to conduct the research compliantly and to monitor the safety and welfare of the enrolled research subjects effectively.

NO YES The PI ensures that the study team is fully aware of his/her involvement in this study and the details of the study protocol.

NO YES The PI ensures that the study teams will only be involved in research procedures for which they have been trained, and are currently certified and/or licensed, if required.

NO YES The PI ensures that all study team members are updated on the progress of the research and the regulatory requirements (including enrolled subjects, unanticipated problems, etc.).

Response:

**10.0 Other Approvals**

10.1 List approvals that will be obtained prior to commencing the research (e.g., University Hospital sign-offs per the UH Application, Cancer Center Scientific review, external site, funding agency, laboratory, Radiation Safety, IBC, SCRO, IACUC, RDRC).

Response:

N/A: This study does not require any other approvals.

**11.0 Provisions to Protect the Privacy Interests of Subjects**

11.1 Describe how you will protect subjects’ privacy interests during the course of this research.

NOTE: Privacy refers to an individual’s desire/right to control access to or to place limits on whom they interact with or whom they provide personal information. Privacy applies to the person. Examples of appropriate responses include: “participant only meets with a study coordinator in a private office setting where no one can overhear”, or “the participant is reminded that they are free to refuse to answer any questions that they do not feel comfortable answering.”

Response:

**12.0 Confidentiality**

**A. Confidentiality/Security of Study Data**

Describe the local procedures for maintenance of security and confidentiality of study data and any records that will be reviewed for data collection.

NOTE: Confidentiality refers to how data collected about individuals for the research will be protected by the researcher from release. Confidentiality applies to the data.

12.1 Where and how will all data and records be stored? Include information about: locked cabinet/locked office, authorization of access, certificates of confidentiality, and separation of identifiers and data, as applicable. Include physical (e.g., paper) and electronic files (e.g., storage of data in REDCap) password protection, encryption.

Response:

12.2 Who will have access to the data?

Response:

12.3 How will the data be transported/transmitted (if applicable)?

Response:

**B. Confidentiality of Study Specimens**

Describe the local procedures for maintenance of confidentiality of study specimens.

N/A: No specimens will be collected or analyzed in this research.

12.4 Where and how will all specimens be stored? Include information about: locked freezers, locked laboratory, authorization of access, and labeling of specimens, as applicable.

Response:

12.5 How long will the specimens be stored for future/unspecified research (including genetic research)?

Response:

12.6 Who is responsible for receipt or transmission of the specimens (if applicable)? If you are transporting specimens to another location not affiliated with Stony Brook University, you must have a Material Transfer Agreement.

Response:

12.7 Banking Data or Specimens for Future Unspecified Use

N/A: This study is not storing data or specimens for research outside the scope of the present protocol. This section does not apply.

NOTE: If you are proposing to bank specimens for future use, you may be subject to licensure requirements under the NYS Department of Health and must be covered under the SBU license. See SOPs section 17.2 at <https://www.stonybrook.edu/research-compliance/Human-Subjects/sops>.

12.8 If data will be banked for research outside of the scope of the present protocol, describe where the data will be stored, how long they will be stored, and who will have access to the data

NOTE: Your response here must be consistent with the information provided to subjects in your Consent Documents

Response:

**13.0 Withdrawal of Subjects**

N/A: This study is not enrolling subjects. This section does not apply.

13.1 Describe anticipated circumstances under which subjects may be withdrawn from the research without their consent.

Response:

13.2 Describe any procedures for orderly termination.

NOTE: Examples may include return of study drug, exit interview with clinician. Include whether additional follow up is recommended for safety reasons for physical or emotional health.

Response:

13.3 Describe procedures that will be followed when subjects withdraw from the research, including retention of already collected data, and partial withdrawal from procedures with continued data collection, as applicable.

Response:

13.4 Describe what will happen to data already collected.

Response:

**14.0 Risks to Subjects**

14.1 Describe if any subjects will be withdrawn from therapeutic procedures or drugs (e.g., washout periods) prior to, or during, their participation in the study.

Response:

14.2 List the reasonably foreseeable risks, discomforts, to the subjects related to their participation in the research. Consider physical, psychological, social, legal, and economic risks.

NOTE: Breach of confidentiality is always a risk for identifiable subject data.

Response:

14.3 Describe the probability, magnitude, duration, and reversibility of the risks and the procedures to minimize these risks.

Response:

14.4 Describe procedures being performed to monitor subjects for safety.

Response:

14.5 If the study poses risks to an embryo or fetus should the subject be or become pregnant, how will you minimize the risk of a pregnancy occurring during the course of the study? (Select all that apply.)

Counseling on birth control and /or abstinence

Pregnancy test during the study

Pregnancy test prior to initiation of the study

Other \_\_\_\_\_

14.6 If applicable, describe possible risks to others who are not subjects (e.g., partner of a subject who is administered a study drug).

Response:

14.7 Provisions to Monitor the Data to Ensure the Safety of Subjects

N/A: This study is not enrolling subjects OR is limited to records review procedures only OR is a minimal risk study. See SBU SOPs section 3.6 for a list of the procedures that are generally considered to be minimal risk: <https://www.stonybrook.edu/research-compliance/Human-Subjects/sops>).

Response:

14.8 Provide information about the Data and Safety Monitoring Plan.

Response:

14.9 Provide information if a medical monitor will be used to monitor the safety of the study.

Response:

14.10 Provide information if a Data and Safety Monitoring Committee/Board will be used to monitor the safety of a study that is greater than minimal risk. Provide justification if a Data and Safety Monitoring Committee/Board will not be used.

N/A:

Response:

14.11 Describe what data are reviewed, including safety data, and efficacy data.

Response:

14.12 Describe how the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).

Response:

14.13 Describe the frequency of safety data collection, including when safety data collection starts.

Response:

14.14 Describe who will review the safety data.

Response:

**15.0 Potential Benefits to Subjects**

15.1 Describe the potential benefits that individual subjects may experience by taking part in the research.

Response:

15.2 Indicate if there is no direct benefit.

NOTE: Compensation cannot be stated as a benefit.

Response:

15.3 Indicate if there is a potential benefit to others, future science, or society.

Response:

**16.0 Economic Burden to Subjects**

N/A: This study is not enrolling subjects, or is limited to records review procedures only.

16.1 Describe any costs that subjects may be responsible for because of participation in the research.

NOTE: Some examples include transportation or parking, insurance co-payments, study drugs.

Response:

**17.0 Compensation for Participation**

N/A: There is no compensation for participation. This section does not apply.

17.1 Describe the amount, method and timing of payment in the form of compensation to the subjects. Include details on how you are paying the subject, including monetary, course credit or gift card compensation. Please note that PayPal (or other cash apps) and money orders are not acceptable forms of payment.  Describe any prorated payments based on participation.  Include the payment information in the consent form and add the IRS tax information to the consent form per the protocol template.

Response:

NOTE: If using West Campus Departmental pools, participation in studies may be offered for credit in class but students MUST be given other options for fulfilling the research component that are comparable in terms of time, effort, and education benefit. Please indicate the alternative activity/related contact information in the consent form.

**18.0 Informed Consent**

18.1 Will you be obtaining consent from subjects?

Yes (If yes, provide responses to each question in this section, and upload your consent documents where indicated in the electronic submission system.)

No (If no, skip to the next section.)

18.2 Describe how the capacity to consent will be assessed for all subjects. Review SBU SOPs section 5.5 for guidance: <https://www.stonybrook.edu/research-compliance/Human-Subjects/sops>).

Response:

18.3 Describe the consent process that will be conducted to ensure that the subject is fully informed regarding study details and subject rights. Include where the consent process will take place, with consideration of the need to protect the subject’s right to privacy.

Response:

18.4 Describe how you will ensure that subjects are provided with sufficient time to consider taking part in the research study. Detail if there is there any time period expected between informing the prospective subject and obtaining the consent.

NOTE: It is required that the prospective subject receive sufficient time to have their questions answered and to consider their participation

Response:

18.5 Describe the process to ensure the subject’s ongoing willingness to continue participation for the duration of the research study.

Response:

Non-English Speaking Subjects

N/A: This study will not enroll Non-English speaking subjects.

18.6 Indicate which language(s) other than English are likely to be spoken/understood by your prospective study population or their legally authorized representatives.

Response:

18.7 If subjects who do not speak English will be enrolled, describe the process to consent the subjects, as well as the process to be used to ensure their understanding of research procedures throughout the conduct of the study. Review SOPs section 17.8 for important policies in this regard: <https://www.stonybrook.edu/research-compliance/Human-Subjects/sops>).

Response:

Adults Unable to Consent

N/A: This study will not enroll adults unable to consent.

18.8 Justify why it is necessary to include adult subjects who are unable to consent.

Response:

18.9 Describe how you will identify Legally Authorized Representatives (LAR) for the subjects that will be consistent with the NYS Family Health Care Decisions Act (FHCDA; see SBU SOPs section 5.2 at <https://www.stonybrook.edu/research-compliance/Human-Subjects/sops>).

Response:

18.10 For research conducted outside of New York State, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the research.

Response:

18.11 Describe the process for obtaining assent from the adult subjects

Indicate whether assent will be obtained from all, some, or none of the subjects. If some, indicate which adults will be required to assent and which will not.

Response:

18.12 Describe whether assent of the adult subjects will be documented and the process to document assent.

Response:

18.13 Describe how you will obtain consent from a subject to use their data if they later become capable of consent. Include information regarding how competence will be assessed.

Response:

**19.0 Waiver or Alteration of Consent Process**

N/A: A waiver or alteration of consent is not being requested.

**Complete this section if:**

* Informed consent will not be obtained at all
* Informed consent will be obtained, but not documented, or
* Informed consent will be obtained, but not all required information will be disclosed (e.g., in deception research)

A waiver is requested. Complete and upload Supplemental Form G.

19.1 If the research involves a waiver of the consent process for planned emergency research, please contact the Office of Research Compliance for guidance regarding assistance in complying with federal regulations governing this activity (see: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/exception-informed-consent-requirements-emergency-research>

**20.0 Drugs and Devices**

N/A: This study does not involve drugs or devices. This section does not apply.

20.1 Does this study involve use of radiopharmaceuticals?

Yes

No

20.2 For investigational devices, provide the following information below:

Where will the device(s) be stored? Note that the storage area must be within an area under the PI’s control. Describe the security of the storage unit/facility. Provide full detail regarding how the dispensing of the device(s) will be controlled (accountability of removal/return of used devices, and disposition of remaining devices at the conclusion of the investigation) and documented (accounting records/logs).

Response:

20.3 For investigational drugs (including marketed drugs being used off label), will the services of the Investigational Drug Pharmacy be used for storage, dispensing, accounting the drug (required for research conducted at UH, HSC, Cancer Center, and Ambulatory Surgery Center)?

Yes

No → Provide the following information below:

* Where will the drugs/biologics be stored? Note that the storage area must be within an area under the PI’s control
* Describe the security of the storage unit/facility:
* Provide full detail regarding dispensing of the drugs(s), how labeled, controlled (accountability, disposition of unused drug at the conclusion of the investigation) and documented (accounting records/logs):

Response:

**21.0 Sharing of Results with Subjects**

21.1 Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject’s primary care physicians) and if so, describe how it will be shared.

Response:

**22.0 Collaboration**

N/A: This study does not include any collaborations.

22.1 Internal Collaboration

Response:

22.2 External Collaboration

Response:

22.3 Community Based Participatory Research (CBPR)

Does this project include community based participatory research? (Also referred to as community-based research (CBR), CBPR is a partnership-based approach to research that takes place in community settings and involves community members in the project’s design and implementation and dissemination of results.)

N/A: This study does not include CBPR.

Response: