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**Institutional Review Board**

3800 Spruce Street First Floor Suite 151

Philadelphia, PA 19104-6006

Phone: 215-573-2540

**Initial Application for IRB Review: Protocol Supplement for Requests to Rely on an External IRB**

**Delete the Instructions – blue text – prior to submitting the application.**

**Note: This form is only required if you are asking the Penn IRB to rely on an External IRB through an IRB Authorization Agreement. If you are asking Penn to review your protocol as the IRB of Record, please do NOT complete this form. For additional guidance on IRB Authorization Agreements, please visit:** [**https://irb.upenn.edu/reliance-agreements**](https://irb.upenn.edu/reliance-agreements)

**GENERAL INFORMATION:**

1. **Name of Principal Investigator (Penn)**: Full name and degree of Principal Investigator
2. **Protocol Title**: Full protocol title
3. **Funding Sponsor:** Identify the agency, organization, company or person providing funds for the research study
4. **Regulatory Sponsor:** Identify the agency, organization, company or person primarily responsible for initiating and overseeing the research and ensuring the study complies with research standards and federal regulations. For clinical trials (studies involving drugs or devices) this is typically the FDA IND holder, for device studies, this is the FDA IDE holder.

For more information about regulatory sponsor status, INDs and IDEs, see the following information provided by the Office of Clinical Research:

* <https://www.med.upenn.edu/pennmanual/secure/responsibilities-and-qualifications-of-ind/ide-sponsors.html>
* <https://www.med.upenn.edu/ocr/sponsor-support-unit.html>
1. **IRB of Record:** Insert name of institution serving as the IRB of record

**General Instruction: This document is designed to supplement the clinical trial protocol uploaded to your online application. The IRB will review this document and may require edits or clarifications to ensure that the protocol meets the requirements of Penn’s Human Research Protections Program. If the uploaded protocol already addresses the information requested in the fields below, please respond with a reference to the appropriate section of the attached protocol. Please do not copy/paste any information from the clinical trial protocol into this document.**

**SITE SPECIFIC INFORMATION:**

1. **Location of Research Activities:**
	1. Please confirm whether all research activities and/or services involving Penn personnel will be conducted at University of Pennsylvania and/or Penn Medicine affiliated sites.
	2. If Penn personnel will be conducting any research activities at extramural locations, please identify the procedures that will be performed and the locations where those activities will be conducted. Please also submit the [Community Based Research supplemental form](https://irb.upenn.edu/forms) when your research involves conducting research procedures at community sites external to Penn (e.g., public places, community centers, shelters, places of worship, etc.).
2. **Resources Necessary for Human Research Protections:**
	1. Describe research staff and justify that the staff are adequate in number and qualifications to conduct the research.
	2. Describe how you will ensure that all staff assisting with the research are adequately informed about the protocol and their research related duties.
	3. Please confirm that there are adequate facilities for the research.
	4. If Penn personnel will be conducting research activities at extramural locations, please identify any additional resources that will be utilized or procedures that will be implemented to ensure human subjects protections. [For example, if an investigational product will be administered at a non-clinical location, please describe your plan to transfer, prepare, and administer the product. If interviews will be conducted in a community location, please describe your plan to ensure a private space for the interview and the confidentiality of research data]
3. **Enrollment Target:** In this section please indicate the number of subjects to be recruited at Penn
4. **Recruitment:**
	1. Please provide an overview of your local approach to subject identification and recruitment, including referrals from physicians and offices. This should include a description of who will approach potential participants, when and where this will happen, and what information will be presented to them during the recruitment process.
	2. Please indicate whether you will use any Penn media services (communications, marketing, etc.) for outreach via social media avenues (examples include: Facebook, Twitter, blogging, etc.) or if the study team plans to directly use social media to recruit for the research.
	3. Please indicate whether or not you will use texting or email to recruit for research. If texting or email will not be used, please explicitly state this.

Note: Recruitment materials (i.e. radio/video scripts, flyers, internet postings, etc.) will be reviewed by the IRB of Record. You are not required to attach recruitment materials to your application to the Penn IRB or submit them to the Penn IRB in the future.

1. **Subject Compensation:** Please indicate whether subjects will be financially compensated for participation.
	1. If yes, summarize the financial compensation that will be offered to subjects including the method (e.g. cash payments, gift card, reimbursement for travel), the schedule for compensation per study visit or session and total amount for entire participation, and clarify whether social security number is required for payment.

Note: The amount of compensation may not constitute an undue inducement to participate in the research. A prorated system of financial compensation is required in most circumstances.

Note: If Penn subjects will be compensated, please review the consent form section on compensation and, if necessary, incorporate the Penn template language regarding reporting compensation for tax purposes.

**PROCEDURAL INFORMATION:**

1. **Enrollment:** Please indicate whether or not subjects will be consented and enrolled by Penn Personnel. Also, if you plan to enroll only a subgroup of subjects, please indicate that in this section. For example, if the protocol allows for the enrollment of adults and children but Penn will only enroll adult subjects, please state that in this section.
2. **Procedures:** Please indicate if Penn will perform all procedures described in the protocol or if Penn will only participate in select activities. If Penn will only participate in some study activities, please provide a description of the activities that will be conducted at Penn.
3. **Additional Procedures:** Please describe any Penn site specific procedures that are not described in the attached protocol. If the protocol provides a complete and accurate description of the procedures that will be performed, please answer N/A.
4. **Mental Health Records:** Please state whether this study involves the review of subjects’ mental health records.
5. **Infectious Diseases Testing:** Please state whether this study requires that infectious diseases testing be performed for research purposes.

Note: If Penn subjects will undergo infectious disease testing for research purposes, please review the consent form and, if necessary, incorporate the Penn template language regarding external reporting requirements for positive test results.

1. **Local Considerations:** Please describe any local, community or cultural issues that may be specific to your targeted population of subjects and your plan to account for them during the conduct of your study. If this is not applicable to your study, please answer N/A
2. **Data Confidentiality:** *Confidentiality* relates to how research data will be handled, managed, and disseminated. The research proposal should outline strategies to maintain confidentiality of identifiable data, including controls on storage, handling, and sharing of data.

 **Within this section, the following must be included:**

* A description of how research data will be handled, managed, and transmitted locally including a description of how this plan complies with any specific requirements for data security and storage that stem from institutional policies, state or federal regulations, requirements of funding agencies, contractual obligations or data access agreements.
* A description of any additional controls that will be implemented for the storage, handling, and sharing of data locally.
* The long-range plan for protecting the confidentiality of research data, including a schedule for destruction of identifiers associated with the data.

For research involving directly identifiable electronic protected health information (PHI) please review the IRB’s requirements titled [Electronic Data Protection Requirements for Research Involving the Use of Protected Health Information (PHI)](http://www.upenn.edu/IRB/initial-review). Additional information may be found in the companion guide [Key Features of Approved Mechanisms for Data Storage/Transmission](http://www.upenn.edu/IRB/initial-review). Please ensure that your local confidentiality plan aligns with these requirements.

1. **Data Disclosure:** Please indicate whether study data will be disclosed to anyone not listed in the Personnel section of the HSERA application. If so, please identify whom the data will be disclosed to, what identifiers, if any will be disclosed and how the data will be securely shared. Please note: the entities to whom data will be disclosed, as listed here, should also be listed in the consent document where applicable.
2. **21st Century Cures Act and Electronic Medical Record:** Please indicate whether this research is being conducted within Penn Medicine and if results may be placed into the electronic medical record, or are otherwise built in the EMR. Please also indicate whether the study will generate clinically relevant results and if those results will be returned to subjects in a timely or delayed manner. For more information on these requirements please see the Electronic Medical Record and Release of Study Related Information guidance on the Penn IRB website: <https://irb.upenn.edu/mission-institutional-review-board-irb/guidance/recruitment-and-consent> and the revised Biomedical Informed Consent Form Template.
3. **Sensitive Research Information:** Please indicate whether this research involves the collection of sensitive information about subjects that should be excluded from the electronic medical record and if you plan to have these tests results marked as sensitive in Epic. [Note: This does not apply to: 10 research information that would not normally be included in the electronic medical record or 2) information that is in the electronic medical record as part of clinical care.]

If yes, please outline your proposed method for verifying that the sensitive information being collected for this research will not be recorded, or later entered into the electronic medical record. Please provide a list of the tests that will be ordered as sensitive in Epic, as well as a list of the staff members that will have access to the results of these test.

If you will not have results marked as sensitive in Epic, please answer N/A.