

**Institutional Review Board**

3800 Spruce Street

First Floor Suite 151

Philadelphia, PA 19104-6006

Phone: 215-573-2540

**Central IRB Review: Participating Site Addition Form**

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| **Instructions:** This form is only required if the Penn IRB is serving as the Central IRB and you are requesting that the Penn IRB serve as the IRB of Record for an external site through an IRB Authorization Agreement. If you are asking the Penn IRB to rely on an External IRB, please do NOT complete this form. For additional guidance on IRB Authorization Agreements, please visit: <https://irb.upenn.edu/reliance-agreements>  This document is designed to collect site specific information about the new site that will be relying on Penn’s IRB and to supplement the clinical trial protocol uploaded to your online application. The IRB recommends that this form be completed by the external site study team after any required local context reviews and ancillary committee reviews have taken place. The completed form should be given to the Penn study team for submission to the Penn IRB.  The IRB will review this document and may require edits or clarifications to ensure that the protocol describes how the study will be conducted at this external study site. 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. |

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| **GENERAL PROTOCOL INFORMATION:** | | | |
| **Penn Principal Investigator** | Full name and degree of Principal Investigator | **Penn IRB Protocol Number:** | The protocol number assigned to the study by the Penn IRB (if available) |
| **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. | **Funding Sponsor:** | Identify the agency, organization, company or person providing funds for the research study |
| **Protocol Title**: | Full protocol title | | |

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| **RELYING SITE TEAM INFORMATION:**  **Instructions:** Please provide the information requested below for the research team at the relying site.  **Study Primary Point of Contact** -Information for the member of the study team that should be contacted with any questions about the project  **IRB Primary Point of Contact-**The individual at the relying site’s IRB that should be contacted with any questions about the IRB authorization agreement.  **Research Team Member Names and Study Positions-** Please list all members of the study team. The section below provides space for local PI, local Sub-I, primary contact and 10 additional members. If you have more study members, please provide an additional attachment for those people with the same requested information.  **Human Subjects Training –**Please provide the date of training completion to confirm that all members of the relying site research team will maintain the local institution’s human subjects research training requirements. Please note that individual copies of CVs and research training completion reports do not need to be provided. The Relying Site IRB will be responsible for ensuring that all training requirements are met.  **Financial Conflict of Interest:** Please indicate whether the PI or any member of the study team has an existing financial conflict of interest.If Yes, please provide the results of the relying site’s institutional review of the potential conflict of interest or indicate that this review is ongoing. |

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| **Name of Relying Institution:** | The name of the site that is relying on the Penn IRB | | |
| **Relying Site Principal Investigator:** | Full name | **Contact Info:** | Email & Telephone |
| **Study Primary Point of Contact:** | Full name | **Contact Info:** | Email & Telephone |
| **IRB Primary Point of Contact:** | Full name | **Contact Info:** | Email & Telephone |

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| **Research Team Members** | **Position** | **Date Training Complete** | **Financial Conflict?** |
| Full name | Principal Investigator |  | Y  N |
| Full name | Co-Investigator |  | Y  N |
| Full name | Primary Study Contact |  | Y  N |
| Full name |  |  | Y  N |
| Full name |  |  | Y  N |
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| **Resources Necessary for Human Research Protections:** Please provide justification for why the staff are adequate in number and qualifications to conduct the research. Describe how you will ensure that all staff assisting with the research are adequately informed about the protocol and their research related duties. Please confirm that there are adequate facilities for the research. |
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**RELYING SITE PROCEDURAL INFORMATION**

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| **Site Specific Activities:** Please state whether you will complete all activities described in the protocol or if your participation is limited to specific activities such as laboratory analysis, or data analysis. |
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| **Recruitment:** Please indicate whether or not subjects will be recruited and enrolled by site personnel. 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 this site will only enroll adult subjects, please state that in this section.*  Please outline a description of your recruitment plan including an overview of your approach to subject identification and recruitment (e.g. referrals from physician offices and clinics). Please also describe how any recruitment materials will be utilized. Copies of any recruitment materials that require IRB approval should be submitted as attachments. |
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| **Consent Process:** Please summarize the process for obtaining informed consent, including how, when, where, and by whom it will be obtained. Describe any waiting period between informing the prospective participant and obtaining the consent. Describe any steps taken to minimize the possibility of coercion or undue influence. Please indicate who will provide consent or permission if the subject is incapable. |
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| **Study-wide Enrollment Distribution –** If this site is engaged in subject enrollment, please describe what portion of the overall study enrollment goal is planned to take place at this site (e.g. percentage, target number, competitive, etc.) or how it will be determined that enrollment has been completed at this site. |
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| **Subject Compensation:** Please summarize the form of financial compensation that will be offered to subjects, (*e.g. cash payments, gift card, or reimbursement for travel.*) Provide the schedule for compensation (amount per study visit or session) and total amount for entire participation. 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. |
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| **Privacy and Confidentiality:** Please describe any site-specific protections put in place to protect the confidentiality of research data and the privacy of research participations. If the protocol adequately describes the confidentiality and privacy protections implemented at your site, please provide a reference to the corresponding section of the protocol. |
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| **Ancillary Committees:** The site is responsible for obtaining any required local institutional ancillary approvals that apply to the conduct of this research protocol. Please identify any institutional ancillary bodies that will review this protocol. Please also provide the status of those reviews. |
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| **State and Local Laws, Regulations, and Policies:** Please describe any state or local laws, regulations, or policies that may impact how the protocol will be conducted at your site. Please detail any revisions or additional actions that you plan to take in order to comply with state and local laws, regulations, and policies. If this is not applicable to your study, please answer N/A. |
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| **Other 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 |
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