**Institutional Review Board**

Phone: 215-573-2540

**Continuing Review Relying Site Supplement**

*This form is required when the Penn IRB is serving as the IRB of Record or Single IRB.*

*Please complete and submit* ***one copy for the Penn site*** *AND* ***one copy for each External Site****.*

PENN PROTOCOL **#:**

RELYING SITE**:**

RELYING SITE PRINCIPAL INVESTIGATOR:

FULL PROTOCOL TITLE**:**

IRB APPROVAL EXPIRATION DATE**:**

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| ***If IRB Approval Expired****: No research related activities may occur after the protocol expiration date, unless the PI contacts the IRB in advance, and it is determined that continuation during expiration is appropriate for participant safety.*  In the space below please indicate if any activity has occurred at your site during the lapse in approval. If yes, please describe the activity in the space provided. |
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| **Continuing Review Supplement Guidance:**  At the time of continuing review, the Penn IRB must evaluate the progress made by the Penn site and by each of the External Sites that have agreed to rely on Penn as the IRB of Record. Therefore, each study team that is relying on the Penn IRB is required to complete this Continuing Review Application Supplement and return the completed form to the research team’s designated Point of Contact. The point of contact will then utilize the site reports to complete the Single IRB Continuing Review form and develop the progress report to capture activity across all sites for submission to the Penn IRB.  Some sections of this form indicate that additional documents may also be necessary. Please be sure to communicate regularly with your Point of Contact regarding your site’s requirements at the time of continuing review. The Penn IRB also provides specific guidance on our website which relying institutions are encouraged to review - <https://irb.upenn.edu/continuing-review>  If while preparing this continuing review your site identifies any deviations or adverse events that should have been reported to the Penn IRB but were not reported, please inform your Point of Contact. |

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| 1. **Please identify the point of contact person who has compiled and submitted the continuing review supplement for this site** | |
| Name: | Telephone: |
| Email: | |

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| 1. **Status of study enrollment:** |

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| 1. **Site Specific Enrollment Reporting (Items A – J)**   *Please be mindful that enrolling beyond the approved target is considered a deviation unless your protocol describes an enrollment plan that accounts for participants who consent to participate and are later determined to be ineligible or were withdrawn for other purposes. Your site’s accrual plan is documented in your Participating Site Application. If you have enrolled participants beyond your target and plan to continue consenting participants, please submit a modification to request an expansion of the target and provide rationale.* | | | | | | | | |
| 1. Total Target Enrollment at your Site: | | | | | |  | | |
| 1. Enrollment target for next 12 months | | | | | |  | | |
| *Note: Please list the maximum number of participants approved by the IRB to be consented at your site. If no maximum was set in the protocol, please enter “No Target Set.”* | | | | | | | | |
| ***CONSENTED PARTICIPANTS BREAKDOWN:*** *(Even if participants do not sign their name to a form they are considered consented if an IRB approved consent process was completed to gain their permission to voluntarily participate)* | | | | | | | | |
| 1. Number of participants consented at your site since the last Continuing Review: | | | | | | |  | |
| 1. Number of participants consented at your site since the initiation of the study: | | | | | | |  | |
| ***PARTICIPANT STATUS BREAKDOWN:*** *When responding to these items please only account for participants enrolled at your site.* ***Do not*** *account for individual participants in multiple categories. D+ E+ F + G = C.* | | | | | | | | |
| 1. Number of participants actively participating in study procedures**:** | | | | | | | |  |
| 1. Number of participants participating only in follow up procedures**:** | | | | | | | |  |
| 1. Please identify what stage of follow-up participants are in (Check all that apply based on participant statuses)   Research remains active to complete protocol required follow-up procedures or interventions  Research remains active only for long-term follow-up  *For guidance on what constitutes long-term follow-up, please see:* [*https://irb.upenn.edu/homepage/faqs/continuing-review-faqs*](https://irb.upenn.edu/homepage/faqs/continuing-review-faqs/) | | | | | | | |  |
| * 1. If research remains active only for long-term follow-up, please detail the ongoing activities: | | | | | | | |  |
| 1. Number of participants completed since enrollment began (no further study activities or contact required): | | | | | | | |  |
| 1. Are there any participants who provided consent that are no longer participating for reasons other than completion? | | | | | | | | **YES** **NO** |
| **If Yes**: Please provide a summarized list below of participants that have ended participation since the last IRB approval (Initial or Continuing Review). Include the reasons other than completion and the number of inactive participants in each category. *(Categories to consider: determined ineligible after consent, lost to follow up, voluntary withdrawal, withdrawal by the PI, disease progression, adverse event, ETC…)* | | | | | | | | |
| ***EQUITABLE PARTICIPANT SELECTION:*** This section should include all participants since enrollment began:  *NOTE: If your study tracks this information, please complete the following sections*.  *NOTE: Not all participants will identify with the sex and/or gender they were assigned at birth. Sex and gender are both social constructs. Sex refers to a set of biological attributes while gender refers to social, psychological, cultural, and behavioral aspects related to a person’s identity.* | | | | | | | | |
| ***Sex and Gender*** | | | | | | | | |
| 1. Is information from OR about participant gender and/or sex being collected?   **YES,** please provide the information you have collected for all participants since enrollment began.  **NO,** please leave sections blank or place N/A in the associated boxes. | | | | | | | | |
| * Sex: | | | | * Gender: | | | | |
| Males: |  | | | Men: |  | | | |
| Females: |  | | | Women: |  | | | |
| Intersex: |  | | | Another Identity: |  | | | |
| Unknown: |  | | | Unknown: |  | | | |
| ***Race and Ethnicity*** | | | | | | | | |
| 1. Is information from /about participants’ race and/or ethnicity collected? Race refers to categories of people based on shared physical and social qualities while ethnicity refers to populations or subgroups of people who share a common cultural background and/or descent. The categories included within this form are not exhaustive and are based on US Census data.   **YES,** please provide the information you have collected for all participants since enrollment began.  **NO,** please explain why this is not collected: | | | | | | | | |
| **Ethnicity:** | | |  | | | | | |
| Hispanic or Latino/x: | | |  | | | | | |
| Not Hispanic or Latino/x: | | |  | | | | | |
| **Race:** | | |  | | | | | |
| American Indian or Alaskan Native: | | |  | | | | | |
| Asian: | | |  | | | | | |
| Black or African American: | | |  | | | | | |
| Native Hawaiian or Pacific Islander: | | |  | | | | | |
| White: | | |  | | | | | |
| Another Race: | | |  | | | | | |
| More than One Race: | | |  | | | | | |
| Unknown or Not Reported: | | |  | | | | | |
| 1. Please comment on the strategies or methods being used to recruit a diverse sample of participants that includes and/or reflects the larger targeted population.      1. If your enrollment does not represent a diverse group of participants, please explain why. | | | | | | | | |
| 1. **Participant Recruitment since the last continuing review** 2. Has participant recruitment been successful?   **YES**  **NO**   1. Please discuss your participant recruitment procedures in terms of what has been successful versus not. Please discuss your plans for the upcoming year, including any changes to the recruitment plan to improve recruitment and increase enrollment. | | | | | | | | |
| 1. ***VULNERABLE POPULATIONS THAT REQUIRE SPECIAL CONSIDERATIONS:*** | | | | | | | | |
| **Has your study enrolled:** | | | | | | | | |
| **Pregnant Individuals?** | | **YES** **NO** | | | | | | |
| **Incarcerated Persons?** | | **YES** **NO** | | | | | | |
| **Children (aged 17 or younger)?** | | **YES** **NO** | | | | | | |
| *Please Note: If your study has enrolled any of the above populations and the inclusion of these populations was not previously approved by the IRB, a separate deviation report must be submitted to the IRB for review/consideration.* | | | | | | | | |

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| 1. **Progress Report:** Please complete the following or provide this information in a separate attachment |
| 1. An overall narrative summary of the study activities that occurred during the approval year at your site, including notable comments on enrollment progress, participant experiences, any delays in study activities, and expected activities for the coming year. |
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| 1. A summary of any planned/outstanding site-specific modifications that will be submitted to the IRB for review including the planned timeline for submission and the impact the modifications have for enrolled participants, as applicable. |
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| 1. If applicable, additional information needed to clarify or elaborate on the details provided in response to other sections within this form. |
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| 1. **Deviations** (required for greater than minimal risk research)  **NA**   Please see <https://irb.upenn.edu/Deviation> for guidance related to documenting and reporting deviations according to the Penn IRB criteria. It is the IRB’s expectation that a multi-site management plan is in place for relying sites to exchange information related to site monitoring for deviations and noncompliance with the lead site in an ongoing fashion. Requirements for submitting aggregate deviations for IRB assessment at the time of continuing review is contingent upon the protocol specified monitoring plan. Please consult with the lead site point of contact to determine what specific information about your site deviations should be included in this section. |
| 1. Please confirm whether all deviations recorded at your site have been individually assessed by the lead PI, local PI, or delegated co-I in context of the Penn IRB criteria for expedited reporting and that all deviations meeting those criteria have already been submitted for IRB review   **YES**  **NO\*,** please explain: |
| 1. Please utilize the space below (or a separate attachment) to provide the required information about your site deviations as instructed by your point of contact. If no deviations are being reported from this site, please note that below. If you are providing a separate attachment, please note that below. |

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| 1. **Adverse Events** (required for greater than minimal risk research)  **NA**   Please see <https://irb.upenn.edu/reportable-event> for guidance related to documenting and reporting Adverse Events. An adverse event is any untoward or unfavorable medical occurrence in a human participant (including both physical and psychological harms). It is the IRBs expectation that a multi-site management plan is in place for relying sites to exchange information related to site monitoring for adverse events and unanticipated problems with the lead site in an ongoing fashion. |
| 1. Please confirm whether all adverse events recorded at your site have been individually assessed by the Lead PI, Local PI, or delegated co-I in context of the Penn IRB’s criteria for expedited reporting and that all events meeting those criteria have already been submitted for IRB review.   **YES**  **NO\*,***please explain:* |

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| 1. **Financial Conflict of Interest Reporting**   *This section is not applicable to the Penn site. The Penn site should ensure all responsible individuals complete their annual disclosure in RIA, and may leave this section blank.* |
| 1. **Does any person who is responsible for the design, conduct, or reporting of this research protocol have a Financial Interest, that requires reporting per your institutional Conflict of Interest SOPs**   **Yes** **No** |
| 1. **If the answer to Question A is “YES”-**For this protocol, was this Financial Interest previously reported per your institutional requirements?   **Yes** **No** \*If No is selected, please report at this time. |
| 1. **If the answer to Question B is “YES”-** For this protocol, has there been a change regarding any Financial Interest(S) from what was previously reported to your institution?   **Yes** **No** \*If yes is selected, please report at this time. |
| 1. **Certification**   I have reviewed my Institutions Policy on Conflict of Interest Related to Research and to the best of my knowledge, all Investigators with a Financial Interest have been identified above. |
| 1. **CR Supplement Form Completion**   By signing this form, the principal investigator and the person completing the form (if other than the investigator) certify that he/she/they has disclosed to the IRB all relevant information that might affect re-approval of this study. **(Electronic PDF Signatures are preferred)** |
| Principal Investigator Signature: Date:  Signature of Person Completing This Form: Date: |