**Institutional Review Board**

3600 Civic Center Blvd. 9th Floor

Philadelphia, PA 19104-6006

Phone: 215-573-2540

**Continuing Review Application – Single IRB Version**

*(Please use this version of the Continuing Review Application when the Penn IRB is serving as the IRB of Record, or Single IRB, for Penn and other External Sites. This form should be completed by the lead site research team to provide an overall assessment of progress across all sites relying on the Penn IRB)*

PENN PROTOCOL **#:**

PENN PRINCIPAL INVESTIGATOR**:**

FULL PROTOCOL TITLE**:**

IRB APPROVAL EXPIRATION DATE**:**

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| ***If IRB Approval Expired or Will Expire****:* No research related activities may occur after the protocol expiration date. If the study has expired or will expire while waiting for IRB review, the following information should be included in the space below:* Please describe any study activities that have occurred at Penn or any relying site during the lapse in approval
* Provide an explanation for what led to the delayed submission of the CR
* Provide a corrective action plan to avoid expiration in the future
* If this is not the first time that the study has expired, comment on whether the existing corrective action plan needs to be corrected
* If your research is greater than minimal risk and activities need to occur at Penn or any relying site during the lapse for the benefit of participants, provide rationale for this to allow consideration of an exception to permit continuation during the lapse
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| **Continuing Review Submission Requirements Guidance:**When the Penn IRB serves as the IRB of record for multiple sites, progress made by all sites that have agreed to rely on the Penn IRB must be assessed. Therefore, each site that is relying on the Penn IRB is required to complete a Continuing Review Relying Site Supplement and return the completed forms to the designated Point of Contact. The Point of Contact should submit each of the site-specific documents with the continuing review submission. In addition, this form must be completed and submitted to provide an overall assessment.Anyone serving as a Point of Contact should reference and be familiar with the [Post Approval Submission Guidance available on the Penn IRB website](https://irb.upenn.edu/reliance-agreements) while composing IRB submissions involving relying sites.Research that requires Convened/Full Annual Continuing Review is due 6 weeks prior to expiration.Research that qualifies for Expedited Annual Continuing Review is due at least 2 weeks prior to expiration.Incomplete submissions may be returned for edits regardless of expiration date.1. **Documents:** ***One Copy*** of each of the following documents are required to be attached to HSERA for continuing approval of research where Penn serves as the IRB of record for external sites:
* Completed Continuing Review Relying Site Supplemental forms for each site that is overseen by the Penn IRB (including the Penn site)
* Completed copy of this form and any additional attachments necessary as a result of completion of various sections of this form
	+ If responses to section VI result in submission of all deviations, please be sure that each site has provided you with the required information to report their site deviations.
	+ Safety monitoring reports as necessary for section VII
* A separate Progress Report document (See B. for information to include in the progress report)
* The currently approved protocol document
* Currently approved versions of Informed Consent Forms for all sites that rely on Penn IRB review (unless enrollment is permanently closed, or no informed consent forms are required or used in the research). These versions should not include any tracked changes or previous IRB approval stamps.
* For Biomedical research, currently approved Investigators Brochures and/or Package Inserts for all study drugs/devices should be included

**B. Progress Report:** Please draft one separate Progress Report document that includes the following information:1. A complete list of documents being submitted for review. Each listed item must include the name of the document, version identifier and date (e.g. – Study Protocol version 7, dated 9/26/2017)
2. A narrative summary of the study activities that occurred across all study sites during the approval year including notable comments, notable participant experiences, any delays in study activities, and expected activities for the coming year. Please do not re-iterate the enrollment numbers provided in the submission forms unless a specific clarification is needed.
3. A summary of any planned/outstanding 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.
4. As the point of contact for all study sites relying on the Penn IRB, please make sure your progress report includes:
	* Any necessary clarifications about enrollment across sites or specific sites that cannot be accurately captured in the submission forms
	* Required information related to deviations (see section VI). Please note that this progress report section should speak broadly regarding all sites that report to the Penn IRB.
	* An overall assessment of unexpected Adverse Events. Please note that this progress report section should speak broadly of adverse events across all sites that report to the Penn IRB, and whether any changes to the study trial are planned in reaction to these events. Please see the IRB website guidance about adverse events prior to submitting

[**Click here to review additional guidance for all continuing review requirements**](https://irb.upenn.edu/continuing-review) **prior to submitting** |

**Continuing Review Submission Questions:**

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| 1. **Please provide the name and contact information for the point of contact person who has compiled and submitted this continuing review application**
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| Name:  | Telephone:  |
| Penn Email:   |

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| 1. **In the field below, please list all the study sites that are relying on the Penn IRB as the IRB of Record**
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| **Are there sites that are participating in the research but are not relying on the Penn IRB** *(i.e. sites relying on their own IRB or on an Independent IRB)***?** | **[ ] YES [ ] NO** |

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| 1. **Status of study:** *The risk level chosen should be based on the risk level determined by the IRB at initial review. Enrollment status should reflect the overall study – not site-specific status. (Click grey button to select)*
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| Risk Level of Research: | Status of enrollment: |

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| 1. **Participant Enrollment Reporting** *Please be mindful that enrolling beyond the approved target is*

*considered a deviation. If you have enrolled participants beyond your target and plan to continue consenting participants, please submit a modification to revise your enrollment target and plan.* |
| ***Study Wide Enrollment Reporting:*** |
| 1. Are participants enrolled at external sites that are not relying on the Penn IRB?
 | [ ] **YES** [ ] **NO** |
| **IF YES:** Please list thestudy wide enrollment target |  |
|  Please list the study wide enrollment progress |  |
| ***Penn IRB Enrollment Reporting (Items B – K)*** |
| 1. Combined enrollment target at sites for which Penn serves as the IRB of record

 *Note: The target reflected here should be the sum of all targets supplied in the site-specific Continuing Review Supplement Application for Relying Site documents that accompany this application.*  |  |
| ***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) Please only account for participants consented at sites for which Penn serves as the IRB of record* |
| 1. Number of participants consented since the last Continuing Review:
 |  |
| 1. Number of participants consented since the initiation of the study:
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| ***PARTICIPANT STATUS BREAKDOWN:*** *When responding to these items please only account for participants enrolled at sites overseen by the Penn IRB . Do not account for individual participants in multiple categories. E+ F + G +H = D. Provide any required clarification in your progress report.* |
| 1. Number of participants actively participating in study procedures**:**
 |  |
| 1. Number of participants participating only in follow up procedures**:**
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| 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…)* |
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| ***EQUITABLE PARTICIPANT SELECTION:*** This section should include all participants since enrollment began for all sites overseen by the Penn IRB:*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: |   |
| NotHispanic 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 utilized 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. ***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. **Research Involving Products/Agents**

*For studies administering the following as part of research procedures: drugs, devices, biologics, foods, food additives, cosmetics, investigational in vitro diagnostics or lab developed tests, vitamins, supplements, etc.*  | [ ]  **NA** (no products or agents being administered) |
| 1. Have there been any updates related to the products administered on this trial in the past year? This may include but is not limited to: revised package inserts, revised investigator brochures, product recalls or bans, new product manufacturer, etc.
 | [ ]  **YES** [ ]  **NO** |
| * 1. If Yes, please confirm that all updates have been submitted to the IRB appropriately, or indicate that an amendment is soon forthcoming:
 |
| 1. Is this study conducted under an IND or IDE ***where the IND or IDE Sponsor is an entity*** *(Faculty member, Department, University)* ***relying on the Penn IRB?***
 | [ ]  **YES: answer 2a****[ ]**  **NO** (i.e., Sponsor is external to the sites conducting the study or the study has an IND/IDE Exemption, etc.)  |
| * 1. Has the protocol, Penn Sponsor, PI, or any sub-investigators been inspected by the FDA or other health authority?

[ ]  **NO** [ ]  **Yes:** Was a FDA Form 483 or other inspection report issued?  |

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| 1. **Study Monitoring / Quality Control** (required for greater than minimal risk research)
 | [ ]  **NA** |
| *Please note: This section is not required if your study has not enrolled any participants to date or you are closed to enrollment and had no active participants during the past year. Please see the* [Post Approval Submission Guidance available on the Penn IRB website](https://irb.upenn.edu/reliance-agreements) *for guidance on completing this section in relation to quality control and identification of deviations.*It is the expectation of the IRB that all greater than minimal risk research protocols will include a plan for site monitoring and quality control as well as a plan for multi-site studies to coordinate. **To complete this section, please choose either A or B** to define the quality control plan for this study. Then address each question in the column associated with your choice and complete your progress report as necessary based on your responses and the form’s instructions.  |
| 1. [ ]  The Regulatory Sponsor’s designated study monitor is conducting quality control activities by reviewing the study records.
 | 1. [ ]  There is no Sponsor appointed monitor. Each site is responsible for meeting their institutional requirements for quality control activities. (For example, the Penn research team will conduct all quality control activities which are documented with the [PICA REDCap form.](https://redcap.med.upenn.edu/surveys/?s=RTJHWJ78973DEXYW))
 |
| * + - 1. Were there any deviations in the past approval period that met the Penn IRB’s criteria for expedited reporting?

[ ]  **NO** [ ]  **YES** ***IF YES*** *- Within your progress report, please provide a summary of all deviations* ***that were submitted in an expedited fashion****. Discuss any related corrective and preventative actions that were taken. Please provide any new information related to these events, if available.** + - 1. Please confirm whether all recorded deviations have been individually assessed by the PI (or delegated co-I) in context of the Penn IRB’s criteria for expedited reporting

 [ ]  **YES** [ ]  **NO\* -***please explain in*  *your progress report* | 1. Quality Control activities for this year have been completed. (For the Penn site, the PICA has been submitted in REDCap and is on file in our study binder.)

[ ]  **YES**[ ]  **NO** *Within your cover letter / progress report, please explain why this has not been submitted.*1. After assessing the results of each site’s quality control activities: Are there any new, unresolved, or ongoing issues that were identified?

[ ]  **NO** [ ]  **YES**: *Within your progress report, please*  *describe these issues and any associated*  *corrective actions*1. Were there any deviations in the past approval period at any sites relying on the Penn IRB?

[ ]  **NO** [ ]  **YES, if yes please see 2a & 2b***–* 1. *Please ensure each site has submitted the required information to report their site deviations appropriately according to the* [*Post Approval Submission Guidance*](https://irb.upenn.edu/reliance-agreements)*. These should be included in your submission.*
2. *The progress report should also include an overall assessment of the deviations. This assessment should provide broader comment on whether the deviations had an adverse impact on* *participants’ rights, welfare /safety (including any potential or actual harm), and the scientific integrity of study.*
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| 1. **Safety Monitoring (required for greater than minimal risk research only)**
 | [ ]  **NA** |
| Please refer to the safety monitoring provisions outlined in the protocol and/or HSERA, Risk-Benefit Page, Data and Safety Monitoring.  |
| 1. Does the protocol identify an independent (i.e. not affiliated with Penn or any other study site) group, entity, or individual that will periodically assess safety data [e.g., independent Data Safety Monitoring Board (DSMB) or Data Safety Monitoring Committee (DSMC), or other safety monitoring entity, independent medical monitor, etc.]
 | [ ]  **YES:** answer 1a[ ]  **NO** |
| 1. Does the entity/individual issue reports to the site? (refer to protocol and/or charter, if applicable)
 | [ ]  **YES:** answer 1ai[ ]  **NO** |
| * 1. Please confirm whether all reports have been submitted previously to the IRB or attach them with your progress report.

[ ]  All reports have already been submitted to the IRB in real-time per IRB [requirements](https://irb.upenn.edu/sites/default/files/Letter%20for%20DSMB%20reporting%20policy.pdf). [ ]  Reports are attached with this submission. Please explain any reasons for reports not submitted in real-time:      [ ]  Reports are unavailable. Please specify reason for unavailability and expected date of receipt:       |

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| 1. **Adverse Events (required for greater than minimal risk research) [ ]  NA**

*Please see* [*https://irb.upenn.edu/reportable-event*](https://irb.upenn.edu/reportable-event) *for guidance*  |
| 1. Please confirm whether all adverse events at all sites relying on Penn IRB review 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 according to the multi-site management plan

[ ]  **YES** [ ]  **NO\*,***please explain:*  |
| 1. Were there any adverse events that occurred at any sites relying on Penn IRB review in the past approval period that met the IRB’s criteria for expedited reporting?
 |
| [ ]  **YES:** *Within your progress report, please provide a summary of all unexpected events that were submitted to the IRB in an expedited fashion. Please ensure your summary mentions the relatedness and seriousness / grading of the event. Please provide any new information related to these events, if available. Summarize the impact of these unexpected events on the risk-benefit ratio of the study. Summarize any actions taken in response.* [ ]  **NO** |

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| 1. **Risk-Benefit Assessment**
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| Is there any **new** information to report that would **alter** the IRB’s previous determination that risks to participants are minimized AND risks to participants are reasonable in relation to anticipated benefits, if any?  | [ ]  **YES**[ ]  **NO**  |
| If yes: Please describe the new information the IRB should consider that may alter the previous determinations for these two IRB approval criteria:       |

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| 1. **CR Completion**-please attach this completed form to a Continuing Review application in the HSERA system along with the other required documents and submit for IRB review
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By submitting this completed 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. ([Click to review PI responsibilities](https://irb.upenn.edu/wp-content/uploads/2023/05/Principal-Investigators-Acknowledgement-of-Responsibilities-2023.pdf))

*\*Reminder: Before submitting, please revisit the requirements section to assure all necessary elements have been addressed. \**