**Institutional Review Board**

3600 Civic Center Blvd. 9th Floor

Philadelphia, PA 19104-6006

Phone: 215-573-2540

**Continuing Review Application**

PROTOCOL **#:**

PRINCIPAL INVESTIGATOR**:**

FULL PROTOCOL TITLE**:**

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 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 during the lapse for the benefit or safety of participants, an exception request should be submitted. Please see <https://irb.upenn.edu/Exception> |
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| **Continuing Review Submission Requirements:**  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 will be returned for edits regardless of expiration date.  **A. Documents:** ***One Copy*** of each of the following documents are required for continuing approval for all research:  -Completed Continuing Review Form, (Paper submissions require PI signature)  -A cover letter with detailed Progress Report (See B. for details on each section required in progress report)  -The currently approved protocol document  -Currently approved versions of Informed Consent Forms (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 Only:  -Currently approved Investigators Brochures and/or Package Inserts for all study drugs/devices  **B. Progress Report:** Please include a cover letter that includes the following information:   1. All IRB submissions for Greater Than Minimal Risk research must include 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. All IRB submissions require a narrative summary of the study activities that occurred during the approval year including notable comments, notable participants experiences, any delays in study activities, and expected activities for the coming year. Please do not re-iterate the enrollment numbers provided in this form unless a specific clarification is needed. 3. All IRB submissions require 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. |

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| 1. **Who should the IRB contact with questions?** | |
| Name: | Telephone: |
| Penn Email: | |

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| 1. **Risk Level & Enrollment Status of study:** *The risk level chosen should be the risk level assigned by the IRB.* | |
| Risk Level of Research: | Current Enrollment Status: |

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| 1. **Participant Enrollment Reporting - (Items A – K)**   *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.* | | | | | | |
| 1. Total target Enrollment for Penn Investigators:   *(Please list the maximum number of participants approved by the IRB to be consented by Penn investigators. If no maximum was set, please enter “No Target Set.”)* | | | | | |  |
| 1. Target enrollment for next 12 months | | | | | |  |
| ***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 Penn since the last Continuing Review: | | | | | |  |
| 1. Number of participants consented at Penn since the initiation of the study: | | | | | |  |
| ***PARTICIPANT STATUS BREAKDOWN:*** *When responding to these items please only account for participants enrolled at Penn. 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**:** | | | | | |  |
| 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 who completed all required procedures since enrollment began (no further study related contact required): | | | | | |  |
| 1. Are there any participants who provided consent that are no longer participating (no further study related contact required) for reasons other than completion?**YES** **NO** | | | | | | |
| ***If Yes****: Please provide a summarized list below of participants that did not complete the study but have ended participation since enrollment began. 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…)* | | | | | | |
| ***MULTI SITE ENROLLMENT:*** *Do not report any Penn enrollment in this section* | | | | | | |
| 1. Are participants enrolled at external sites not overseen by a Penn PI? | | | | | **YES** **NO** | |
| **IF YES:**  Total target Enrollment for other sites combined: | | | | |  | |
| Current Enrollment for other sites combined: | | | | |  | |
| ***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 persons: |  | | | 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:* | | | | | | |
| **RACE & ETHNICITY BREAKDOWN**: | | | | | | |
| **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. **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 IRB website* [*How to Submit Continuing Review*](https://irb.upenn.edu/continuing-review) *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. 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, the PI and study team conduct all quality control activities which are documented with a [PICA REDCap form.](https://redcap.med.upenn.edu/surveys/?s=RTJHWJ78973DEXYW) | |
| * + - 1. Were there any deviations in the past approval period that met the IRB’s criteria for expedited reporting?   **NO**  **YES**  ***IF YES*** *- Within your cover*  *letter / 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 deviations have been individually assessed by the PI (or delegated co-I) in context of the IRB’s criteria for expedited reporting     **YES**  **NO\* -***please explain in*  *your progress report* |  | 1. The PICA for this year 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. As a result of completing the PICA form: Are there any new, unresolved, or ongoing issues that were identified?   **NO**  **YES**: *Within your cover letter / progress*  *report, please describe these issues and*  *any associated corrective actions*   1. Were there any deviations in the past approval period?   **NO**  **YES**  ***IF YES*** *- Within your cover letter / progress report, please provide a summary of* ***all*** *deviations that occurred in the past approval period. Discuss any related corrective and preventative actions that were taken.* ***Your summary should distinguish major deviations from minor deviations*** *and include PI (or delegated co-I)* *assessment of whether the events had an adverse impact on the following:*   * *participants’ rights,* * *participants’ welfare /safety (including any potential or actual harm), and* * *the scientific integrity of study* | |
| *\*If while preparing the continuing review submission you identify a deviation that meets the criteria for expedited reporting to the IRB and was not previously reported, please submit a separate deviation submission. For more guidance on events that require real time reporting to the IRB please refer to the* [*IRB website.*](https://irb.upenn.edu/Deviation) | | | |

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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 Penn Faculty, Penn Department, or the University?*** | **YES: answer 2a**  **NO** (i.e., Sponsor is external to the University, 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. **Safety Monitoring** (required for greater than minimal risk research) | **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 a **non-Penn** 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** |
| 1. Were there any adverse events that occurred in the past approval period that met the IRB’s criteria for expedited reporting?   ***Please see*** [***https://irb.upenn.edu/reportable-event***](https://irb.upenn.edu/reportable-event) ***for guidance on what events require expedited reporting to the IRB.*** | |
| **YES:** *Within your cover letter / 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** | |
| 1. Please confirm that all adverse events have been individually assessed by the PI (or delegated co-I) in context of the IRB’s criteria for expedited reporting?   **YES**  **NO\*,***please explain:* | |
| *\*If while preparing the continuing review submission you identify an adverse event that meets the criteria for expedited reporting to the IRB and was not previously reported, please briefly note above and submit a separate reportable event submission. For more guidance on events that require real time reporting to the IRB please refer to the* [*IRB website.*](https://irb.upenn.edu/reportable-event) | |

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| 1. **Risk-Benefit Assessment** | |
| 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 Form Completion- This section not required if submitting via HSERA**   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. ([Click to review PI responsibilities](https://irb.upenn.edu/wp-content/uploads/2023/05/Principal-Investigators-Acknowledgement-of-Responsibilities-2023.pdf)) |

Principal Investigator Signature: Date:

Name of Person Completing this Form:

Signature of Person Completing This Form: Date:

*\*Reminder: Before submitting, please revisit the requirements section on Pgs. 1 -3 to assure all necessary elements have been addressed. \**

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| **THIS SECTION FOR EXPEDITED AND ADMINISTRATIVE IRB USE ONLY** |

**APPROVED VIA EXPEDITED IRB REVIEW:**

**Issues Identified – Referred to IRB staff with instructions**

**Signature of Expedited Approver: DATE:**