**Institutional Review Board**

Phone: 215-573-2540

**Modification Application**

FULL PROTOCOL TITLE**:**

PROTOCOL **#:**

PENN PRINCIPAL INVESTIGATOR**:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Federal regulations require IRB approval before implementing proposed changes, including any alteration in content or form to the protocol, consent form or supportive materials (Investigator’s Brochure, questionnaires, surveys, recruitment materials, study personnel list etc.…)  **Before completing this form, please review the IRB guidance on submitting** [**modifications**](https://irb.upenn.edu/homepage/how-to-submit/modifications)**.**  ***Please note: If your continuing review submission due date is approaching, please review guidance under “Can I submit a modification at the same time as a continuing review?” Online here:*** [***https://irb.upenn.edu/homepage/faqs/continuing-review-faqs***](https://irb.upenn.edu/homepage/faqs/continuing-review-faqs)**.**  **DOCUMENTS REQUIRED FOR MODIFICATION APPROVAL: Please provide one copy of the following:**   * Completed IRB Modification Form *(paper submissions must be physically signed by the PI)* * A summary of changes that outlines all changes and provides rationale for each revision. Please see the IRB website for [how to draft a summary of changes](https://irb.upenn.edu/wp-content/uploads/2023/02/How-to-Draft-a-Modification-Summary-of-Changes-.pdf) & *consider using the* [*Summary of Changes template*](https://irb.upenn.edu/wp-content/uploads/2023/02/Summary-of-Changes-Template.docx). * Applicable source documentation for the changes, when applicable (e.g., revised IB for ICF risk changes) * Tracked changes versions of all amended documents * Clean versions of all amended documents * Any new documentation that has not yet been submitted to the IRB (*please ensure new documents are identified as such*) * All submissions for studies determined to be Greater Than Minimal Risk by the IRB must include a complete list of documents being submitted for review as they should appear in your determination letter (document name, version #, date). *If there are multiple consent forms, please ensure they are clearly differentiated.* | | | | | |
| 1. **Who should the IRB contact with questions?** *Note: If Penn is serving as the Single IRB (IRB of Record) for a multi-site protocol, please list the name and contact information for the designated Point of Contact who is creating and submitting this modification in HSERA.* | | | | | |
| Name: | | | Telephone: | | |
| Email: | | | | | |
| Is this a multi-site study where Penn is serving as the Single IRB or IRB of record for external sites? | | | | | **YES** **NO** |
| ***If Yes,*** is this a study-wide amendment? (i.e. does this modification affect all sites?) | | | | | **YES** **NO** |
| ***If this is not a study wide amendment,*** please indicate which sites are affected by the modification in the text box below and provide the names, email addresses & phone numbers for the site Investigator and Study Contact that the IRB can contact with questions related to the substance of the modification. | | | | | |
|  | | | | | |
| 1. **The purpose of this amendment is to:** *(please select all that apply)* | | | | | |
| Update Personnel- *if this is the ONLY change being submitted; please only check this box, skip to the personnel change section and continue completing the form. All personnel changes must also be made in the HSERA application.*  Submit revisions to/ addition of study documents and/or procedures (*provide a summary of the changes below or in a separate cover letter. Consider using the* [*Summary of Changes template*](https://irb.upenn.edu/wp-content/uploads/2023/02/Summary-of-Changes-Template.docx))  Provide regulatory documentation that does not alter study activity (e.g., administrative updates)  Respond to IRB stipulations from a previous review *(please provide original submission date below or confirmation code in cover letter)* | | | | | |
| ***If you need to submit a Reportable Event or a Deviation do not complete this form. Please see:***[***IRB website guidance***](https://irb.upenn.edu/homepage/how-to-submit) ***on how to submit these types of submissions.*** | | | | | |
| 1. **Amendment Summary** | | | | | |
| 1. This amendment requires the following level of review: | | | | | |
| 1. In the box below please **provide a rationale for level of IRB review.** Please alsoprovidethe **summary of changes for all documents** being revised**.** The summary of changes **should include rationale** for the changes**.** The summary of changes can be provided below or in a separate word document. | | | | | |
| 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. Does the modification involve changes to the investigational product or its management (e.g., new product being added, changes to dosing, administration, design, formulation, preparation, etc.)? | | | | **YES** **NO** | |
| If Yes, please briefly explain the changes: | | | | | |
| 1. Does this study utilize the hospital pharmacy or IDS? | | | | **YES** **NO** | |
| 1. **Current status of study** | | | | | |
| Enrollment Status *(please check only one)*  Study has not begun (no subjects consented)  Open to subject enrollment  Closed to subject enrollment | | | | | |
| 1. **Current Penn enrollment:** *to be completed only if this is NOT a multi-site study where Penn serves as the IRB for record for external sites* | | | | | |
| Total number of subjects consented at Penn: |  | | | | |
| Number of active subjects: |  | | | | |
| Number of subjects in follow up: |  | | | | |
| Number of completed subjects *(please include any screen failures, withdrawals, etc. in this section):* |  | | | | |
| 1. **Current study wide enrollment:** *to be completed only if this IS a multi-site study where Penn serves as the IRB for record for external sites* | | | | | |
| Total number of subjects consented at sites relying on Penn IRB that are affected by this modification: | |  | | | |
| Number of active subjects: | |  | | | |
| Number of subjects in follow up: | |  | | | |
| Number of completed subjects: | |  | | | |
| 1. **Changes to the consent form and re-consent plan:** | | | | | |
| Does the current modification change the content of the consent form? | | | | | |
| ***If yes,*** *please indicate the re-consent plan:*  N/A- no subjects enrolled  Our site plans to re- consent all subjects (active, follow-up, and completed subjects)  Our site plans to re- consent only a select number of subjects. Please explain below  Our site does not plan to obtain re-consent | | | | | |
| Please provide rationale for the chosen re-consent plan in the box below: | | | | | |
|  | | | | | |
| 1. **Alteration of the risk/benefit profile of study:** | | | | | |
| Please comment on whether any elements of the amendment pose any new or increased risk to subjects. When making this determination, please consider how the amendment may affect any previous determinations such as exemptions from IND or IDE regulations, or a non-significant risk (NSR) determination made by the IRB. | | | | | |
|  | | | | | |
| 1. **Changes to personnel:** Any changes shown here should also be made on the Personnel page in HSERA | | | | | |
| No changes to personnel  Removing personnel-please list in summary of changes document and indicate whether any study documents require revision (Emergency Contacts in ICF, recruitment contacts etc…)  Updating CITI training for existing personnel-please list in summary of changes that accompanies this modification and provide renewed CITI training reports/certificates  Adding new personnel   * Please refer to guidance here: [https://irb.upenn.edu/documents/personnel-modification-guidance](https://irb.upenn.edu/documents/personnel-modification-guidance/) * Please include the name, affiliation, and role in the study for all staff being added in your summary of changes document that accompanies this modification. * Please ensure any new personnel that are “responsible for the design, conduct, or reporting of the research” disclose financial interests in [RIA](https://apps.research.upenn.edu/login), when prompted by the system. * **If a change of PI is being submitted, a letter indicating transfer and acceptance of PI responsibilities is required with signatures from both the former and current PI.** | | | | | |
| *The IRB requires documentation of completed CITI training for the Human Subjects Research curriculum for all personnel; please include reports for each person added to the protocol. If you require assistance in obtaining CITI training please see* [*the IRB website guidance*](https://irb.upenn.edu/mission-institutional-review-board-irb/guidance/citi-training)*.* | | | | | |
| **Completion of modification: (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 has disclosed to the IRB all relevant information that might affect the analysis of this study. | | | | | |

Name of person completing this form:

Signature of person completing the form:

Principal Investigator Name:

Principal Investigator Signature:

Date: