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 see the IRB guidance on submitting modifications

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
- Applicable source documentation for the 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

- All IRB submissions for Greater Than Minimal Risk research must include a complete list of documents being submitted for review as they should appear in your determination letter (document name, version #, date)

A. 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.

<table>
<thead>
<tr>
<th>Name:</th>
<th>Telephone:</th>
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<tbody>
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<td>Email:</td>
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If this is 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.

B. The purpose of this amendment is to: (please select all that apply)

Commented [A1]: This has been added to ensure compliance with modification requirements. The link provides access to a guidance document.
If you need to submit a Reportable Event or a Deviation do not complete this form. Please see: IRB website guidance on how to submit these types of submissions.

C. Amendment Summary

1. This amendment requires the following level of review:
   Click to choose response

2. In the box below please provide a rationale for level of IRB review. Please also provide the 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.

3. 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)

   a. 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:

   b. Does this study utilize the hospital pharmacy or IDS? □ YES □ NO

D. Current status of study: (please check only one)

□ Study has not begun (no subjects consented)
□ Open to subject enrollment
□ Closed to subject enrollment

E. 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):

F. 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:

Commented [A2]: Added as a reminder that all research staff need to be reflected in the application.

Commented [A3]: Question updated for clarity.

Commented [A4]: This new question has been added in support of IDS and pharmacy communications. The IRB may remind you to inform IDS of the approval of this modification prior to implementing it.

Commented [A5]: Added for clarity
### Number of active subjects:

### Number of subjects in follow up:

### Number of completed subjects:

### G. Changes to the consent form and re-consent plan:

Does the current modification change the content of the consent form? **Click to choose response**

- 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:

### H. 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.

### I. Changes to personnel:

**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 include the name, affiliation, and role in the study for all staff being added in your summary of changes document that accompanies this modification. **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.*

**Are there any changes to previously reported financial interests or newly identified significant financial interests that require reporting related to these personnel changes?**

**Click to choose response**

*If yes: please ensure any new conflicts or changes to existing conflicts are documented on the Personnel page of your HSERA application and reported to the Office of the Vice Provost for Research through FIDES.*

**Commented [A6]: Added to ensure compliance with reporting conflicts**
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:

FOR EXPEDITED AND ADMINISTRATIVE IRB USE ONLY

☐ ACKNOWLEDGED ☐ APPROVED EXPEDITED ☐ Issues Identified – Referred to IRB Staff with Instructions

Notes:

Signature of Final Reviewer:

DATE: