1.0 Purpose
The purpose of this SOP is to describe the process for requesting changes to an approved protocol.

2.0 Policy
It is the policy of the IRB that review of all requests for changes in approved protocols will be conducted in full accordance with regulations at Health and Human Services 45 CFR §46.

2.1 Introduction
Any proposed change in a protocol which affects the human participants must be reviewed and approved by the IRB prior to implementation except when an immediate change is necessary to eliminate a hazard to the participants, or to provide participants with new information on adverse events or research results considered essential to a participant’s decision whether to continue participating.

2.2 Submission Requirements
Investigators must submit:
A. IRB Request for Change in Protocol form on-line via NUgrant.

B. Complete description of the changes requested.

C. Revised protocol (as appropriate).

D. Revised consent/assent document(s) (as appropriate).

[NOTE: The IRB files must contain a complete and accurate description of the research. Therefore, changes indicated in the Request for Change in protocol must be described clearly.]

E. When a change in protocol is the result of a new or revised grant application, a copy of the complete grant narrative must accompany the Request for Change form.

2.3 IRB Review
As a Request for Change in Protocol form is received in the HRPP office, the IRB staff will pre-review and document the requests to determine whether the requested change is indeed minor.
A. The change is minor in nature and the risk to the participant is minimal. Examples of minor changes include: changes in telephone numbers, addition or deletion of staff, correction of typographical errors, and addition of procedures found on the expedited review list (e.g., minor change in eligibility requirements, deletion of an intervention, and change in follow-up schedules). Minor changes are approvable
under expedited review. It must be documented that it is a minor change. While re-consent of current participants utilizing the revised IRB-approved consent document is normally not required by the IRB, the PI must provide a plan, as necessary, for notification of current participants.

B. The change is **major**, but does not require immediate implementation in order to reduce a hazard to participants. Examples of major changes include: changing the treatment or revising eligibility requirements. The changes cannot be implemented until reviewed by the full IRB for **full board** projects. Re-consent of current participants utilizing the revised IRB-approved consent document or addendum is normally required.

C. The change is **significant** and requires **immediate implementation** in order to decrease risk to participants and requires full disclosure to the participants immediately. These changes may include: addition of a major risk resulting from a reported adverse event or other major changes enacted to reduce risk to participants. Re-consent of current participants utilizing the revised IRB-approved consent document or addendum is required. A witness is required during the re-consent process.

All IRB members have access to all submitted materials for the review of modifications to previously approved research by the convened IRB via NUgrant. It is expected that primary and secondary reviewers will perform an in-depth review of all pertinent documentation. All other IRB members will review all provided materials in enough depth to discuss the information at the convened meeting. (HRPP Policy 2.009)

When conducting review using the expedited procedure, the reviewer has access and reviews all submitted information including the complete protocol history via NUgrant. The reviewer(s) complete the Institutional Review Board – Change in Protocol checklist to determine whether the modifications meet the criteria allowing review using the expedited procedure, and if so, whether the research with the proposed modifications meets the regulatory criteria for approval. (HRPP Policy 2.009)

For full review, at the meeting, the primary reviewer presents an overview of the modifications and leads the IRB through the completion of the regulatory criteria for approval. (HRPP Policy 2.009)

### 2.4 Change to Eliminate Immediate Risk Prior to IRB Approval

If a change is initiated without any IRB approval in order to eliminate immediate hazards to the participants or to provide essential information to the participants, the IRB must be notified as soon as possible, but no later than two (2) business days from the time the change was initiated. If the change was initiated for all participants, the IRB Request for Change in Protocol must be completed.

1. The investigator is authorized to implement changes without IRB approval in order to eliminate apparent immediate hazards to participants.
2. The IRB chair or designee has no authority to approve more than minor changes even if needed to eliminate immediate hazards to participants.
**Administrative Approval:**

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<tr>
<th>Dan R. Hoyt, Ph.D.</th>
<th>Kimberly Andrews Espy, Ph.D.</th>
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<tbody>
<tr>
<td>IRB Chair</td>
<td>Associate Vice Chancellor for Research</td>
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