1.0 Amendment (Protocol Revision)

An amendment involves any changes, or additions, to be made in a protocol, whether initiated by the investigator or a study sponsor.

Examples of amendments may include, but not limited to, a change or revision to any of the following:

- Procedure
- Drug dose
- Number of participating subjects
- Length of participation
- Changes in location
- Changes in focus group interview questions
- Changes in approved research initiated without prior IRB approval to eliminate apparent immediate hazards to the participant
- Principal investigator/sub-investigator/study coordinator
- Administrative issues
- Changes in study status (i.e. enrollment suspension, study hold, closure to enrollment)- please note this type of amendment must be submitted within 5 business days of notification

Revisions include changes in the study team, laboratories, sites, etc. or it may be part of an amendment that requires a revised informed consent document or other research document (see Research Documents Policy).

Implementation of Amendments

Amendments must be approved in writing by the IRB prior to its enactment. Conduct of the study under the revised protocol may not proceed until the IRB approval is granted. An exception can only occur when changes to eliminate an apparent immediate hazard to subjects must be implemented for the safety of the subject.

2.0 Levels of Review for Amendments

Amendments may be reviewed by the IRB via the expedited procedure or review by the fully convened IRB.

Amendments reviewed via the expedited procedure

The following examples are amendments that would allow expedited review:

- Central lab changes
- Study coordinator/Sub-investigator/Admin contact changes
Amendments reviewed by the fully convened IRB

The following examples include, but are not limited, to amendments that would require by the fully convened IRB:

- Changes in the dosing regimen (i.e., amount, number of times, etc.)
- Any increased risk to subject whether the risks involve physical, psychological, social, economic, confidentiality risks, etc. (i.e., increased number of blood draws, more procedures, adverse events, etc.)
- Addition of a vulnerable population (adding pediatric subjects to an approved protocol is a major change and requires full Committee review)

Amendments to Exempt Protocols

Amendments are not allowed for protocols that have received an exemption. If the revision to the protocol changes the scope of the study, a new protocol must be submitted for review by the expedited procedure. Review the IRB policy regarding exempt protocols for more information

3.0 How to Submit an Amendment

Amendments must be submitted via the electronic IRB submission system. Other forms or support documentation may be necessary.

If the protocol was initiated by industry or a cooperative group, it is highly recommended that investigators indicate the date the amendment was received. A memo indicating a summary of the changes to the protocol should be submitted.

If specific wording is required for amendment approval letters, the PI must request this via a cover memo submitted with the amendment.
Revised Informed Consent Document/Children’s Assent Documents

A protocol amendment may require a revision to the Informed Consent Document (ICD) and/or Children’s Assent Document (CAD). The revised ICD and/or CAD must be submitted to the IRB and must be in compliance with current IRB Policies and Procedures. To ensure faster routing and approval, provide a copy of the ICD and/or CAD of all changes noted. Changes must be noted by using the track changes feature in Microsoft Word or other software. A document listing all changes is strongly encouraged and appreciated.

The approved, stamped copy must be used for to enroll participants.

ICD Addendum
Sometimes an amendment may only require an ICD and/or CAD addendum. All revisions must be in compliance with current IRB policies and procedures and should follow the same formatting procedures as the original ICD and /or CAD. A listing of all changes is also encouraged. These are only to be used if the protocol has enrolled subjects who must be informed of small changes to the conduct of the protocol.

Subject Information Letters
This letter may be requested in situations where the study is no longer in the enrollment phase and new subjects will not be added. The purpose of this type of letter would be to provide current subjects with information regarding personnel changes. A listing of all changes is also encouraged.

Subject Newsletter
Newsletters and informational material provided to currently enrolled subjects must receive approval from the IRB before the newsletter/information material is distributed to subjects. The manner of distribution (mail, email, etc...) must also be described in the amendment to ensure the information is transmitted in a secure manner that is compliant with privacy regulations.

If the newsletter will be distributed electronically, the following must occur:
1. The subject must be given the opportunity opt-out of receiving study oriented newsletters. This may be done via a section in the IRB approved informed consent document or an enrollment form.
2. The newsletter must be approved by the IRB before it is distributed to those subjects who wish to receive newsletters (electronic or printed).
3. All electronic correspondence with the subject must be sent blind copying (“bc”) the subject.

Revisions to Protocol Title
Revisions to a protocol title may be submitted via a protocol revision.
**Personnel Changes**

Personnel changes may include the following:

- Sub-Investigator (Sub-I)
- Study Coordinator (SC)
- Name changes due to marriage or divorce

Personnel changes must be approved by the IRB prior to the individual performing any study-related duties. Changes to the Principal Investigator are submitted as a protocol revision.

When adding new members to the research team, please confirm that they have completed the required web-based education program initially or the recertification part of the CITI program prior to IRB submission.

Individuals who are not affiliated with GRU or the CNVAMC should submit documentation of the clinical research education required by their institution. If their institution does not require research education, they must complete the GRU-CITI program. If a non-affiliated individual is not associated with an institution which holds a Federal Wide Assurance (FWA), they must sign an Individual Investigator Agreement (IIA) located on the IRB Office website.

For research conducted in the GR Medical Center, the PI is responsible for notifying the GR Medical Center Investigational Pharmacy if the personnel change affects study drug dispensing and the Division of Sponsored Program Administration (DSPA) if the personnel change affects the budget.

For research conducted at the CNVAMC, the PI is responsible for notifying the Augusta VAMC Pharmacy and the Augusta Biomedical Research Center (ABRC).

**Amendments that Affect the Budget**

A protocol amendment may affect the budget for the study. If the protocol will utilize GR Medical Center resources (e.g., patients, personnel, equipment, space, supplies or records) and will have an impact on the budget, the amendment must be submitted to the GR Research Development Services Office for their review prior to submitting the amendment to the IRB. For more information on their submission requirements, please view their web page.

**Amendments for Closed Protocols**

If a study has been closed for 90 days or less, the PI is responsible for submitting any sponsor-issued amendments to the IRB.
Amendments that May Require Scientific Review

If the protocol amendment involves a significant change in the objectives, study, arms, and/or statistical analysis plan, the IRB may require review by the Department Chair or Scientific Review Committee for the Center/Department, if applicable.

4.0 Approval of Amendments

Approval timelines

Expedited Amendments: the processing and approval time for expedited amendments is 7 to 10 business days, if there are no stipulations based on the administrative review or review by an IRB reviewer.

Full Review Amendments: the processing and approval time for amendments that require review and discussion at the fully convened IRB meeting is dependent upon the submission date and the date of fully convened IRB meeting.