

PARKVIEW HEALTH	INSTITUTIONAL REVIEW BOARD MANUAL
Policy & Procedure Title: Amendments Category: IRB Review Process	

I. Policy Statement

"An IRB shall review and have authority to approve, require modifications in, or disapprove all research activities covered by these regulations." ([21 CFR 56.109](#)) ([45 CFR 46.109](#))

II. Definition of Terms

(This section intentionally left blank.)

III. Procedure

- A. Amendments to previously approved Protocols may not be initiated until PH IRB approval has been obtained, except where necessary to eliminate apparent immediate hazards to the subject.
- B. When any revision to an approved research Protocol, written consent form, Investigator's Brochure (IB) revision, Sub-Investigator change or addition and/or advertisement for subject recruitment is desired, an Amendment form must be filed with the PH IRB.
 1. To request an Amendment approval, the Investigator must submit an Amendment Submission Form.
- C. The form must be completed indicating the changes, revisions within the Protocol itself, the written consent form, updated IB, Sub-Investigator change or the advertisement.
 - The form should explain what changes have been made and the rationale for the change.
 - A revised copy of the pertinent original documents (Protocol, consent form, IB and/or advertisement) should also be submitted with the changes highlighted.
 - When an IB is submitted for revision, a current version of the Informed Consent Form must also be submitted.
- D. The PH IRB reserves the right to determine if proposed changes are substantive and to request further information or a new Protocol submission, as appropriate.
- E. Amendments usually require full PH IRB review at the scheduled monthly meetings; therefore, the regular submission deadlines must be met.
- F. An Amendment may be submitted for expedited review. At the discretion of the PH IRB Chair, Amendments of a non-substantive nature may be

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acknowledged by a letter of Expedited review approval sent to the Investigator and recorded in the PH IRB files.

- All Protocol Amendments and/or consent forms approved through Expedited review will require full PH IRB review at the next scheduled monthly meeting. (See Expedited Review List of Categories and Checklist for Expedited Review.)

G. Generally, an alteration in a Protocol will be approved as long as the proposed changes do not affect the intent or stated purpose of the original Protocol and are within the parameters utilized for patient protection in the original Protocol.

- A change in Protocol may require a revised informed consent.

H. The Investigator and when appropriate, the institution, will be notified in writing of the status of the Amendment.

IV. References

A. [21 CFR 56.109](#)

B. [45 CFR 46.109](#)

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