

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

I. Policy Statement

In accordance with federal regulations, continuing review and approval is required for all studies reviewed by PH IRB until final study closure has been granted to ensure the rights and welfare of human subjects are protected.

II. Definition of Terms

(This section intentionally left blank.)

III. Procedure

- A. PH IRB shall conduct Continuing Reviews of research at intervals appropriate to the degree of risk (set at the initial review), but not less than one year. There is no provision for a lapse or grace period per federal regulations.
- B. Continuing Review requests shall be submitted on the Continuing Review Form and must be received by PH IRB by the PH IRB Submission Deadline to be placed on the PH IRB Meeting Agenda. This document is provided to Investigators at the time of Continuing Review notice, and sent electronically, mailed or faxed to Investigators upon request.
 1. Investigators are responsible for submitting a Continuing Review Form prior to the expiration date of PH IRB approval.
 2. At the time of initial PH IRB approval, PH IRB will include the study expiration date in its approval letter to the Principal Investigator.
 3. If not received, and study approval automatically expires, the PH IRB will provide a written notice of study suspension to the Investigator, Institution, Sponsor, and FDA/OHRP, as appropriate. (See PH IRB P&P Suspension or Termination of IRB Approval of Research)
- C. The PH IRB shall determine that all the following criteria be satisfied for the Continuing Review and renewal of ongoing research:
 1. The risks to subjects continue to be minimized and reasonable in relation to anticipated benefits.
 2. The selection of subjects continues to be reasonable in relation to anticipated benefits.
 3. Informed consent continues to be appropriately documented.
 4. Provisions for safety monitoring of the data are in place.
 5. Protections to ensure the privacy of subjects and confidentiality of data are adequate.
 6. Appropriate safeguards are in place for vulnerable populations.
 7. Other issues the PH IRB may consider appropriate to the study and information at hand.

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- D. PH IRB's Continuing Review of ongoing research must be substantive and meaningful and will be based upon the information obtained in the Continuing Review Form including but not limited to:
1. Total number of subjects enrolled, withdrawn, completed, and in ongoing follow-up;
 2. If the Protocol has been amended since last approval, a brief explanation of the revision and amendment number;
 3. Occurrence of any serious adverse events, unanticipated problems, or hospitalizations in the past year or since last approval listed by type and date of event, patient initials and a brief summary of the event;
 4. Comments regarding research results obtained thus far;
 5. Reports of any significant new findings relevant to the study and subjects' willingness to continue participation;
 6. Copy of current version of the informed consent form;
 7. Annual review and / or reports from any sub-committees as required, if not previously submitted, (for example, Bio-Safety Committee)
 8. A review of the Continuing Review period based on the materials presented at Continuing Review. The PH IRB will determine the Continuing Review period at the time of each Continuing Review.
 9. Other information provided by the site, or as requested by the PH IRB for consideration.
- E. The PH IRB may obtain verification of the information on the ongoing research from other sources, such as the research Sponsor, if;
1. The current risk-benefit assessment is greater than the anticipated degree of risk,
 2. The occurrence of serious adverse events is greater than anticipated, and/or,
 3. The validity or quality of the Continuing Review Form information is in question.
- F. PH IRB Members will receive the Continuing Review Form and current consent form. In addition, any PH IRB Member will have access to the relevant PH IRB File(s) and PH IRB Meeting minutes upon request.
- G. Upon receipt of the complete Continuing Review Form and attachments (current informed consent must be attached), the PH IRB Office will place the request on the PH IRB Meeting Agenda. The Investigator will be notified of the date of review.
- H. The PH IRB may ask the Principal Investigator or designee to attend the Meeting to answer questions concerning the Continuing Review.

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- I. The Continuing Review will be reviewed, deliberated and discussed in the same manner as the original review and approval and the minutes will reflect separate deliberations, actions and votes for each Protocol undergoing Continuing Review by the convened PH IRB.
- J. Based on its review of the information submitted at Continuing Review, the PH IRB will take one of the following actions for each individual Study:
 - 1. Approve the Study for continuation
 - 2. Approve the Study with modifications
 - 3. Suspend the Study
 - 4. Terminate the Study
- K. Following the PH IRB Meeting, the Investigator, and when appropriate, PH will be notified in writing of the ongoing research status. The PH IRB correspondence will include the new approval period (dates) and any conditions of re-approval.
- L. If a Continuing Review Form and supporting material have not been received prior to the PH IRB deadline date of the month the study is to expire, the Study will be placed on the agenda of that month's PH IRB Meeting for determination of suspension or termination. (See PH IRB P&P: Suspension and Termination of a Protocol)
- M. Should there be a failure to obtain re-approval of a study prior to the expiration date of the preceding approval period, all unapproved research activity must cease until re-approval is established. This may be reported by PH IRB to the Sponsor and FDA/OHRP, as appropriate.
 - The Investigator may resume the research when the proper review has been completed and written notification of renewed approval from the PH IRB has been received.
- N. Re-approval cannot be expedited unless the initial approval met expedited criteria and was approved in that manner, except in limited circumstances. It is also possible that research activities that previously qualified for Expedited Review will have changed or will change, such that Expedited Review would no longer be permitted for Continuing Review. (See PH IRB P&P: Expedited Review)

IV. References

- A. [21 CFR 56.109](#), [21 CFR 56.111](#)
- B. [45 CFR 46.109\(e\)](#), [45 CFR 46.111](#)
- C. OHRP- Guidance on Continuing Review (01-15-07) at:
<http://www.hhs.gov/ohrp/humansubjects/guidance/contrev0107.htm>

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- D. OHRP – Guidance on Written IRB Procedures (01-15-07) at:
<http://www.hhs.gov/ohrp/humansubjects/guidance/irbgd107.htm>
- E. FDA Information Sheets – Continuing Review After Study Approval (1998)
at: <http://www.fda.gov/oc/ohrt/irbs/review.html>

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