

PARKVIEW HEALTH	INSTITUTIONAL REVIEW BOARD MANUAL
Policy & Procedure Title: Review of Research 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](#))

PH IRB has the authority to perform the following functions:

- Conduct initial and continuing review of any research activities involving drug, device, biological, behavioral, psychosocial, educational, or other studies involving human subjects prior to the start of the research.
- Report findings and actions to Investigator and Sponsor, when applicable.
- Determine which studies need more than annual review.
- Determine which studies need verification from sources other than the Investigator that no material changes have occurred since previous PH IRB review
- Insure prompt reporting to the PH IRB of changes in research activities.
- Insure that changes in previously approved human subject research are not initiated without PH IRB review and approval
- Insure prompt reporting to the PH IRB of unanticipated problems or scientific misconduct involving risks to subjects or others.
- Review and ensure the adequacy of the informed consent document and process.
- Review and consider requests for Consent and/or HIPAA waivers, and HIPAA authorizations incorporated into the informed consent.
- Suspend or terminate the research or revoke approval of any study under its review.

To assist Investigators in the submission process, the PH IRB Policy and Procedure Manual is available from the PH IRB Office upon request.

II. Definition of Terms

Research: A systematic investigation designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research even if they are a component of a larger non-research activity (e.g., instruction, demonstration).

Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Emergency Use: The use of a test article on a human subject in a life-threatening situation in which no standard acceptable treatment is available, and

Origination Date: 04-2007 Revision Date(s): 04/09	Source: PH IRB Authorized by: Institutional Official
------------------------------------------------------	---------------------------------------------------------

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

in which there is insufficient time to obtain FDA or PH IRB approval.

PH IRB Approval: The determination of the PH IRB that a clinical study involving human subjects has been reviewed and may be conducted at the specified site(s) under the provisions set forth by PH IRB, local, state and federal regulations, guidelines and rules.

HIPAA: Means “Health Insurance Portability and Accountability Act”. A section of HIPAA mandates standards for the storage and transmission of health care information in certain situations. Two requirements for research and PH IRB purposes are:

- The addition of required elements in order to waive informed consent if protected health information (PHI) is used.
- Specific information related to the use of subject data must be contained in the consent form.

III. Procedure

- A. A request to administer investigational techniques, devices or medications shall be submitted in the form of a Protocol which shall contain a statement of the objectives of the procedure, the criteria for selecting the subject, a detailed explanation of all procedures, specific instructions for implementing all procedures and a written informed consent to be signed by the volunteer subject. The Protocol shall be accompanied by such data and reports of prior studies as may be of assistance in determining the potential risks and potential benefits involved in the procedure.
- B. All Protocols for investigation and research involving human subjects conducted at PH will be reviewed and approved by the PH IRB prior to initiation of studies.
1. Approval of clinical research Protocols by PH IRB is not in itself a commitment or approval by the institution(s) where the research will be done for the use of the institution’s facilities or personnel for the research.
 2. Institutional approval must be obtained prior to PH IRB review of the research. Parkview Health Clinical Research Proposal Form (PHCRPF) shall be completed by the Investigator and submitted to the PH IRB Office for such approval.
 3. Parkview Health Administration shall have the right to disapprove any Protocol prior to implementation.
 4. Disapproval by the PH IRB may not be overruled by the PH Administration.

Origination Date: 04-2007 Revision Date(s): 04/09	Source: PH IRB Authorized by: Institutional Official
------------------------------------------------------	---------------------------------------------------------

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

- C. The PH IRB shall determine that all the following criteria be satisfied to approve the research:
- Risks to subjects are minimized;
 - Risks to subjects are reasonable in relation to anticipated benefits;
 - Selection of subjects is equitable;
 - Informed consent is adequate and appropriately documented;
 - Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects;
 - Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data; and
 - Appropriate additional safeguards have been included to protect vulnerable subjects.
- D. Focused attention will be placed on studies involving:
- Vulnerable populations or studies where the PH IRB feels a population warrants additional considerations
 - Use of placebos
 - Challenge studies
 - Radiation exposure
 - Deviations from standards of care
 - Significant risk studies
- E. The PH IRB Office will determine the review category of the research (full board review, Expedited (see PH IRB P&P: Expedited Review of Research), or Exempt (from further PH IRB review) (see PH IRB P&P: Exempt Research Protocols).
- F. Full Board Review will be required of all studies involving a vulnerable population (see PH IRB P&P Vulnerable Populations) or involve more than minimal risk to human subjects, and do not qualify for Expedited or Exempt Review.
- G. The Expedited Review process is an alternative to a convened meeting and may be used for those activities listed in PH IRB: Expedited Review- Categories of Research That May Be Reviewed by An IRB through an Expedited Review. Expedited Review is subject to ratification by the full Board at the next convened regularly scheduled meeting.
- H. The complete submission packet will be available to PH IRB Members upon request and will be available to the Members at the PH IRB Meeting.

Origination Date: 04-2007 Revision Date(s): 04/09	Source: PH IRB Authorized by: Institutional Official
------------------------------------------------------	---------------------------------------------------------

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

- I. Information such as the Investigator’s Brochure, other available safety information, etc. will be available to Members prior to the PH IRB Meeting upon request.
- J. Primary Reviewer: Two PH IRB Members will conduct a detailed review of the research study and may discuss any unanswered questions with the Sponsor, PI, or consultants before the full board meeting. ALL Members of the full PH IRB are to receive the consent form and Protocol summary or enough information about the study to conduct a substantive review.
- K. Individuals with experience and competence in special areas may be invited to assist in the review of complex issues which require expertise beyond or in addition to that available on the PH IRB. These individuals may not vote with the PH IRB.
- L. All PH IRB Members voting on a Protocol will be free of conflicting interests with respect to the Protocol, institution, or sponsor involved, and any Member having a conflicting interest in a given Protocol, institution, or sponsor, shall disqualify himself/herself in a given review. PH IRB Members who are Investigators, Sub-Investigators or have a conflict of interest shall leave the meeting room at the time indicated by the Chair for discussion / deliberation and voting.
- M. An Investigator submitting a Protocol, or a person selected by the Sponsor or Investigator, may be present during the PH IRB Meeting in order to provide information the PH IRB may request, but only for that portion of the Meeting pertaining to that specific Protocol. They will be asked to leave the meeting room at the time indicated by the Chair for discussion / deliberation and voting.
- N. Decisions are made independently for each research proposal submitted.
- O. Contingent Approval: When the convened PH IRB recommends clarifications or modifications regarding a Protocol or informed consent that are directly relevant to determinations required by the PH IRB, the approval of the research will be deferred, pending subsequent review by the convened PH IRB of responsive material. When the convened PH IRB stipulates specific revisions requiring simple concurrence by the Investigator, the Chair or another PH IRB member designated by the Chair may subsequently approve the revised research Protocol, consent, or materials on behalf of the PH IRB unless the full PH IRB requests that the item(s) come back for full board review.

Origination Date: 04-2007 Revision Date(s): 04/09	Source: PH IRB Authorized by: Institutional Official
------------------------------------------------------	---------------------------------------------------------

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

- P. Tabling and deferring are considered disapproval of the research until the required modifications have been secured.
- Q. Should a quorum fail during a meeting, the PH IRB may not take further action until a quorum is restored. Loss of quorum can occur due to early departures, absence of a nonscientist, those with conflicts being excused.
- R. Minutes shall be completed for each specific review or meeting.
- S. Parkview Health IRB has established review fees that will be charged for all industry-sponsored research. (See PH IRB Review Fee Schedule and Charging Policy in PH IRB Administrative P&P section.)
- T. To request PH IRB review of a new research proposal a PH IRB New Protocol Submission Form must be submitted. (See PH IRB P & P: New Protocol Submissions.)
- U. Upon receipt of the Protocol application, it will be reviewed by the PH IRB Office for completeness and the Investigator will be notified of any deficiencies. Review of a Protocol could be delayed if further information is required. When preparing a Protocol, it is advisable to contact the PH IRB Office for assistance with any questions in order to ensure an acceptable submission. (See PH IRB Submission Flow Chart.)
- V. The PH IRB requires the Principal Investigator, or his/her designee, to present the Protocol for original approval at the full Board meeting. (See PH IRB Presenter's Format Form.) This Form is to be used when presenting all Protocols to the PH IRB. The PH IRB may request additional information from the Principal Investigator regarding the Protocol at any time during the review process.
- W. 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, a PH IRB Amendment Form must be filed with the PH IRB.
 - To request an Amendment approval, the Investigator must submit a PH IRB Amendment Submission Form. (See PH IRB P & P: Amendments.)
- X. PH IRB approves research for intervals appropriate to the degree of risk but at least annually.
 - To request a Continuing Review of a Protocol the Investigator must submit a PH IRB Continuing Review Form. (See PH IRB P & P: Continuing Review.)

Origination Date: 04-2007	Source: PH IRB
Revision Date(s): 04/09	Authorized by: Institutional Official

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

IV. References

- A. ([21 CFR 56.109](#)), ([21 CFR 56.111](#))
- B. ([45 CFR 46.109](#)), ([45 CFR 46.111](#))

Origination Date: 04-2007 Revision Date(s): 04/09	Source: PH IRB Authorized by: Institutional Official
------------------------------------------------------	---------------------------------------------------------