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.
- Ensure prompt reporting to the PH IRB of changes in research activities.
- Ensure that changes in previously approved human subject research are not initiated without PH IRB review and approval.
- Ensure 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 Policies, Procedures, and Forms are available on the PH IRB Website at irb.parkview.com, and in the PH IRB Online Binder at https://extranet.parkview.com/PHIOB/Pages/default.aspx.

II. Definition of Terms

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

**HIPAA:** Means the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") as supplemented by the Health Information Technology for Economic and Clinical Health Act ("HITECH") and includes the Standards for Privacy of Individually Identifiable Health Information found at 45 C.F.R. Part 160 and Part 164, Subparts A and E and the Security Standards for the Protection of
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.

PH IRB Approval: The determination of the PH IRB that a Research 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.

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

See additional definitions of terms in the PH IRB List of Definitions

III. Procedure

A. A request to conduct Research shall be submitted in the form of a written Protocol which shall contain a statement of the objectives of the Research, the criteria for selecting the subjects, 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 Research.

B. Prior to its initiation, all Research involving human subjects conducted at PH must be reviewed and approved by the PH IRB.
   1. Approval of Research by PH IRB is not a commitment or approval by the institution(s) where the Research will be done for the use of its facilities or personnel.
   2. Institutional approval must be obtained prior to PH IRB review of the Research. A Parkview Health Clinical Research Proposal Form (PHCRPF) shall be completed and submitted to the PH IRB Office for such approval.
   3. PH Administration shall have the right to disapprove any Research at PH prior to initiation.
4. Disapproval of the Research by the PH IRB may not be overruled by PH Administration.

C. The PH IRB shall determine that all the following criteria are 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;
   - There are adequate provisions for monitoring the data collected to ensure the safety of subjects;
   - 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 Research 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 involving more than Minimal Risk to human subjects, and which 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 P&P: Expedited Review-Categories of Research That May Be Reviewed by An IRB through an Expedited Review. All PH IRB Members shall be advised of Research that has been approved under the Expedited Review procedure. A copy of the Research materials shall be provided and will be reviewed at a convened regularly scheduled PH IRB Meeting.
H. All Research submission materials, including Investigator’s Brochures and other available safety information, will be available to PH IRB Members prior to and during a PH IRB Meeting.

I. Two PH IRB Members assigned by PH IRB Staff to be Primary Reviewers will conduct a detailed review of the Research and may discuss any unanswered questions with the Sponsor, PI, or consultants before the PH IRB Meeting.

J. 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.

K. All PH IRB Members voting on the Research must be free of conflicting interests with respect to the Research, Institution, and Sponsor involved, and any Member having a conflicting interest in a given Research, Institution, or Sponsor, shall disqualify himself/herself for that particular 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.

L. The PH IRB will not conduct a full board review of a nursing protocol unless a voting nurse IRB Member without conflict of interest with respect to the nursing protocol is present. In the event there are no nurse IRB Members without conflict of interest with respect to a nursing protocol requiring full board review, the PH IRB will facilitate the review of the protocol by a different IRB.

M. An Investigator submitting Research, 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. They will be asked to leave the meeting room at the time indicated by the Chair for discussion, deliberation and voting by the PH IRB Members.

N. Decisions are made independently for each Research proposal submitted.

O. Generally, when the convened PH IRB recommends clarifications or modifications regarding the Research or informed consent or other Research materials 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.

P. Tabling and deferring are considered disapproval, and the Research must be brought back to a Full Board Meeting for review and decision.
Q. However, when the convened PH IRB stipulates specific revisions requiring simple concurrence by the Investigator, the Research or other matter can be approved contingently pending the Chair, or another PH IRB Member or PH IRB Staff designated by the Chair, confirming that the revision has been made and the concurrence obtained.

R. 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, or those with conflicts being recused.

S. Minutes shall be completed for each specific review or meeting.

T. PH IRB has established review fees. (See PH IRB Review Fee Schedule and Charging Policy.)


V. Upon receipt of the New Protocol Submission Form and accompanying material, it will be reviewed by the PH IRB Staff for completeness and the Investigator will be notified of any deficiencies. Review of Research could be delayed if further information is required. When preparing a New Protocol Submission Form, 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.)

W. When the Research must be reviewed at a convened Full Board PH IRB Meeting, the PH IRB requires the Principal Investigator, or his/her designee, to present the Research at that meeting. (See PH IRB Presenter’s Format Form.) This Form is to be used when presenting all Research to the PH IRB. The PH IRB may request additional information from the Principal Investigator regarding the Research at any time during the review process.

X. When any revision to an approved Research study, such as a revision to the Protocol, written consent form, Investigator’s Brochure (IB) revision, Sub-Investigator change or addition and/or advertisement for subject recruitment is desired, the Investigator must file a PH IRB Amendment Submission Form with the PH IRB. (See PH IRB P & P: Amendments.)

Y. 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.)
IV. References

A. (21 CFR 56.109), (21 CFR 56.111)

B. (45 CFR 46.109), (45 CFR 46.111)