

<b>PARKVIEW HEALTH</b>	<b>INSTITUTIONAL REVIEW BOARD MANUAL</b>
Policy and Procedure: Use of A Centralized IRB	
Category: IRB Review Process	

## I. Policy Statement

Regulations require that IRBs be sufficiently qualified through the diversity of members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its counsel and ability to ascertain the acceptability of the research in terms of institutional commitments, regulations, applicable laws and standards of professional conduct and practice. This responsibility exists regardless of geographic location of the Central IRB relative to the institution conducting the research. When the research involves minimal risk to subjects, the Central IRB must document it has obtained necessary information about the local context through written materials or discussions with appropriate consultants. When the research involves greater than minimal risk, the Central IRB should also document that provisions to protect the privacy and confidentiality of subjects are also adequate.

As needed, use of a Central (non-local, commercial, professional) IRB by a Principal Investigator may be approved by the Parkview Health Institutional Review Board (PH IRB) for Protocols under its jurisdiction, as long as 21 CFR parts 50 and 56, and 45 CFR 46 requirements are met. In all cases, PH IRB retains the right of reviewing any Protocol under its jurisdiction.

## II. Definition of Terms

Central IRB: An independent (non-local, commercial, professional) IRB that performs review of research in a location other than where the research is to be performed. The IRB that conducts reviews on behalf of all study sites that agree to participate in the centralized review process.

## III. Procedure

- A. One or more of the following may be used to ensure the Central IRB is aware of community attitude, community laws and mores pertaining to research:
1. A consultant from that community may participate in the Central IRB deliberations or may be interviewed by the Central IRB Staff or designee, or provide written information. Consultants chosen may include, but are not limited to the following: local PH IRB Char or PH IRB Member, member of the community, or other professional (physician, educator, businessman, clergy, attorney, PH Institutional Official).
  2. Personal knowledge of the local research context on the part of one or more Central IRB members, such knowledge having been obtained through extended, direct experience with the research institution, its subject population, and its surrounding community.
  3. Information received from an Investigator Site Questionnaire.

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4. Discussions with members of the Sponsor Company and / or CRO managing the study.
  5. In addition, when the Central IRB sends a representative or auditor to the site, they may conduct interviews to ascertain the community attitudes, applicable laws, standards of professional conduct and practice, state and local laws, etc.
  6. Periodic discussions with appropriate consultants knowledgeable about the local context.
  7. Regular interaction with one or more designated institutional liaisons.
  8. Review of relevant written material(s).
- B. This participation can be done by telephone call during the Central IRB meeting when possible or by interview prior to the meeting by the Central IRB Administrator or agent of the Central IRB. The Investigator or Sponsor / CRO may also provide the Central IRB with a copy of the site(s) state laws on informed consent and any other applicable state and local laws.
- C. In addition, PH IRB may include participation (either physically or through audiovisual or teleconference) by one or more consultants in convened meetings of the Central IRB. Such consultant(s) will be chosen from those who have personnel knowledge of the local research context, its subject populations and surrounding community.
- D. Qualification of the Investigator is determined by documents submitted by the Investigator and other sources as necessary (i.e. letters of reference, information from the Sponsor, state licensing Board or other regulatory agencies, FDA debarment lists).
- E. Serious Adverse Reactions: The Central IRB and PH IRB are to be informed of the facility to be used in case of an emergency and its distance from the research site.
- F. Continuing non-local review will consist of written reports from the Investigator concerning the conduct of the study, and when possible, by person-to-person contact arranged with the Investigator / staff and may include a visit to the research site by a representative of PH IRB.
- G. Frequency of written reports to PH IRB will be determined by the following:
1. The potential risks to the subjects
  2. The vulnerability of the subjects
  3. The length of the study
  4. Previous experiences with the Investigator.

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- H. When an institution holding an Assurance is participating in research covered by that Assurance, and that institution relies upon the IRB review of another Assurance holding institution, in order to avoid duplication:
1. The review arrangement must be reviewed and approved in writing by the United States Department of Health and Human Services, Office for Human Research Protections (OHRP) and appropriate institutional officials.
  2. The institution relying on another IRB will assure that the particular characteristics of the local context are considered.
  3. No IRB member may hold an equity interest (e.g., partnership, stock, or profit sharing) in the organization providing IRB review.
  4. No member shall be paid more than reasonable benefits for IRB related activities; and
  5. No IRB member may receive compensation or benefits under arrangements that could impede or discourage decision making on behalf of human subjects.
- I. A single Central IRB, or list of “approved” Central IRBs, shall be submitted to PH IRB on an as-needed basis, and on an annual basis for review and continued approval for use. These IRBs may be currently accredited by a national accreditation organization, such as (but not restricted to) Association for Accreditation of Human Research Protection Programs, Inc. (AAHRPP), and must be registered with OHRP.
- J. Revocation of approval of the use of a Central IRB and/or removal from the “approved” list will be considered at the time of notice of any FDA, OHRP, or other federal agency investigations, actions, audits, or warnings involving the Central IRB.
- K. To use a Central IRB, the Investigator must submit a letter to PH IRB requesting the use of a Central IRB. The letter must include:
1. Central IRB contact information
  2. Title of the study
  3. Description of the study
  4. Potential risks to the subjects
  5. Vulnerability of the subjects
  6. Length of the study
  7. Study sponsor contact information
  8. Investigator’s current curriculum vitae (CV)
- L. PH IRB may also request the PH IRB Central IRB Submission Form and the PH IRB Continuing Review Form be submitted for review and approval.
- M. PH IRB may request copies of any review or action taken with the local Investigator.

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- N. Types of studies that qualify for review by a Central IRB may include:
1. Any pharmaceutical studies, including IND studies
  2. Any device studies, including IDE studies
  3. Minimal risk studies
  4. Study-by-study basis, based on the scope of the research activities to be performed at our facility, and the risk to the participant
- O. A written agreement between the Central IRB and PH IRB will document the role and responsibility of the Central IRB along with the Investigator and research site. The Investigator will also comply with the policies and procedures of the Central IRB responsible for the review, approval and oversight of the research, and PH IRB Policies and Procedures as appropriate. The following documentation may be required in order to fulfill this obligation:
1. PH IRB review of the Protocol for our hospital's suitability/feasibility
  2. PH IRB review of the Consent Form
  3. Statement of Principles commitment from the Investigator
- P. While the Central IRB assumes responsibility for oversight and continuing review, the clinical Investigator and the research site retain the responsibility for the conduct of the study.
- Q. The following information may be required from the Central IRB during the course of the study: Items will be checked on the written agreement for inclusion on a study-by-study basis, depending on the scope of research activities, and risk to participants:
1. DSMB (Data Safety Monitoring Board) reports
  2. Notice of all approvals (initial, amendments, continuing reviews)
  3. Study closure
  4. Any FDA, OHRP, or other federal agency investigations, actions, audits, or warnings involving the Central IRB
  5. Any allegations of scientific misconduct, or noncompliance with the federal regulations or the requirements or determinations of the Central IRB involving the local Investigator;
  6. Suspension or termination of IRB approval;
  7. Relevant IRB Meeting Minutes, as requested;
  8. Or, no study related materials at all.

#### **IV. References:**

- A. FDA Guidance for Industry: Using a Centralized IRB Review Process in Multicenter Clinical Trials, 03-2006  
<http://www.fda.gov/cber/gdlns/irbclintrial.htm>

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- B. Division of Human Subject Protections, OPRR: IRB Knowledge of Local Research Context, 07-21-2000:  
<http://www.hhs.gov/ohrp/humansubjects/guidance/local.htm>
- C. [21 CFR 56.114](#)
- D. [45 CFR 46.114](#)