

PARKVIEW HEALTH	INSTITUTIONAL REVIEW BOARD MANUAL
Policy & Procedure Title: IRB Operations Category: IRB Administrative Process	

I. Policy Statement

Parkview Health IRB is responsible for coordinating all PH IRB activity. The address for PH IRB is 2426 East State Blvd., Fort Wayne, IN 46805. For questions or concerns related to PH IRB activities, the PH IRB staff can be reached at (260) 373-8195.

The PH IRB may invite non-voting individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available among the current PH IRB members.

At the discretion of the PH IRB Chairperson, a PH IRB team of reviewers may review new Protocols. A copy of the complete submission is given to each team reviewer including the complete Protocol, informed consent, HIPAA Authorization, any surveys or questionnaires, and materials to be given to subjects. A copy of the complete Protocol must be available to all PH IRB members on request.

II. Definition of Terms

(This section intentionally left blank.)

III. Procedure

A. Parkview Health IRB Functions

In accordance with the federal regulations (Cooperative Research), Parkview Health IRB may serve as a multi-institutional IRB for the institutions in Parkview Health. Parkview Health affiliates consist of, in part: Parkview Hospital, Parkview Huntington Hospital, Parkview LaGrange Hospital, Parkview Noble Hospital, Parkview North Hospital, Parkview Whitley Hospital, Orthopaedic Hospital at Parkview North, Parkview Behavioral Health, and Parkview Medical Group.

[The FDA Information Sheets-Guidance for Institutional Review Boards and Clinical Investigators Page 3, 1998 Update](#) states:

"...An institution may agree to delegate the responsibility for initial and continuing review to another institution's IRB. In turn, the IRB agrees to assume responsibility for initial and continuing review. The institution delegating the responsibility for review should understand that it is agreeing to abide by the reviewing IRB's decisions. The delegating institution remains responsible for ensuring that the research conducted within its own Institution is in

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full accordance with the determinations of the IRB providing the review and oversight.”

[The FDA Information Sheets-Guidance for Institutional Review Boards and Clinical Investigators](#) Page 3, 1998 Update continues to state: “...a multi-institutional IRB oversees the research activities of more than one institution in a defined area, such as a city or county. Such an IRB is formed by separate but cooperating institutions and eliminates the need for each facility to organize and staff its own IRB. A variation of this is an IRB that is established by a corporate entity to oversee research at its operating components, for example, a hospital system with facilities at several locations.”

B. Non-local IRB Functions

Parkview Health IRB may serve as a non-local IRB to area institutions not a member of Parkview Health as requested. Parkview Health IRB will follow the cooperative research guidelines as outlined in the regulations. A PH IRB Research Review Form will be completed and submitted to the Parkview Health IRB from the investigator / institution requesting PH IRB review. A written agreement for the Parkview Health IRB review will document the role and responsibility of the PH IRB along with the investigator and research site. The Investigator / Institution will comply with the policies and procedures of the Parkview Health IRB for review and approval of the research.

[The FDA Information Sheets-Guidance for Institutional Review Boards and Clinical Investigators](#) Page 3, 1998 Update states: “...an IRB may review studies that are not performed on-site as long as the 21 CFR parts 50 and 56 are met. When non-local IRB review takes place, the reviewing IRB must document its role and responsibility. A written agreement should be executed between the performance site where the research is to be conducted and the IRB or its institution. The agreement should confirm the authority of the IRB to oversee the study. While the IRB assumes responsibility for oversight and continuing review, the clinical investigator and the research site retain the responsibility for the conduct of the study.”

IV. References

- A. [21 CFR 56.107](#), [21 CFR 56.114](#)
- B. [45 CFR 46.107](#), [45 CFR 46.114](#)
- C. [The FDA Information Sheets-Guidance for Institutional Review Boards and Clinical Investigators](#)

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