

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

I. Policy Statement

Parkview Health IRB supports human subject research and may engage in the Expedited Review of research when appropriate.

The Department of Health and Human Services (HHS) has established a list of categories of research that may be reviewed by an IRB through an Expedited Review procedure.

II. Definition of Terms

Expedited Review: The review of research involving human subjects by the PH IRB Chairperson or designated PH IRB Member or group of PH IRB Members rather than by the entire PH IRB. See Section III of this policy and the HHS list of categories of research that may be reviewed by an IRB through an Expedited Review.

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.

III. Procedure

- A. If Investigators wish Expedited Review of a research proposal, i.e., Protocol, Amendment or Continuing Review, they must submit the completed appropriate submission form to the PH IRB Office as required for PH IRB review.
- B. Expedited Review can take place independently of the scheduled PH IRB meetings.
- C. The PH IRB Chairperson designates those PH IRB Member(s) who may conduct an Expedited Review.
- D. The PH IRB Chairperson or designee is responsible for determining whether a research proposal is eligible for Expedited Review.
- E. Reviewers conducting Expedited Review may exercise all the authority of the PH IRB except to disapprove the research. If the reviewer decides that the request does not meet Expedited Review requirements, or feels the request needs to go before the convened PH IRB, the research proposal must be reviewed by the convened PH IRB.

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- F. PH IRB may use the Expedited Review procedure for certain categories of research involving either or both of the following:
1. For minor changes in previously approved research during the period for which approval is authorized.
 2. Research involving only procedures listed in one or more of the allowable categories and found to present no more than minimal risk to human subjects.
 - a. The research categories that may be reviewed by Expedited Review are listed in the PH IRB document entitled "Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure", and is available through the PH IRB Office, or see Sec. IV C below.
- G. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably be expected to place them at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
- H. When an Expedited Review of a research proposal has been conducted and approval granted, the Investigator and when appropriate, the Institution, will be informed in writing; otherwise, the Investigator will be notified that the research proposal must go through PH IRB review at the next convened PH IRB meeting.
- I. As soon as Investigators receive Expedited Approval, research activities may be initiated.
- J. All Members of the PH IRB will be advised of the use of an Expedited Review procedure through the distribution of PH IRB agendas and minutes.

IV. References

- A. [45 CFR 46.110](#)
- B. [21 CFR 56.110](#)
- C. Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure (11-09-98) at: <http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm>
- D. OHRP Guidance on the Use of Expedited Review Procedures (08-11-03) at: <http://www.hhs.gov/ohrp/humansubjects/guidance/exprev.htm>
- E. FDA Protection of Human Subjects: Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) Through an Expedited Review Procedure (11-09-98) at: <http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm118099.htm>

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