

**PARTNERS HUMAN RESEARCH COMMITTEE
POLICIES AND PROCEDURES**

Proposed Changes in IRB-Approved Research Activities

1.0 PURPOSE

The purpose of this policy is to define the procedures the Partners Human Research Committees (PHRC) follow to ensure prompt reporting to the PHRC of proposed changes in approved non-exempt human-subjects research and clinical investigations and for ensuring that changes are not initiated without PHRC review and approval, except where necessary to eliminate apparent immediate hazards to the subject. [45 CFR 46.103(4)(iii) and 21 CFR 56.108(3)(4)]

2.0 SCOPE

Non-exempt human-subjects research and clinical investigations approved by the PHRC are subject to this policy.

3.0 DEFINITIONS

As used in this document, human-subjects research encompasses activities that meet the DHHS definitions of *research* and *human subject* and/or the FDA definitions of *clinical investigation* and *human subject*. The DHHS definition for *research* and *human subject* and the FDA definition for *clinical investigation* and *human subject* are provided below.

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. [45 CFR 46.102(d)]

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information. *Intervention* includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. *Interaction* includes communication or interpersonal contact between investigator and subject. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the

individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects. [45 CFR 46.102(f)(1)(2)]

Clinical investigation means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58 of this chapter, regarding nonclinical studies. The terms *research*, *clinical research*, *clinical study*, *study*, and *clinical investigation* are deemed to be synonymous... [21 CFR 50.3(c) and 21 CFR 56.102(c)]

Human subject means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. [21 CFR 50.3(g) and 21 CFR 56.102(g)]

4.0 POLICY

Investigators conducting human-subjects research approved by the PHRC are required to submit proposed changes in approved research for review and approval prior to initiation of the change, except where necessary to eliminate apparent immediate hazards to the subject.

5.0 PROCEDURES

The procedures the PHRC follows to ensure that investigators submit proposed changes in approved human-subjects research for approval prior to initiation are as follows:

5.1 Proposed Changes in PHRC-Approved Research

5.1.1 The PHRC reviews proposed changes in non-exempt approved human-subjects research according to the procedures described in the policies for initial and continuing review of non-exempt

human-subjects research, and review of proposed changes in approved research.

- 5.1.2 The PHRC, in its written approval notification letters, inform investigators that they must submit changes in approved research to the PHRC for approval prior to initiation.
 - 5.1.3 The PHRC, in its written review notification letters, inform investigators that proposed changes cannot be initiated until approved.
 - 5.1.4 The PHRC, in its continuing review application form, remind investigators that all changes in approved research must be submitted to the PHRC for approval prior to initiation.
 - 5.1.5 The Partners Human Research Quality Improvement Program (QI Program) assesses compliance with applicable regulations and requirements of the PHRC during onsite reviews. Such reviews may identify failure to obtain PHRC approval of proposed changes in approved research prior to initiation. In such cases, investigators are required to complete and submit a violation form to the PHRC for review.
 - 5.1.6 Educational programs, such as research coordinator orientation, lectures, random QI roundtable discussions, focus groups, and departmental Q/A sessions held by the chairperson address this requirement.
- 5.2 Changes Made Without Prospective PHRC Approval to Eliminate Apparent Immediate Hazards to the Subjects

Changes made without PHRC approval to eliminate apparent immediate hazards to the subjects must be reported to the PHRC within 24 hours. Changes made to eliminate apparent immediate hazards to the subjects will be reviewed by the PHRC according to the procedures described in the policy on *Review of Unanticipated Problems Involving Risks to Subjects or Others*.