

**PARTNERS HUMAN RESEARCH COMMITTEE
POLICIES AND PROCEDURES**

Continuing Review Requirements

1.0 PURPOSE

The purpose of this policy is to define the requirement for continuing review and the procedures the Partners Human Research Committees (PHRC) follow to ensure continuing review of non-exempt human-subjects research and clinical investigations prior to expiration of PHRC approval.

This policy is established to comply in part with the regulatory requirement in 45 CFR 46.109(e) and 21 CFR 56.109(f) requiring IRBs to conduct continuing review at intervals appropriate to the degree of risk, but not less than once per year.

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

The PHRC must conduct continuing review of non-exempt human-subjects research and clinical investigations at intervals appropriate to the degree of risk, but not less than once per year.

5.0 PROCEDURES

Continuing review of the research is required until the research has been completed or has been closed prior to completion. The investigator must submit the continuing review form to document that the study has been completed or is being closed prior to completion. For multi-site research, the research may be considered completed or may be closed prior to completion when the investigator at this site is no longer collecting, receiving, or analyzing identifiable data.

5.1 Continuing Review Notifications

- 5.1.1 Ninety (90) days, sixty (60) days, and thirty (30) days prior to expiration of PHRC approval, the Human Research Office sends a written notice to the Principal Investigator (PI) reminding him/her that continuing review of the research is coming due.
 - 5.1.2 The PI must complete and submit the relevant continuing review form and provide required protocol-related information and documents to the Human Research Office for PHRC review.
 - 5.1.3 The protocol is then reviewed in accordance with PHRC policies and procedures for continuing review either at a convened meeting of the PHRC or by expedited review as authorized by 45 CFR 46.110 and 21 CFR 56.110.
- 5.2 Notification of Expiration of PHRC Approval
- 5.2.1 When PHRC approval expires, the Human Research Office notifies the PI in writing that all research activities must stop. Research activities include, but are not limited to, recruitment and enrollment of subjects, collection of specimens, research on previously collected specimens, review of medical records or other health information, data analysis, and performance of research tests/procedures, treatment or follow-up on previously enrolled subjects. In addition, the Human Research Office forwards copies of notifications of expiration of PHRC approval to the Office of Grants and Contracts.
 - 5.2.2 If treatment or follow-up of subjects is necessary for subject safety and welfare, the PI must request permission of the PHRC to continue previously enrolled subjects on study. The reviewing PHRC Chairperson is responsible for considering these requests on a case-by-case basis and providing the investigator with written documentation of permission, when granted.
 - 5.2.3 Expiration of PHRC approval is not considered suspension or termination of research and is not subject to the policy on *Suspension or Termination of Human-Subjects Research*.