

PARTNERS HUMAN RESEARCH COMMITTEE POLICIES AND PROCEDURES

Suspension or Termination of Research

1.0 PURPOSE

The purpose of this policy is to define the procedures the Partners Human Research Committees (PHRC) follow when suspending or terminating PHRC-approved human-subjects research and clinical investigations.

This policy is established to comply with the regulatory requirement in 45 CFR 46.103(b)(5)(ii) and 21 CFR 56.108(b)(3) requiring IRBs to have written procedures ensuring prompt reporting to the IRB, appropriate institutional officials, Office for Human Research Protections, and, when applicable, the Food and Drug Administration (FDA), any suspension or termination of IRB approval.

2.0 SCOPE

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

3.0 DEFINITIONS

Human-subject research means activities that meet the DHHS definition of *research* and involve a *human subject* as defined by DHHS or meet the FDA definition of *clinical investigation* and involve a *human subject* or *subject* as defined by FDA. The DHHS definition for *research* and *human subject* and the FDA definition for *clinical investigation*, *human subject*, and *subject* are provided below:

Research as defined by DHHS 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 as defined by DHHS 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 as defined by FDA 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 as defined by FDA 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)]

Test article as defined by FDA means any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product or any other article subject to regulation under the act or under sections 351 and 354-360F of the Public Health Service Act (42 U.S.C. 262 and 263b-263n).

Subject as defined by FDA means a human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control. A subject may be in normal health or have a medical condition or disease [21 CFR 812.3(p)].

Suspension means to cause some aspect of the research to be stopped temporarily or permanently while the research continues under review or an investigation takes place.

Termination means to cause the research to be stopped permanently in its entirety. Of note, expiration of PHRC approval is not considered termination of research.

4.0 POLICY

Consistent with federal regulations, the PHRC has the authority to suspend or terminate approval of research that is not being conducted in accordance with the requirements or determinations of the PHRC or that has been associated with unexpected serious harm to subjects. Additionally, the Institutional Official may suspend or terminate research approved by the PHRC for human subject protection, administrative, financial or other reasons.

When the Institutional Official suspends or terminates PHRC-approved research, s/he is responsible for promptly notifying the Principal Investigator, Department Chair/Chief of Service, and the PHRC of the suspension or termination and the reasons for doing so.

When the PHRC suspends or terminates approved research, the PHRC is responsible for promptly reporting the suspension or termination and the reasons for doing so in accordance with the policy *Reporting to Regulatory Agencies and Institutional Officials*.

5.0 PROCEDURES

- 5.1 When research approved by the PHRC is suspended or terminated, the PHRC Chairperson/PHRC considers and determines whether:
- subjects currently on active treatment must be withdrawn from the study;
 - subjects will be placed at risk of harm by withdrawing them from the study; and
 - subjects must continue to be followed for safety reasons.

5.2 Early Withdrawal of Subjects

- 5.2.1 When the suspension or termination involves withdrawal of subjects from an interventional study, the PHRC Chairperson/PHRC considers and determines what, if any, termination procedures are required for the safety and welfare of

those subjects. Termination procedures may include, but are not limited to the following:

- tapering of the drug;
- making a final study visit at which a physical exam and/or laboratory or other tests will be performed; or
- making arrangements for subjects to receive medical care by their primary care physician or specialist or through referrals to other healthcare providers.

5.3 When Subjects are at Risk of Harm

5.3.1 When the PHRC determines that the suspension or termination will place subjects at risk of harm, the PHRC must determine what subjects are to be told and the manner in which they are to be notified, e.g., in writing, in person, or by telephone.

5.4 Subject Follow-Up

5.4.1 When the PHRC requires or approves subject follow-up for safety reasons, the investigator is subject to continuing review and requirement to promptly report any unanticipated problems involving risks to subjects or others, including adverse events, to the PHRC and, when applicable, the sponsor.

5.5 Notification of Subjects

5.5.1 Depending upon the reasons for the suspension or termination and the design of the protocol, the PHRC may require that the following subjects be notified of the suspension or termination:

- all subjects who have been or are enrolled;
- subjects currently on protocol; or
- subjects who participated in a certain aspect of the protocol.

5.6 Reporting Requirements

Whenever the Institutional Official or PHRC suspends or terminates a research protocol involving human subjects, the Director and Chair of the PHRC or designee shall be responsible for submitting a report of the suspension or termination of the research in accordance with the policy *Reporting to Regulatory Agencies and Institutional Officials*.