

# PARTNERS HUMAN RESEARCH COMMITTEE POLICIES AND PROCEDURES

## Exemption Determinations

### 1.0 PURPOSE

The purpose of this policy is to define the applicability of the exemptions from the requirements of 45 CFR 46 and/or 21 CFR 56 and the review procedures the Partners Human Research Committees (PHRC) follow when conducting review of exempt human-subjects research and clinical investigations.

### 2.0 SCOPE

Human-subjects research and clinical investigations conducted by BWH or MGH employees or agents (e.g., professional staff) in connection with their institutional responsibilities, regardless of the source of funding, with the exception of oncology and non-malignant hematology research collaborations conducted under the auspices of the Dana Farber/Partners Cancer Care joint venture 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 may determine that human-subjects research is exempt from the requirements in 45 CFR 46 in accordance with 45 CFR 46.101(b)(1-6) or exempt from the requirements of 21 CFR 56. The PHRC Chairpersons are subject to the *Partners Conflicts of Interest Policy for IRB Members* when reviewing and making exemption determinations.

#### 5.0 PROCEDURES

Investigators relying on the PHRC for IRB review of human-subjects research are required to complete application forms and provide all required information and documents to the Partners Human Research for review by the PHRC as described in the *Protocol Submission Instructions*.

5.1 All of the required forms and documents submitted by the investigator for review are provided by the Human Research Office staff to one of the PHRC Chairpersons for review.

#### 5.1.1 DHHS Regulated Research

The reviewing PHRC Chairperson is responsible for making determinations of exemption from the requirements of 45 CFR 46 in accordance with 46.101(b)(1-6) as quoted below:

- (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- (2) Research involving the use of education tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless: (i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) The human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- (5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate,

or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

- (6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Exemptions 46.101(b)(1-6) do not apply to research involving prisoners, subpart C.

Exemption 46.101(b)(2) does not apply to research involving children, subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

Exemptions 46.101(b)(1-6) do not apply to *clinical investigations* regulated by the Food and Drug Administration (FDA).

### 5.1.2 FDA-Regulated Research

The reviewing PHRC Chairperson is responsible for making determinations of exemption from the requirements of 21 CFR 56 in accordance with 56.104(c)(d) as quoted below:

- (c) Emergency use of a test article provided that such emergency use is reported to the IRB within 5 working days. Any subsequent use of the test article at the institution is subject to IRB review.
- (d) Taste and food quality evaluation and consumer acceptance studies. If wholesome foods without additives are consumed or if the food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural, chemical, or environmental contaminant at or below the level found to be safe by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food

Safety and Inspection Services of the U.S. Department of Agriculture.

Exemption 56.104(c), the emergency use of a test article, is covered in a separate policy *Emergency Use of an Investigational Drug or Biological Product, or Unapproved Medical Device*.

- 5.1.3 When providing ethical review of exempt research, the reviewing PHRC Chairperson is also responsible for determining that the research meets the institution's ethical principles for human subject protection, specifically the *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* and the *Partners Guiding Principles for Human Studies* and the requirements of the Health Insurance Portability and Accountability Act (HIPAA) of 1996.
- 5.1.4 The reviewing PHRC Chairperson uses checklists and review sheets to document review and exemption determinations.
- 5.1.5 If the reviewing PHRC Chairperson determines that the research is exempt from the requirements of 45 CFR 46, continuing review is not required.
- 5.1.6 The Human Research Office notifies the PI in writing that the research is exempt from further PHRC review and that they may not make changes to the research activity without first discussing the changes with the PHRC to ensure that the changes are within the parameters for exemption. If the research no longer meets the criteria for exemption, the investigator must resubmit the research for review by the PHRC at a convened meeting or using the expedited review procedure, whichever is appropriate to the research activities.
- 5.1.7 The reviewing PHRC Chairperson may request additional information from the Principal Investigator (PI) to make the determination or request changes in the research to meet the institution's ethical principles for human subject protection and the requirements of the Health Insurance Portability and Accountability Act (HIPAA) of 1996.
- 5.1.8 When the reviewing PHRC Chairperson requires additional information or modifications in the research to secure the exemption determination, the Human Research Office notifies in the PI in writing of the required modifications or additional information required to make the determination.

- 5.1.9 When received, the reviewing PHRC Chairperson reviews the PI's response and, when applicable, makes the exemption determination. The reviewing PHRC Chairperson may continue to request information or require modifications until a determination can be made.
- 5.1.10 If the research does not meet the criteria for exemption, the protocol is reviewed either at a convened meeting of the PHRC or using the expedited review procedure, whichever is appropriate to the research activities.
- 5.1.11 The Human Research Office is responsible for preparing and distributing a report of all human-subjects research activities approved as exempt from requirements of 45 CFR 46. The report is distributed with the agenda and meeting materials for convened PHRC meetings.
- 5.1.12 The report is made available electronically to the Institutional Officials in a shared file area. In addition, the Human Research Office provides individuals and/or departments within Partners with responsibility for some aspect of the human research protection program electronic access to PHRC review information via the Insight Research Portal.