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AND MASSACHUSETTS GENERAL HOSPITAL

Title:	Exempt Human-Subjects Research
Department:	Human Research Affairs
Policy Type:	<input checked="" type="checkbox"/> Partners System-wide <input type="checkbox"/> Partners System-wide Template <input type="checkbox"/> Partners Corporate <input type="checkbox"/> Partners Corporate Departmental <input type="checkbox"/> Entity
Applies to:	Employees, Professional Staff or Other Agents of Brigham and Women's Hospital (BWH), Faulkner Hospital (FH), Massachusetts General Hospital (MGH), McLean Hospital (McLean), and North Shore Medical Center (NSMC)
Approved by:	Chief Academic Officer
Approval Date:	June 4, 2007
Effective Date:	June 4, 2007
Revision Date(s):	December 6, 2007; September 8, 2010; March 7, 2014
Next Review Date:	March 7, 2017
Contact Person:	Director, Human Research Review and Compliance

KEYWORDS:

IRB, Institutional Review Board

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 procedures the Partners Human Research Committees (PHRC) follow when conducting review of exempt human-subjects research and clinical investigations.

DEFINITIONS:

See Definition of Human-Subjects Research

POLICY STATEMENT:

The PHRC is responsible for determining whether a research activity is exempt from 45 CFR 46 and 21 CFR 56. Investigators or others within the organization may not make exemption determinations. The PHRC Chairpersons are subject to the Partners policy on *IRB Member Conflicts of Interest* when reviewing and making exemption determinations.

PROCEDURES:

Investigators relying on the PHRC for IRB review of human-subjects research are required to complete Insight/eIRB 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*.

All of the required forms and documents submitted by the investigator for review are reviewed by the Human Research Office staff for completeness and accuracy, and when complete and accurate, are assigned to a PHRC Chairperson for review.

DHHS Regulated Research

The reviewing PHRC Chairperson is responsible for making determinations of exemption from the requirements of federal regulations 45 CFR 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.

Note: OHRP has determined that the following criteria must be satisfied to invoke the exemption for research and demonstration projects examining "public benefit or service programs": (1) The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social supportive, or nutrition services as provided under the Older Americans Act); (2) The research or demonstration project must be conducted pursuant to specific federal statutory authority; (3) There must be no statutory requirement that the project be

reviewed by an Institutional Review Board (IRB); and (4) The project must not involve significant physical invasions or intrusions upon the privacy of participants.

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

Exemption (2) for research involving survey or interview procedures or observation of public behavior does not apply to research involving children, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

Exemptions (1)-(5) do not apply to *clinical investigations* regulated by the Food and Drug Administration (FDA).

FDA-Regulated Research

The reviewing PHRC Chairperson is responsible for making determinations of exemption from IRB requirement in accordance with 21 CFR 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.

The exemption at 21 CFR 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*.

The exemption at 21 CFR 56.104(c) does not apply to human-subjects research regulated by the DHHS.

FDA-regulated research determined to be exempt from 21 CFR 56 IRB requirements is subject to 21 CFR 50 Informed Consent of Human Subjects.

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* (the "Belmont Report") and the requirements of the Health Insurance Portability and Accountability Act (HIPAA) of 1996.

Specifically, the PHRC Chairperson is responsible for determining that (1) the research presents no more than minimal risk to subjects; (2) the selection of subjects is equitable; and (3) if applicable, there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of identifiable data.

When exempt research involves an interaction with participants, the PHRC Chairperson will review the consent process to ensure that subjects are (1) informed that the activity is research and that their participation is voluntary; and (2) given a description of the research activity and the name and contact information for the investigator conducting the research.

The reviewing PHRC Chairperson uses Insight/eIRB review checklists to document review and exemption determinations.

If the reviewing PHRC Chairperson determines that the research is exempt from all regulatory requirements, continuing review is not required.

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.

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.

When the reviewing PHRC Chairperson requires additional information or modifications in the research to secure the exemption determination, the Human Research Office notifies the PI in writing of the required modifications to secure the exemption determination or additional information required to make the determination.

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.

If the reviewing PHRC Chairperson determines that 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.

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 and 21 CFR 56. Reports are distributed on a monthly basis to the members of the IRBs registered to the institution responsible for review of the research.

Reports are made available to the Institutional Officials in a secure area on the Partners network. In addition, the Human Research Office provides individuals and/or departments within Partners with responsibility for some aspect of the human research protection program access to PHRC-approved research and PHRC review information via the Insight Research Portal.

OTHER APPLICABLE PARTNERS HEALTHCARE POLICIES:

IRB Member Conflicts of Interest

Emergency Use of an Investigational Drug or Biological Product, or Unapproved Medical Device

REFERENCE:

45 CFR 46
21 CFR 50, 56

DEVELOPMENT AND CONSULTATION

Human Research Office

Reviewed by:	Original Review Date:	Revision Approval Dates: