



Title:	Continuing Review and Expiration of PHRC Approval
Department:	Human Research Affairs/Research Management
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) and Massachusetts General Hospital (MGH)
Approved by:	Chief Scientific Officer
Approval Date:	June 4, 2007
Effective Date:	June 4, 2007
Revision Date(s):	September 8, 2010
Next Review Date:	September 8, 2013
Contact Person:	Director, Human Research Review and Compliance

KEYWORDS:

IRB, Institutional Review Board

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. For federally funded research, continuing review must be conducted not less than once per year.

DEFINITIONS:

See Definition of Human-Subjects Research

POLICY STATEMENT:

The PHRC will conduct continuing review of non-exempt human-subjects research and clinical investigations at intervals appropriate to the degree of risk and in compliance with federal regulations. The expiration date is the first date the protocol is no longer approved by the PHRC.

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.

Continuing Review Reminder Notifications

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.
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.
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.

Expiration of PHRC Approval

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.
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.
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*.

OTHER APPLICABLE PARTNERS HEALTHCARE POLICIES:

Review of Human-Subjects Research Using Expedited Review

Review of Human-Subjects Research at a Convened Meeting of the PHRC

Suspension or Termination of Human-Subjects Research

REFERENCE:

45 CFR 46
21 CFR 56

DEVELOPMENT AND CONSULTATION

Human Research Office

Reviewed by:	Original Review Date:	Revision Approval Dates: