

Title:	Continuing Review, Expiration of IRB Approval, and Expedited Check-In
Department:	Human Research Affairs
Policy Type:	Mass General Brigham System-wide
Applies to:	Employees, Professional Staff or Other Agents of Mass General Brigham
Approved by:	Chief Academic Officer
Original Approval Date:	June 4, 2007
Original Effective Date:	June 4, 2007
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Current Revision Effective Date:	December 1, 2020
Next Review Date:	January 15, 2022
Contact Person:	Director, Human Research Office

KEYWORDS:

IRB, Institutional Review Board, Continuing Review, Expedited Check-In

PURPOSE:

The purpose of this policy is to define the requirement for continuing review and the procedures the Mass General Brigham Institutional Review Board follow to ensure continuing review of non-exempt human subject research and clinical investigations prior to expiration of IRB approval and oversight of research not requiring continuing review.

This policy is established to comply in part with the regulatory requirement in 45 CFR 46.109(e-f) and 21 CFR 56.109(f) requiring IRBs to conduct continuing review at intervals appropriate to the degree of risk.

DEFINITIONS:

See Definitions in Human Subject Research

POLICY STATEMENT:

The IRB will conduct continuing review of non-exempt human subject research and clinical investigations at intervals appropriate to the degree of risk where required by federal regulations. The IRB may require more frequent continuing review than is required by the applicable regulations. Documentation of the determination of the length of the approval period is made in Insight and, if applicable, the minutes of the convened board meeting. The determination of the length of the approval period is made by the IRB considering the degree of risk, and according to the following requirements:

Research under FDA regulations or the Pre-2018 Common Rule Requirement (Pre 2018 Requirements)

- For studies reviewed at a convened meeting, continuing review must occur within one (1) year from the date of the convened meeting at which the IRB reviewed and approved the research study.
- For studies approved using expedited review procedures, continuing review must occur within one (1) year from the date the IRB Chair or designated expedited reviewer gives final approval of the protocol.

Continuing review for research regulated by the 2018 Common Rule Requirements (2018 Requirements), but not conducted under FDA regulations.

- For studies reviewed at a convened meeting, the continuing review must occur within one (1) year from the date of the convened meeting at which the IRB reviewed and approved the research study.
- Unless the IRB determines and documents otherwise, continuing review of research is not required for research eligible for expedited review or research reviewed by the IRB in accordance with the limited IRB review for exempt studies.
- Unless the IRB determines otherwise, continuing review of research is not required for research that has progressed to the point that it involves only one or both of the following:
 - Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
 - Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

PROCEDURES:

Continuing Review Submission and IRB Review

1. Investigators are responsible for submitting the appropriate continuing review form in Insight with enough time to allow IRB review and approval prior to expiration of the study.
2. The IRB reviews the study at a convened meeting or uses the expedited review procedure in compliance with federal regulations at 45 CFR 46.110 and 21 CFR 56.110.

Continuing Review Reminder Notifications

As a courtesy, the Human Research Office via Insight sends a written notice to the Principal Investigator (PI) ninety (90) days, sixty (60) days, and forty-five (45) days prior to expiration of IRB approval, reminding him/her that continuing review of the research is coming due. It is ultimately the Principal Investigator's responsibility to be aware of the date of IRB expiration and allow sufficient time for review and re-approval of the research.

Study Closure

1. For research requiring continuing review, submission of the Insight continuing review is required as long as the research activity continues to meet the definition of human subject research.
2. To close out a study, the investigator must submit the continuing review form to document that the study has been completed or is being closed prior to completion.
3. For multi-site research, the research may be considered completed or may be closed prior to completion when the site is no longer collecting, receiving, or analyzing identifiable data.
4. If an investigator does not submit a continuing review within thirty (30) days after the approval expiration date, the study will be administratively closed by the IRB. To reactivate the study, the investigator will need to submit and receive approval for a new study.

Expiration of IRB Approval

1. At each initial and continuing review, the IRB specifies the duration of the next approval period. This establishes the expiration date by which the next continuing review must occur. The expiration date is the first date the research is no longer approved by the IRB.
2. When 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, performance of research tests/procedures, and treatment or follow-up on previously enrolled subjects.
 - a. If treatment or follow-up of subjects is necessary for subject safety and welfare, the PI must request permission from an IRB Chair to continue to conduct these procedures for currently enrolled subjects.
 - b. An IRB Chair considers each request on a case-by-case basis and provides the investigator with written documentation of permission, when granted.
3. Expiration of IRB approval is not considered suspension or termination of research and is not subject to the policy on Suspension or Termination of Human Subject Research.

Expedited Check-In

1. When continuing review is not required, the Mass General Brigham Human Research Office (HRO) is still responsible for tracking and overseeing ongoing human subjects research.
2. Non-exempt research not requiring continuing review will be assigned an Expedited Check-In expiration date that is two years from the date of initial approval.
3. Investigators are required to submit the Expedited Check-In form through Insight every two years while the study is active.
4. Investigators will receive notification for Expedited Check-In at ninety (90), sixty (60) and forty-five (45) days prior to expiration.
5. Approval to conduct the research automatically expires on the first date the research is no longer approved by the IRB.
 - a. For studies that the Investigator indicates are ongoing, Insight will generate a letter documenting completion of the Expedited Check-In submission, the status of the protocol will be updated, consent forms and recruitment materials are published and active protocols scheduled for another Expedited Check-In at two years from acceptance of the submission.
 - b. Investigators must close a study when it is completed by submitting an Expedited Check-In form and indicating the appropriate reason for closure.
 - c. If an investigator does not submit an Expedited Check-In within thirty (30) days after the approval expiration date, the study will be administratively closed by the IRB. To reactivate the study, the investigator will need to submit and receive approval for a new study.

OTHER APPLICABLE PARTNERS HEALTHCARE POLICIES:

Review of Human Subject Research Using Expedited Review
Review of Human Subject Research at a Convened Meeting of the IRB
Suspension or Termination of Human Subject Research

REFERENCE:

45 CFR 46
21 CFR 56

DEVELOPMENT AND CONSULTATION:

Human Research Office