Continuing Review of Research Projects

Content Applies To

Mayo Clinic Human Research Protection Program

Research for which the Mayo Clinic is the IRB of Record

Policy

Federal regulations require and it is the policy of Mayo Clinic's Office for Human Research Protection - Institutional Review Board (IRB) - that research activities be periodically reviewed at intervals appropriate to the degree of risk.

Criteria for Continuing Review

The approval criteria for continuing review are the same as the criteria for approval at initial review and are described in the IRB document: *IRB Initial Approval of Research*. The IRB will determine the interval for continuing review of research as described in IRB document: *IRB Initial Approval of Research.*

Research activities initially approved by the convened IRB will be reviewed by a convened IRB at continuation unless:

- The IRB determines and documents at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified; OR
- One of the following criteria are met at the site(s) approved under the investigator's application:
    a. The research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects; or
    b. No subjects have ever been enrolled at the site(s) approved under the application and no additional risks have been identified from **any** institution engaged in the research or from any other relevant source; or
    c. The remaining research activities are limited to data analysis.

Research activities originally approved using expedited review may receive continuing review using expedited review procedures, unless the research activities no longer meet the criteria for expedited review(45 CFR 46.110 and 21 CFR 56.110). See *Expedited Review of Human Subject Research* for a description of the expedited review process.

Investigator Responsibilities

The Investigator:

- Submits a Continuing Review report via the electronic system (submission is requested by 21 days prior to the expiration date of the study) when he/she intends to continue to conduct the research beyond the duration of the current approval. Submission to the IRB is representation that the report contains current and accurate information regarding the status of the research activity at the site(s) approved under the investigator's application.

IRB Responsibilities

The IRB:

- Reviews and determines whether the research study continues to meet the criteria for approval of research (45 CFR.46.111 and 21 CFR 56.111). The IRB determines that:
    - Risks to subjects continue to be minimized and reasonable in relation to the anticipated benefits;
    - Selection of subjects continues to be equitable;
    - Informed consent continues to be appropriately obtained and documented;
    - Adequate provisions for monitoring the data collected to ensure the safety of the subjects is provided, when appropriate;
    - Adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data, is provided, when appropriate;
    - Appropriate safeguards for vulnerable populations are provided.
- Determines if any new information resulting from the specific research under review or from other sources necessitates an adjustment to the IRB's earlier determination(s).
- Determines the appropriate interval for continuing review
- Except when the IRB has waived the requirement for informed consent, reviews the currently approved consent/assent document(s) attached to the electronic continuing review report to ensure that the information is still accurate and complete. Any significant new findings that may relate to the subject's willingness to continue participation will be provided to the subject using updated document(s) or other mechanisms the IRB determines to be appropriate.

Verification from Other Sources of No Material Changes

The IRB may determine that it needs verification from sources other than the investigator that no material changes have occurred since the last continuing review. See *Verification of No Material Changes since Previous IRB Review*.

Continuing Review Intervals

Appropriate continuing review intervals are addressed with each review conducted by the IRB. The IRB takes into consideration numerous factors including, but not limited to the following when determining the appropriate continuing review intervals:

- Risks to subjects, as determined by the IRB
- Involvement of vulnerable populations
- Research conducted internationally
- Classified research
- Involvement of recombinant DNA or other types of gene transfer protocols
- Use or waiver of informed consent procedures
- Research for which subjects would be exposed to additional risks, (e.g. breach of confidentiality, phase I clinical studies, disproportionate number or severity of adverse events)
- Previous administrative holds or suspensions of the research due to compliance, recordkeeping or other concerns
- Serious and/or continuing non-compliance, or non-serious, non-compliance with federal regulations or Mayo Clinic policies are identified
- Problems/events that are determined by the convened IRB to represent unanticipated problems involving risks to subjects or others (UPIRTSOs)
- Recommendations from other Mayo Clinic Institutional Committees

IRB Continuing Review

The IRB conducts continuing review of research proposals, with the exception of research that meets the criteria for exemption from review, at intervals appropriate to the degree of risk.

Research that meets the criteria for continuing review undergoes review within one year of the date of the full, convened IRB meeting at which the research was initially approved or last underwent continuing review.

If the study is reviewed by expedited review, the approval date will be determined by the date the study is approved.

Research meeting all of the following criteria may, at the discretion of the IRB, be reviewed at intervals of up to three years:

- Per IRB determination, the research presents no greater than minimal risk to subjects.
- The research does not include contact with subjects.
- The research is unfunded, there is Mayo Clinic funding only, OR

  the research is grant or foundation funded and the funding is not from a federal or industry source.

- The research does not include FDA regulated components.
- The research is conducted by Mayo Clinic investigators. Extended continuing review intervals do not apply to studies where the Mayo Clinic IRB is the IRB of record for an external investigator.

Research activities reviewed by the convened IRB will not initially be eligible for an extended (greater than one year) continuing review interval. Should the convened IRB determine the research meets the regulatory criteria for expedited review, eligibility for an extended continuing review interval may be reassessed by the designated expedited reviewer at the time of subsequent review.

Expiration Date

The expiration date is the last date that research may be conducted without re-approval by the IRB. Typically, the expiration date is calculated as 364 days from this date, unless the IRB has determined more, or less, frequent review of the research is appropriate.

Expiration and Extensions of Approval Period

If the IRB does not approve the research by the specified expiration date, all research study activities must cease and the investigator must inform the IRB what – if any – research was conducted since the date of expiration.

If the investigator does not submit a sufficient continuing review application to the IRB or the IRB does not approve continuation of the research prior to the expiration date of the IRB approval, research interventions and interactions on current study subjects must stop, and all other study activities must cease unless the IRB finds an over-riding safety concern or ethical issue involved such that it is in the best interests of individual subjects to continue research activities. Research study activities include recruitment and enrollment of new subjects, collection and data analysis, and interactions and interventions with existing subjects. See *Expiration of IRB Approval* for additional information.

Related Documents

IRB Initial Approval of Research

Expedited Review of Human Subjects Research

Expedited Review and Processing of a Continuing Review Report for Minimal Risk Research (Work Instructions)

Expedited Review of Continuing Review to Research Previously Approved by the Convened IRB – Work Instructions

Verification of No Material Changes since Previous IRB Review

Expired IRB Approval

References

45 CFR 46 Protections of Human Subjects

21 CFR 56 Institutional Review Boards

Association for the Accreditation of Human Research Protection Programs vs1/2012

Effective Date

February 17, 2016

Revision History

Date	Synopsis of Change
2/17/2016	1) Removed reference to staff only work instructions; 2) Clarified requested CR submission date; 3) Specified that all criteria for 3 year approval must be met; 4) Clarified 'appropriate' review period for expiration dates; and 5) Adding paragraph regarding initial ineligibility for extended (>1 year) CR interval for activities reviewed by the convened IRB.