

Continuing Review of Research Policy

Scope

Applies to all Human Subjects Research when Mayo Clinic is the Institutional Review Board (IRB) of Record.

Purpose

To comply with Mayo Clinic's Office for Human Research Protection and IRB's requirement that human subject research activities be reviewed in accordance with federal regulations and at intervals appropriate to the degree of risk.

Policy

Continuing Review Requirements

Research requiring continuing review undergoes review within one year of the date on which the research was initially approved or last underwent continuing review, unless the exceptions outlined below apply.

Research Approved Prior to 2018 Revised Common Rule Requirements

Research initially approved before January 21, 2019, may, at the discretion of the IRB, be reviewed at intervals of up to three years or determined that continuing review is no longer required, provided NONE of the following apply:

- Per IRB determination, the research presents greater than minimal risk to subjects,
- The research includes contact with subjects,
- The research is funded by a federal or industry source,
- The research includes FDA regulated components, OR
- The Mayo Clinic IRB is the IRB of record for an external investigator/organization.

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.

Research Approved Following 2018 Revised Common Rule Requirements

As of January 21, 2019, research meeting the following criteria does not require continuing review, unless the IRB specifically documents that continuing review is required:

- Per IRB determination, the research presents no greater than minimal risk to subjects, OR the research has progressed to the point that it involves only data analysis or accessing follow-up data from procedures that subjects would undergo as part of clinical care, and
- The research does not include FDA regulated components.

Nevertheless, the IRB may determine that research meeting the above criteria is required to undergo continuing review, for example:

- The research involves regulatory oversight that must be monitored, such as Conflict of Interest (COI)
- The Principal Investigator (PI) or other research personnel have had serious non-compliance or a pattern of non-serious non-compliance in their research practice (reviewed on a case by case basis)

In such cases, the IRB will specifically document that continuing review is required for the research, including the justification for requiring continuing review.

When continuing review is not required, investigators continue to be responsible for submitting to the IRB any adverse events, compliance issues, and modifications for the life of the research, and for notifying the IRB of the completion of the research using the "Update Application Status" to "Completed" activity within the IRB electronic system (IRBe).

Conduct of 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 location(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 location(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 Subjects Research](#) for a description of the expedited review process.

Investigator Responsibilities

When the IRB requires continuing review, the Investigator:

- Submits a Continuing Review report via the electronic system (submission is requested by 21 days prior to the IRB approval expiration) 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 location(s) approved under the investigator's application.

IRB Responsibilities

The IRB:

- Reviews and determines whether the research 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 (as applicable) 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.
- Reviews (as applicable) the IRB-approved consent/assent document(s) attached to the continuing review report. Any significant new information 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 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

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 of IRB Approval

If the IRB does not approve the research by the specified expiration date, all research activities must cease. See [Expired IRB Approval](#) for additional information.

Policy Notes

N/A

Related Procedures

[IRB Initial Approval of Research](#)

[Expedited Review of Human Subjects Research](#)

[Verification of No Material Changes since Previous IRB Review](#)

[Expired IRB Approval](#)

Related Documents

N/A

Definitions

N/A

References

[45 CFR 46 Protections of Human Subjects](#)

[21 CFR 56 Institutional Review Boards](#)

[Association for the Accreditation of Human Research Protection Programs](#)

Owner

[Tammy Neseth](#) on behalf of Office for Human Research Protection

Contact

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Revision History

Date	Synopsis of Change
09/02/2021	Revision outside of Scheduled Review. Updated to allow no additional continuing review for studies approved prior to January 21, 2019 that met and continue to meet the criteria to be approved for intervals up to 3 years.
04/08/2020	Scheduled review. Updated Contact to Heidi Hanf. Minor edits by Policy office.
01/21/2019	Updated per Revised 2018 Common Rule. Other edits for clarity. Updated Owner to Tammy Neseth.
06/28/2018	Scheduled review: Updated to new template, related documents were moved to related procedures, No other changes due to AAHRPP Accreditation process.
02/17/2016	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.
03/17/2007	Approval for need to establish document: Office for Human Research Protection

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