

Institutional Review Board (IRB) Initial Approval of Research Policy

Scope

Applies to Mayo Clinic Human Research Protection Program and the IRB when processing the initial approval of Research for which Mayo Clinic is the IRB of Record.

Purpose

To describe the criteria defined by Code of Federal Regulations that must be met to allow approval of research using human subjects and for the IRB to determine the level of review, and when applicable, the frequency of review required.

Policy

Mayo Clinic's Office for Human Research Protection and IRB must review and approve research in accordance with the criteria as defined by the Code of Federal Regulations (45 CFR 46.111 and 21 CFR 56.111):

Criteria for IRB Approval of Research

- Risks to subjects are minimized:
 - By using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and
 - Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes, whenever appropriate.
- Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
- Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.
- Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by Federal and State regulations and Institutional policies and procedures including those of the IRB.
- Informed Consent will be appropriately documented, in accordance with, and to the extent required by the Federal and State regulations and Institutional policies and procedures including those of the IRB.

- When appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects.
- When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

Determining the Applicability and Interval for Continuing Review

At the time of initial or continuing IRB approval, the Convened IRB or Expedited Reviewer determines the applicability and interval for continuing review in accordance with the requirements defined in the policy *Continuing Review of Research*.

Investigator Responsibilities

The Investigator prepares and submits only those research projects that he/she believes meet the criteria for IRB approval of research.

IRB Responsibilities

- The IRB must review the research proposal and determine whether it meets the criteria for approval of research. These criteria will be applied to all research projects that require IRB approval.
- The IRB will consider any other committee reviews and determinations submitted as part of the research project when making its determination.
- The IRB will seek the expertise of any individual or committee necessary or appropriate for making its determination.
- IRB reviewers must document their findings in the IRB electronic system (IRBe).

Policy Notes

N/A

Related Procedures

N/A

Related Documents

[Continuing Review of Research Projects](#)

Definitions

N/A

References

[Code of Federal Regulations](#) (45 CFR 46.111 Criteria for IRB Approval of Research & 21 CFR 56.111 Criteria for IRB Approval of Research)

Owner

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Contact

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Revision History

Date	Synopsis of Change
06/13/2022	Scheduled review. Updated Contact and Owner and minor edits.
01/21/2019	Updated to reflect 2018 Revised Common Rule, and to remove information duplicated from Continuing Review of Research Projects. Changed Owner to Tammy Neseth.
03/23/2018	Updated to new Policy template, no other changes at this time due to AAHRPP Accreditation cycle.
03/24/2016	1) Criteria for 3 year approvals modified to match the 'Continuing Review of Research Projects' policy; 2) added that "all of" the criteria need to be met for 3 year approval and 3) Added qualification that research reviewed by the convened IRB will not initially be eligible for an extended (greater than one year) continuing review interval; however, eligibility for an extended continuing review interval may be reassessed by the designated expedited reviewer at the time of subsequent review.