IRB Initial Approval of Research

Content Applies To

Mayo Clinic Human Research Protection Program

Research for which the Mayo Clinic is the IRB of Record

Purpose

Federal regulations establish criteria which must be met to allow approval of research using human subjects (45 CFR 46.111 and 21 CFR 56.111). Further, the IRB determines the frequency of review required for each use of human subjects both at the time of initial review and at each continuing review interval.

Policy

It is the policy of Mayo Clinic's Office for Human Research Protection – Institutional Review Board (IRB) to review and approve research in accordance with the criteria as defined by Federal regulations.

Criteria for IRB Approval of Research

1. Risks to subjects are minimized by:
    - The use of procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk,

      And
    - The use of procedures already being performed on the subjects for diagnostic or treatment purposes, whenever appropriate
2. 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 considers 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 does 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;
3. Selection of subjects is equitable considering the purposes of the research and the setting in which the research will be conducted and is particularly cognizant of the special problems of research involving vulnerable populations and the potential need for additional protections, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons;
4. Informed consent is 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;

5. Informed Consent is 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;
6. When appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects;
7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
8. There are adequate provisions to protect the rights and welfare of vulnerable populations from coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
    - The IRB determines if additional safeguards need to be included in the study to protect the rights and welfare of these subjects.

Determining the Interval for Continuing Review

At the time of initial or continuing approval, the Convened IRB or Expedited Reviewer determines the interval for continuing review which is not less than once per year but could be an interval shorter than one year. In addition, 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.

In making this determination, the Convened IRB or Expedited Reviewer considers the criteria listed in this policy and may also consider new factors such as, but not limited to previous Administrative Holds or suspensions of the research due to compliance, record-keeping or other concerns and/or recommendations from other Mayo Clinic institutional committees. See *Continuing Review of Research Projects.*

Investigator Responsibilities

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

IRB Responsibilities

- The IRB reviews the research proposal and determines whether it meets the criteria for approval of research. These criteria apply to all research projects that require IRB approval, including those requiring convened IRB review and those eligible for expedited review.
- The IRB takes into account any other committee reviews and determinations submitted as part of the research project when making its determination.
- The IRB seeks the expertise of any individual or committee necessary or appropriate for making its determination.
- IRB reviewers document their findings in IRBe.

Related Documents

Continuing Review of Research Projects

References

45 CFR 46.111 Criteria for IRB Approval of Research

21 CFR 56.111 Criteria for IRB Approval of Research

Effective Date

March 24, 2016

Revision History

Date	Synopsis of Change
3/24/2016	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.