Scientific Review of Research Involving Human Subjects

Content Applies To

Mayo Clinic Human Research Protection Program

Research for which Mayo Clinic IRB is the IRB of Record

Purpose

The purpose of scientific review of research involving human subjects, by individuals who have relevant expertise, is to evaluate the scientific or scholarly validity of the proposed research and report this to the IRB for consideration during review of research applications. The scientific review process evaluates the soundness of the research design; the ability of the research to answer the proposed questions and provides the IRB the information it needs to determine whether regulatory criteria for approval are met (i.e. risks to subjects are minimized by using procedures consistent with sound research design, and risks to subjects are reasonable in relation to anticipated benefits, if any, and the important knowledge that may reasonably be expected to result).

Policy

Proposed new human research studies that are deemed greater than minimal risk (by either the investigator or a convened IRB) are to undergo departmental scientific review by a research committee, chairperson or designee within the primary scientific discipline relevant to the research, or other Institutionally recognized subcommittee or review group. Such review is to encompass scientific merit, available resources, and feasibility.

The convened IRB may waive this requirement, provided an experienced IRB member with suitable expertise is available to assess the scientific merit, adequacy of resources, and feasibility of the proposed research.

For studies deemed by a convened IRB or designated expedited reviewer to involve no more than minimal risk to subjects, an experienced IRB reviewer may assess the scientific merit, feasibility and adequacy of resources.

Scientific reviewers must be independent of the proposed study.

Reviews for Mayo Clinic investigator applications are documented using the Scientific Review Form. Scientific review for non-Mayo Clinic applications may be submitted in other formats, but must address the following:

- Scientific merit of the proposal
- Human subject protection measures
- Any ethical considerations or concerns
- Informed consent process and document (as applicable)
- Adequacy of study personnel credentials and time to conduct the research
- Adequacy of institutional resources and facilities
- Availability of a sufficient subject population to complete the research

Key Terms

Minimal risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. (45 CFR 46.102(i))

Greater than minimal risk: The research involves more than minimal risk to subjects.

Department of Defense (DoD) involvement: Use of DoD funding to support the research; cooperation, collaboration, or any other type of agreement with the DoD; use of DoD facilities, property or other assets; and intentional inclusion of subjects who are personnel (active or reserve military, or civilian) from a component of the DoD, or data or specimens from such personnel.

Mayo Clinic: Mayo Clinic in Arizona, Florida, and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

Procedure Statements

1. Each department, subcommittee, or review group may develop its own mechanism for conducting the scientific review and must designate an appropriate individual to be responsible for overseeing the review process. This individual should be a Department Chair or Vice-Chair for Research or Chair of the respective subcommittee or review group.
2. Scientific reviewers must be independent of the proposed study (i.e. not a member of the study team).
3. The Scientific Review Form (IRB 10390) will be used to summarize and document the scientific review for IRB applications from Mayo Clinic investigators. Scientific review for non-Mayo Clinic investigator applications may be documented in other formats, but must address the required elements as defined by the above policy.
4. The scientific review documentation will be attached, where designated, to the IRB electronic application and submitted to the IRB.

Department of Defense

Regardless of level of risk, IRB applications where research involves the Department of Defense must include documentation of scientific review. In addition, major modifications to approved research involving the Department of Defense must undergo scientific review prior to IRB review. Major modifications are changes to the research that would materially affect the assessment of risks and benefits or may alter prior IRB decisions or determinations. Examples of major modifications include, but are not limited to:

- Changes in the Principal Investigator for research projects that have been deemed as greater than minimal risk
- Changes in study design, population, or procedures that increase risk (e.g. revision of study purpose, broadening of eligibility criteria, addition of vulnerable populations, alteration of a data safety monitoring plan, change in drug dosage or frequency).

- Changes to the consent form(s) that have the potential to alter/affect the potential participant's understanding of the risk/benefit ratio of the study, the study requirements, or his/her rights, e.g. new study procedures, new risks or increase in severity or frequency of known risks, changes to subject remuneration, reimbursement, or out of pocket expenses, extended duration of study participation, and/or changes to the HIPAA authorization).
- Premature completion of the research project due to an unanticipated problem or determination by an oversight entity

References

Association for the Accreditation of Human Research Protection Programs (AAHRP) version 1/2012

45 CFR Part 46 Protection of Human Subjects

21 CFR Part 56 - Institutional Review Boards

Department of Defense Instruction 3216.02

Related Documents

Scientific Review Form (IRB 10390)

http://intranet.mayo.edu/charlie/irb/child-of-page-1/forms-library/

Effective Date

October 17, 2014