

Scientific Review of Research Involving Human Subjects Policy

Scope

Applies to individuals who review scientific research involving human subjects for scientific or scholarly validity of the proposed research and report this to the IRB of Record for consideration during review of research applications and to the Institution for oversight under the Mayo Clinic's Human Research Protection Program.

Purpose

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 of Record 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 the IRB of Record) must 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.
- Each department, subcommittee, or review group may develop its own mechanism to conduct 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.
- For studies deemed by the IRB of Record or its designated expedited reviewer(s) to involve no more than minimal risk to subjects, an experienced IRB reviewer can assess the scientific merit, feasibility and adequacy of resources.
- Scientific reviewers must not have a conflict of interest (financial or non-financial).
- Scientific reviewers must be independent of the proposed study (i.e. not a member of the study team).
- The *Scientific Review Form* (IRB 10390) will be used to summarize and document the scientific review for IRB applications from Mayo Clinic investigators. The Form must identify (by name) the individual scientific reviewer(s).
- The scientific review documentation will be attached, where designated, to the Mayo Clinic IRB electronic application (IRBe) and submitted to the IRB.
- An external IRB of Record may waive the requirement to submit documentation of scientific review as part of the IRB review process. However, for all research conducted at Mayo Clinic and requiring scientific review per this policy,

documentation of scientific review must be included in “Request to Rely on External IRB” applications registered via the Mayo Clinic IRB electronic system.

- Scientific review for non-Mayo Clinic applications can 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
Identity (by name of the scientific reviewer(s))

Department of Defense

- IRB applications where research involves the Department of Defense, regardless of level of risk, must include documentation of scientific review.
- 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

Related Procedure(s)

N/A

Related Document(s)

[Scientific Review Form \(IRB 10390\)](#)

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

Definitions

Conflict of Interest: Any interest that could reasonably be expected to affect the objectivity of an IRB member or Consultant in relation to an application or other matter under IRB review. An IRB member or Consultant has a conflict of interest if the individual:

- Is or will be an investigator or member of the research team (i.e. listed on the IRB application).
- Has an immediate family member (i.e. spouse, dependent children) or personal relationship with an individual who is one of the investigators.
- Has a financial or managerial interest in a sponsoring entity or product being evaluated or provided by a commercial entity in the research, as defined by Mayo Clinic Conflict of Interest Policy.
- Has received or will receive compensation with value (as defined by Mayo Clinic Conflict of Interest Policy) that may be affected by the outcome of the research project.
- Has a proprietary interest in the research, such as a non-provisional patent application, patent, trademark, copyright, or licensing agreement as defined by Mayo Clinic Conflict of Interest Policy.
- Has a nonfinancial interest (personal circumstance, ethical belief, or other factor) that may be conflicting, e.g., the IRB member has an interest that he/she believes conflicts with his/her ability to review a project objectively.
- Has responsibility for Institutional business development, such as raising funds or garnering support for research or as an officer within the Department of Development.

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.

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.

IRB of Record: A reviewing IRB that assumes IRB responsibilities for another organization and is designated to do so through an approved Federal-wide Assurance (FWA) on file with the Office for Human Research Protections (OHRP). Note: Commercial IRBs will not have FWAs, but must be registered with OHRP.

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

Relying Organization: An organization, including an academic institution, with whom Mayo Clinic has either entered into an IRB Authorization Agreement or an agreement entered into as part of a cooperative research project.

References

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

45 CFR Part 46 - Protection of Human Subjects

21 CFR Part 56 - Institutional Review Boards

Department of Defense Instruction 3216.02

Approved by

Pamela Kwon on behalf of the Mayo Clinic Human Research Protection Program
Oversight Committee, 1/17/2017

Owner

Pamela Kwon on behalf of the Office for Human Research Protections

Contact

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Revision History

Date	Synopsis of Change
9/21/2017	Minor review. Updated the following definitions per Glossary review: IRB of Record; Mayo Clinic; Minimal Risk; and Relying Organization.
1/17/2017	Scheduled review, policy reformatting and minor editorial changes