

# Scientific Review of Research Involving Human Subjects Policy

## Scope

Applies to individuals evaluating scientific and/or scholarly validity of human subjects research proposed to be conducted at or by Mayo Clinic and reporting related findings to the Reviewing Institutional Review Board (IRB)

## Purpose

To define requirements for evaluating the soundness of the research design and the ability of the research to answer the proposed questions; and for providing the Reviewing IRB information necessary 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 Reviewing IRB) must undergo departmental scientific review by a research committee, chairperson, or designee with a consultant in 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 Reviewing IRB 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 (IRBe) application and submitted to the institutional record via the IRBe system.

- An external Reviewing IRB 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 IRBe.
- Scientific review conducted external to Mayo Clinic 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 reviewers)

### **Department of Defense (DoD)**

- IRB applications where research involves the DoD, regardless of level of risk, must include documentation of scientific review.
- Major modifications to approved research involving the DoD 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 informed consent forms that have the potential to alter/affect the potential participant's understanding of the risk/benefit ratio of the study, the study requirements, or the participant's 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 Health Information Portability and Accountability Act (HIPAA) authorization.
  - Premature completion of the research project due to an unanticipated problem or determination by an oversight entity

### **Policy Notes**

N/A

## Related Procedures

N/A

## Related Documents

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

## 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.

**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.

**Greater Than Minimal Risk:** The research involves more than minimal risk to subjects.

**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.

**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.

**Reliance Agreement:** A document (e.g., IRB Authorization Agreement, Master Service Agreement, etc.) signed by two or more organizations that permits one or more organizations engaged in human subjects research to cede review to a designated Reviewed IRB. The signed Agreement may permit a single IRB to review human subject research activities for more than one organization/site.

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

**Reviewing IRB:** The IRB to which one or more Relying Organizations have granted authority for IRB review and oversight. The Reviewing IRB may be internal or external to the Relying Organization. Authority is granted through designation of an internal IRB on the Organization's approved Federal-wide Assurance (FWA) on file with the Office for Human Research Protections (OHRP), or through a Reliance Agreement with an external IRB. The Reviewing IRB may also be referred to as the "IRB of Record."

## References

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

[AAHRPP Accreditation Standards](#)

[45 CFR Part 46](#) - Protection of Human Subjects

[21 CFR Part 56](#) - Institutional Review Boards

[Department of Defense Instruction 3216.02](#)

## Owner

[Michelle K. Daiss](#) on behalf of the Office for Human Research Protections

## Contact

[Bill Rossini and Aleisha Chappell](#)

## Revision History

Date	Synopsis of Change
11/29/2023	Fixed Scientific Review Form link; updated Contact to Bill and Aleisha
06/14/2022	Scheduled review. Transferred to standardized template. Owner and contact updated.
06/14/2019	Clarified a Mayo Clinic staff appointment is required. Updated Owner to Tammy Neseth.
05/02/2018	Scheduled review, no changes at this time due to AAHRPP Accreditation cycle.
09/21/2017	Minor review. Updated the following definitions per Glossary review: IRB of Record; Mayo Clinic; Minimal Risk; and Relying Organization.

01/17/2017	Scheduled review, policy reformatting and minor editorial changes
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Applicable Sites
<b>Arizona Sites:</b> Arizona
<b>Florida Sites:</b> Florida
<b>Rochester Sites:</b> Duluth, Kasson, Litchfield, Little Falls, Minneapolis, Northfield, Rochester, St. Cloud, Superior
<b>NW WI Region:</b> Barron, Bloomer, Chetek, Chippewa Falls, Eau Claire, Glenwood City, Menomonie, Mondovi, Osseo, Rice Lake
<b>SE MN Region:</b> Adams, Albert Lea, Austin, Cannon Falls, Ellsworth, Faribault, Lake City, Lake Mills, New Richland, Owatonna, Plainview, Red Wing, Wells, Zumbrota
<b>SW MN Region:</b> Belle Plaine, Fairmont, Janesville, Le Sueur, Mankato, Montgomery, New Prague, St. James, St. Peter, Waseca, Waterville
<b>SW WI Region:</b> Arcadia, Caledonia, Holmen, La Crosse, Onalaska, Prairie du Chien, Sparta, Tomah

Reviewer(s):
Aleisha K. Chappell
William J. Rossini

Approver(s):
Michelle K. Daiss

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