# Institutional Commitment and Authority Policy

## Scope

Applies to Mayo Clinic Human Research Protection Program and personnel in research for which Mayo Clinic is the Reviewing Institutional Review Board (IRB).

## Purpose

To describe Mayo Clinic's commitment to protecting human research subjects, the appointment of IRB Committees, the authority and independence of the IRB, and activities subject to IRB jurisdiction.

## Policy

### Institutional Commitment

Mayo Clinic protects the rights and welfare of subjects in human research. All of Mayo Clinic's human research activities, regardless of whether the research is subject to the Federal Policy for the Protection of Human Subjects ('Common Rule'), is guided by a statement of principles governing the institution in the discharge of its responsibilities to protect the rights and welfare of human subjects of research conducted at or sponsored by the institution.

### Statement of Principles

In the conduct of all human research, Mayo Clinic (including its investigators, research staff, students involved with the conduct of Human Research, IRB members and chairs, IRB staff, and Institutional Official) upholds the ethical principles of the Belmont Report (outlined in the April 18, 1979 report to The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research) and applies the Department of Human Health Services (DHHS) regulations. The ethical principles set forth in the Belmont Report are:

- Respect for Persons: Recognition of the personal dignity and autonomy of individuals and special protection of those persons with diminished autonomy;
- Beneficence: Obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risk of harm; and
- Justice: Fairness in the distribution of research benefits and burdens.

Mayo Clinic applies additional regulations, such as the U.S. Food and Drug Administration (FDA) Human Subjects Regulations, the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and the Department of Defense Human Subject Regulations when applicable, to research involving human subjects.

### Federalwide Assurance (FWA)

Mayo Clinic has a Federalwide Assurance (FWA 00005001) on file with the Federal Office for Human Research Protection (OHRP). Through the FWA, Mayo Clinic commits to DHHS that it complies with the requirements in the HHS 45 CFR Part 46 Protection of Human Subjects. Mayo Clinic's FWA also requires that each IRB Committee be registered with OHRP. IRB registration is documented electronically via the HHS.gov

website. Mayo Clinic's FWA is maintained by the office of the IRB Administrator. The Mayo Clinic Federalwide Assurance (FWA) is available to the Mayo Clinic research community.

## IRB Administration Responsibilities

- Establish and maintain written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, the head of any U.S. federal department or agency conducting or supporting the research and OHRP of any:
    - unanticipated problems involving risk to subjects or others;
    - serious or continuing noncompliance with the applicable U.S. federal regulations or the requirements of determinations of the IRB; and
    - suspension or termination of IRB approval.
- Establish and maintain written procedures for:
    - conducting IRB initial and continuing review of research, and reporting IRB findings to the investigator and the Institution;
    - determining appropriate review interval for projects that require review more often than annually and for projects that need verification from sources other than the investigator that no material changes have occurred since the previous IRB review; and
    - ensuring prompt reporting to the IRB of proposed changes in a research activity, and ensure that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval, except when necessary to eliminate apparent immediate hazards to the subjects.
- Renew or update the FWA within 90 days after changes occur regarding the legal name of the institution, the Human Protections Administrator, or the Signatory Official. The FWA is effective for 5 years and must be renewed every 5 years, even if no changes have occurred, in order to maintain an active FWA. Renewals or updates to the FWA are submitted to OHRP electronically via the HHS.gov website.
- Register and maintain registration of each Mayo Clinic IRB with the federal OHRP.
- Maintain current rosters of members serving on the Mayo Clinic IRBs, in accordance with the Composition of Institutional Review Boards Policy
- Establish a written authorization agreement whenever Mayo Clinic relies upon an IRB operated by an external organization for review of human research to which the FWA applies, or whenever Mayo Clinic IRBs serve as the reviewing IRB for an external relying organization. The written agreement must outline the roles and responsibilities of both organizations and must be kept on file at both organizations and made available upon request to OHRP or any U.S. federal department or agency conducting or supporting research to which the FWA applies.
- Review the IRB operating budget of Mayo Clinic's Human Research Protection Program and communicate to Research Administration any necessary

modifications to accommodate the volume and type of research reviewed, space, facilities, equipment, and staff needed to support the IRB's review and recordkeeping duties.

- Secure and maintain accreditation of the Human Research Protection Program by an independent accrediting body such as the Association for the Accreditation of Human Research Protection Programs (AAHRPP).

## IRB Responsibilities

- Review all human research activities and document its findings regarding the ethical considerations, scientific merit, and adherence to Federal regulations and Mayo Clinic policies.
- Review and monitor ongoing human research for adherence to the Federal regulations and Mayo Clinic policies.

## Investigator Responsibilities

- Acquire the appropriate knowledge regarding human research protections, ethics, and Federal regulations, applicable to his/her proposed research.
- Assure that his/her key study personnel are sufficient in number to complete proposed studies and are adequately trained and knowledgeable regarding human research protections, ethical considerations, and Federal regulations applicable to the proposed research.
- Comply with training, monitoring, and human research protection requirements as determined by Mayo Clinic or the IRB.
- Ensure that research involving human subjects does not commence until the research has received all approvals required by Mayo Clinic and the IRB.

## Appointment of IRB Members

IRB members are appointed by the Mayo Clinic Institutional Official. As such, the IRB serves Mayo Clinic as a whole, rather than a particular school or department, and any relying organization for which the Mayo Clinic IRB is designated as the IRB of Record in a FWA filed with the Federal Office of Human Subjects Research Protection (OHRP).

## Independence of the IRB

The IRB is independent and does not report to departments or individuals that rely on the IRB review of his/her research. Attempts to inappropriately influence the IRB Chairs or IRB members are reported to the Institutional Official or the IRB Medical Director. The IRB Medical Director, IRB Chairs, and IRB members have direct access to the Institutional Official if they experience undue influence or have other concerns about the function of the IRB.

## Authority of the IRB

The Board of Governors, through the Institutional Official, grants to the IRB the authority:

- To determine whether an activity is human research.

- To approve, require modifications to secure approval, or disapprove all human research activities overseen and conducted by the organization.
- To suspend or terminate approval of human research not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects.
- To observe, or have a third party observe, the consent process and the conduct of the human research.
- To evaluate financial interests of investigators and research staff and/or the organization that have been reviewed by the Conflict of Interest (COI) Board, and have the final authority to decide whether the financial interest and management plan, if any, allow the human research to be approved.
- Human research that has been approved by the IRB may be subject to further review and approval or disapproval by officials of Mayo Clinic. However, those officials of Mayo Clinic may not approve human research to move forward if it has not been approved by the IRB.

### Activities Subject to IRB Jurisdiction

- All research projects involving human subjects *at* Mayo Clinic or *on behalf of* Mayo Clinic (e.g. conducted by Mayo Clinic employees, students, and/or research appointees) fall under the jurisdiction of the IRB. This includes any clinical investigation under the jurisdiction of the Food and Drug Administration (FDA).
- No intervention or interaction with human subjects in research, including advertising, recruitment or screening activities, may begin until the IRB has reviewed and approved the research or has determined it to be exempt from IRB approval.
- Regardless of sponsorship, the IRB reviews all human research for which Mayo Clinic is the reviewing IRB.
- If research involving human subjects is conducted without prior IRB review and approval (or exemption determination), the matter is referred to the Institutional Official or the IRB Medical Director for follow-up.

## Policy Notes

N/A

## Related Procedures

N/A

## Related Documents

Composition of Institutional Review Boards Policy

Mayo Clinic Federalwide Assurance (FWA)

## Definitions

**Federalwide Assurance (FWA):** A formal, written, binding attestation in which an institution ensures to the Department of Health and Human Services (DHHS) that it will comply with applicable regulations governing research with human subjects.

## References

Association for the Accreditation of Human Research Protection Programs (AAHRPP)

45 CFR Part 46 Protection of Human Subjects

## Owner

Michelle K. Daiss on behalf of Office for Human Research Protection

## Contact

Nicole R. Ritacca

## Revision History

| Date | Synopsis of Change |
|---|---|
| 10/31/2023 | Scheduled review. Minor edits. Updates to Owner and Contact. |
| 01/20/2021 | Scheduled review. Transferred to current template and updated Contact. Updated links under Related Documents and References. |
| 01/21/2019 | Removed requirement to update FWA within 90 days of IRB membership/roster changes (Revised 2018 Common Rule) and updated activities subject to IRB jurisdiction to reflect research conducted on behalf of Mayo Clinic. |
| 10/23/2018 | Minor revision to reflect that the Institutional Official appoints IRB members. Updated the Owner to Tammy Neseth from Pam Kwon. |
| 01/23/2018 | Minor revision. Updated the following definition per Glossary review: Federalwide Assurance (FWA). |
| 09/20/2017 | Scheduled review. Added Mayo Clinic definition and minor other edits. |

# Content Information Stamp

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## Applicable Sites

**Arizona Sites:**
Arizona

**Florida Sites:**
Florida

**Rochester Sites:**
Duluth, Kasson, Litchfield, Little Falls, Minneapolis, Northfield, Rochester, St. Cloud, Superior

**NW WI Region:**
Barron, Bloomer, Chetek, Chippewa Falls, Eau Claire, Glenwood City, Menomonie, Mondovi, Osseo, Rice Lake

**SE MN Region:**
Adams, Albert Lea, Austin, Cannon Falls, Ellsworth, Faribault, Lake City, Lake Mills, New Richland, Owatonna, Plainview, Red Wing, Wells, Zumbrota

**SW MN Region:**
Belle Plaine, Fairmont, Janesville, Le Sueur, Mankato, Montgomery, New Prague, St. James, St. Peter, Waseca, Waterville

**SW WI Region:**
Arcadia, Caledonia, Holmen, La Crosse, Onalaska, Prairie du Chien, Sparta, Tomah

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