Institutional Commitment and Authority

Content Applies To

Mayo Clinic Human Research Protection Program

Purpose

The purpose of this policy is to describe Mayo Clinic's commitment to protecting human research subjects, the appointment of IRB Committees, the authority and independence of the Institutional Review Board (IRB), and activities subject to IRB jurisdiction.

Key Terms

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

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 U.S. Federal Policy for the Protection of Human Subjects (also known as the 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 apply 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 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 under review.

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 Protection of Human Subjects regulations at 45 CFR 46. 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 FWA is available on the IRB website and is available to the Mayo Clinic research community including the Mayo Clinic Health System.

IRB Administration Responsibilities

1. 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 (a) unanticipated problems involving risk to subjects or others; (b) serious or continuing noncompliance with the applicable U.S. federal regulations or the requirements of determinations of the IRB; and (c) suspension or termination of IRB approval.
2. Establish and maintain written procedures for (a) conducting IRB initial and continuing review (not less than once per year), of research, and reporting IRB findings to the investigator and the Institution; (b) determining which projects require review more often than annually and which projects need verification from sources other than the investigator that no material changes have occurred since the previous IRB review; and (c) 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.
3. Renew or update the FWA within 90 days after changes occur regarding the legal name of the institution, the Human Protections Administrator, the Signatory Official, or changes in IRB committee membership (i.e. OHRP roster). 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.
4. 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 IRB of Record for a 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.
5. 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.

6. Secure and maintain accreditation of the Human Research Protection Program by an independent accrediting body such as the Accreditation of Human Research Protection Programs (AAHRPP).
7. Evaluate Mayo Clinic's Human Research Protection Program (HRPP) and provide results to Mayo Clinic's HRPP Oversight Group.

IRB Committee Responsibilities

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

Investigator Responsibilities

1. Acquire the appropriate knowledge regarding human research protections, ethics, and Federal regulations, applicable to his/her proposed research.
2. 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.
3. Comply with training, monitoring, and human research protection requirements as determined by the organization or IRB.
4. Ensure that research involving human subjects does not commence until the research has received all approvals required by the organization and the IRB.

Appointment of IRB Committees

IRB Committees are appointed as Mayo Clinic Committees by the Mayo Clinic Board of Governors. As such, the IRB Committees serve 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 IRBs

The IRBs are independent and do 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 IRBs

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

1. To determine whether an activity is human research.
2. To approve, require modifications to secure approval, or disapprove all human research activities overseen and conducted by the organization.
3. 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.
4. To observe, or have a third party observe, the consent process and the conduct of the human research.
5. To evaluate financial interests of investigators and research staff 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.
6. 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 of human research if it has not been approved by the IRB.

Activities Subject to IRB Jurisdiction

1. All research projects involving human subjects at Mayo Clinic fall under the jurisdiction of the IRB. This includes any clinical investigation under the jurisdiction of the Food and Drug Administration (FDA).
2. 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.
3. Regardless of sponsorship, the IRB reviews all human research for which Mayo Clinic is the IRB of Record.
4. If research involving human subjects is conducted without prior IRB review and approval, the matter is referred to the Institutional Official or the IRB Medical Director for follow-up.

References

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

45 CFR Part 46 Protection of Human Subjects

Effective Date

July 1, 2012