

Program for the Protection of Human Subjects / Institutional Review Board

The general requirements for the conduct of human subjects research and the required components of informed consent are published in the Code of Federal Regulations (CFR), Title 45, Part 46 (45 CFR 46).

As a condition of receiving federal research support, Icahn School of Medicine at Mount Sinai has signed a Federal-Wide Assurance (FWA) that has been approved by the federal agency that oversees human subject research. **It is important to note that the School has assured that ALL School investigators, including those at affiliated institutions, will comply with ALL federal regulations, regardless of the funding source that supports their research in human subjects.**

The definition of federally regulated human subjects' research is very specific and is not necessarily intuitive. Pertinent definitions, taken directly from the regulations are as follows:

- Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.
- Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains
 - (1) Data through intervention or interaction with the individual; or
 - (2) Identifiable private information.
- **Intervention** includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject.
- Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

A. Distinction Between Research In Human Subjects And Clinical Care

The Belmont Report, which defined the Ethical Principles and Guidelines for the Protection of Human Subjects of Research, was published in the Federal Register in 1979. The guidelines put forth in the Report are still accepted as the "gold standard" for conducting research in human subjects. An important section of the Belmont Report was a description of the boundaries between research and clinical practice and, therefore, the following is quoted directly from the Report:

"It is important to distinguish between biomedical and behavioral research, on the one hand, and the practice of accepted therapy on the other, in order to know what activities ought to undergo review for the protection of human subjects of research. The distinction between research and practice is blurred partly because both often occur together (as in research designed to evaluate a therapy) and partly because notable departures from standard practice are often called "experimental" when the terms "experimental" and "research" are not carefully defined.

For the most part, the term "practice" refers to interventions that are designed solely to enhance the well being of an individual patient or client and that have a reasonable expectation of success. The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment or therapy to particular individuals. By contrast, the term "research" designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.

When a clinician departs in a significant way from standard or accepted practice, the innovation does not, in and of itself, constitute research. The fact that a procedure is "experimental" in the sense of new, untested or different, does not automatically place it in the category of research. Radically new procedures of this description should, however, be made the object of formal research at an early stage in order to determine whether they are safe and effective. Thus, it is the responsibility of medical practice committees, for example, to insist that a major innovation be incorporated into a formal research project.

Research and practice may be carried on together when research is designed to evaluate the safety and efficacy of a therapy. This need not cause any confusion regarding whether or not the activity requires review; the general rule is that if there is any element of research in an activity, that activity should undergo review for the protection of human subjects."

B. Requirements of Icahn School of Medicine PPHS/IRB

It is beyond the scope of the Faculty Handbook to discuss all the nuances and intricacies of the federal regulations, additional FDA requirements, local New York laws and regulations, HIPAA requirements, etc. that all impact the conduct of research at Mount Sinai. Full requirements of the PPHS as well as administrative information, the School's Federal-Wide Assurance, the IRB Guidelines and Policies, the PPHS Investigator Manual, and links to several federal documents including the Code of Federal Regulations (45 CFR 46), FDA information sheets and the Belmont Report can be found on the PPHS Office website (<http://icahn.mssm.edu/research/pphs>) .

1. General Requirements

All research that is to be conducted in human subjects by individuals with full-time, voluntary, or part-time faculty appointments in the Icahn School of Medicine must be submitted to the Program for the Protection of Human Subjects Office (PPHS) and must be reviewed by the Icahn School of Medicine IRB (<http://icahn.mssm.edu/about-us/services-and-resources/faculty-resources/handbooks-and-policies/faculty-handbook/research-environment/institutional-review-board>). No research in human subjects can be initiated without IRB approval (unless specifically categorized as exempt from IRB review). The period of approval will be indicated in a written communication with the Principal Investigator. It is important to note that the IRB is only authorized to approve a project for a maximum period of 365 days. To renew the approval period of a project, the investigator must submit an application to the PPHS Office for review and approval by the IRB. It is the responsibility of the Principal Investigator to provide an annual submission for uninterrupted IRB approval. Applications must be submitted six weeks prior to the date that approval terminates. The IRB is not authorized to issue an extension of time.

The IRB reviews projects based on a schedule posted on the PPHS website (<http://icahn.mssm.edu/research/pphs>). At least one person on the project must hold a Mount Sinai School of Medicine faculty appointment, although any of the researchers listed on the project may be listed as the Principal Investigator.

In reviewing research protocols involving human subjects, the IRB considers the expertise and experience of the investigators to be a major indicator that risks to the subjects will be minimized and benefits from the study maximized. The IRB encourages principal investigators to include co-investigators who are knowledgeable and experienced in the performance and evaluation of procedures to be used in the research. The co-investigators should have an active role in developing the research proposal and they must assume responsibility for the accuracy and appropriateness of those parts of the proposal related to their particular expertise. They are responsible to have knowledge of all study procedures as well as the risks, benefits and adverse effects. This information is provided to subjects as part of the informed consent process.

2. Requirements for Research in Human Subjects at Affiliates of the School

In each case in which Icahn School of Medicine at Mount Sinai is the IRB of record the following applies:

2.1. Human subjects research committees at affiliates of the School, e.g., Elmhurst Hospital Center, the Bronx Veterans' Administration Medical Center, have a liaison serving as a member of the MSSM IRB. Recommendations of committees at the affiliates will be reviewed by the School IRB, but the School's IRB will make the final determination regarding approval of the project. Research cannot be conducted at an affiliate until approval is granted by the School's IRB.

2.2. For research conducted at affiliate institutions, concurrent submissions to the affiliate institution and the School's IRB are required. The School's IRB requires that consent documents utilize the School format. For major affiliates some components of the consent document have been adapted to meet the needs of the affiliate institution. Consent templates for the School and the major affiliated institutions, as well as the School PPHS/IRB Policies and Guidelines Manual, are

available on the PPHS website (<http://icahn.mssm.edu/research/pphs>). When approval of a project is granted, the School IRB will notify the investigator as well as the research office at the affiliate institution. Research at sites outside of the Mount Sinai Health System cannot begin unless approval has been granted by the appropriate office at that out of system site.

2.3. Reports of adverse events, requests for approval of modifications in protocols and/or consent forms must be submitted to the affiliate's research office as well as to the School's PPHS. The format for reporting adverse events must be that used by School investigators. Transmission to the PPHS is the responsibility of the investigator, although the research office at each affiliate will frequently agree to assist in the prompt transmission of all such information to the School IRB. Requirements for Informed Consent

The general requirements for informed consent are published in the Code of Federal Regulations (CFR), Title 45, Part 46 (45 CFR 46). Based on the Multiple Project Assurance (MPA) that the Dean of MSSM has signed and the federal agency that has oversight for human subject research has approved, MSSM has assured that ALL MSSM investigators, including those at affiliated institutions, will comply with ALL federal regulations, regardless of the funding source that supports their research in human subjects.

Please see the IRB website (<http://icahn.mssm.edu/research/resources/program-for-the-protection-of-human-subjects>) for administrative information, application forms, the MSSM Multiple Project Assurance, the IRB Guidelines and Policy Manual, the IRB Procedures Manual, and links to several federal documents including the Code of Federal Regulations (45 CFR 46), FDA information sheets and the Belmont Report.

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Contact Us

1 Gustave L. Levy Place
New York, NY 10029-5674

P: 212-241-6500

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