

Institutional Review Board (IRB)

✓ **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."

✓ **General Requirements of Icahn School of Medicine IRB**

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 Grants and Contracts Office (GCO) ([research/portal/resources/garc](#)) and must be reviewed by the Icahn School of Medicine IRB. 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 GCO 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 at least one month prior to the date that approval terminates. The IRB is not authorized to issue an extension of time.

The MSSM IRB meets the first and third Tuesday of each month. All new and continuing applications that are submitted to the GCO between the 16th of the preceding month and first of the month (or the next business day) will be considered at the IRB meeting on the third Tuesday of that month and those that are submitted between the second of the month and fifteenth of the month (or the next business day) will be considered at the meeting on the first Tuesday of the following month.

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.

To document the acceptance of this responsibility and the agreement to participate in the study once it is approved, each co-investigator must sign the human subjects research application in the section of the GCO packet labeled Programmatic

Assurance.

Principal investigators are urged to consult with the appropriate co-investigators early in the process of protocol development and arrange to obtain the required signatures before the application is submitted to the IRB.

✓ **Requirements for Research in Human Subjects at Affiliates of MSSM**

In each case in which MSSM is the IRB of record the following applies:

Human subjects research committees at affiliates of MSSM have a liaison serving as a member of the MSSM IRB. Recommendations of committees at the affiliates will be reviewed by the MSSM IRB, however, the MSSM IRB will make the final determination regarding approval of the project. Research cannot be conducted at an affiliate until approval is granted by the MSSM IRB.

For research conducted at affiliate institutions, concurrent submissions to the affiliate institution and the MSSM IRB are required. With the exception of components of the consent document which are not directly applicable to the affiliate institution, the MSSM IRB requires that consent documents utilize the MSSM format. The MSSM IRB Policies and Guidelines Manual and GCO forms for conducting research in human subjects are available at each affiliate site. When approval of a project is granted, the MSSM IRB will notify the investigator as well as the research office at the affiliate institution.

Reports of adverse events, requests for approval of modifications in protocols, and/or consent forms or administrative matters relative to a project must be submitted to the affiliate's research office. The format for reporting adverse events must be that used by MSSM investigators. It is the responsibility of the research offices at each affiliate to promptly transmit all such information to the MSSM IRB or to require direct transmission of the information by the investigator to the MSSM 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 ([/research/pphs](http://research/pphs)), 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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