

INSTITUTIONAL REVIEW BOARD (IRB)

The mission of the Institutional Review Board is to facilitate ethical research by providing human subjects protection as guided by the Belmont Report and consistent with Florida and Federal regulations, and the International Conference on Harmonization Good Clinical Practices. The University of Florida requires that **ALL research involving human subjects must be submitted to the IRB for review and approval prior to implementation.**

There is sometimes a question of whether a planned activity is considered "research" or if it involves "Human subjects". The Code of Federal Regulations provides the following definitions:

Research: a systematic investigation, including research development, testing and evaluation, designed to develop or to contribute to generalizable knowledge.

Human subject: 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 associate with the information) in order for obtaining the information to constitute research involving human subjects.

There are three (3) categories of IRB review: **Full Board, Expedited and Exempt.** For **Full Board** reviews, the IRB meets twice a month and there are specific deadlines for submission. The Jacksonville IRB utilizes an **expedited** process for studies that do not involve greater than minimal risk and meet specific criteria. Studies that qualify for expedited review may be approved administratively and there are no deadlines for submission. For the specific criteria see "Criteria for Expedited Review".

There is occasional confusion about research that is "**exempt**". It has been mistakenly assumed that "exempt research" does not need IRB review. "Exempt" means that it falls within a narrowly defined category of research needing administrative review. For specific criteria see "Criteria for Exemption". It is the IRB's responsibility to review and determine whether a study qualifies as "exempt" from IRB oversight. It is the investigator's responsibility to submit the information to the IRB.

The **IRB office** is located on the 9th Floor of Tower 2, Suite 9015. Hours of operation are 8:00 AM - 5:00 PM, Monday through Friday. Contact Alan Halperin, M.D., IRB Chair or Sheila Heim, IRB Coordinator at 4-9478. The website is located at <http://www.hscj.ufl.edu/irb>

Research Day and IRB Review

All residents and faculty with plans to participate in Research Day must submit proposed research plans to the IRB before the research begins. While most of these projects are academic in nature, and involve little or no risk to participants, it is UF policy to review all proposed research before it is implemented. Human subject protections issues are best resolved before study activities begin, as opposed to afterward. Failure to meet these requirements could lead to a suspension of all sponsorship and possible further actions that could ultimately affect the academic or professional standing of the resident or faculty sponsor.

Case studies and IRB review

A case study often involves the collection of data using a retrospective chart review. However, the typical case study does not usually meet the Federal definition of research. The investigation is usually not systematic, and there is usually no data analysis or testing of a hypothesis. The typical case study, which documents innovative treatment practices, does not require IRB review. However, a case series (more than one case reported) does require IRB review.