

IRB 101

The UCF Institutional Review Board is responsible for the protection of human subjects in research studies. The IRB reviews, and monitors biomedical research involving human subjects in accordance with FDA regulations.

An IRB has the authority to approve, require modifications or disapproves research studies should they not meet federal regulations, state statutes and UCF policies. The IRB evaluates the application, protocol, consent documents and, participants' materials, when applicable, to ensure that all procedures are adequately described, meet regulations and are documented properly. The IRB staff submits research to the board for full review in a convened meeting when necessary.

IRB approval is necessary to conduct human subject research, which will likely result in publication in a journal, a graduate or senior student essay or thesis.

Levels of Review

There are three categories of research under the IRB umbrella. They all require IRB review, but at different levels. They are:

Exempt: Even though the category name implies this kind of research is exempt, it still requires IRB review, albeit at the least rigorous level. If the research falls into one of six federally defined (<https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html#c2>) exempt categories, the research can qualify for exemption determination by the IRB after a simplified review. This type of research is usually that of lowest risk to the potential human subjects. On average, 60 percent of the submissions to the UCF IRB fall under this category.

Expedited: If the research is not exempt and falls into one of nine federally-defined expedited categories (<https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html#c9>), it may not need full board review. These categories involve collection of samples and data in a manner that is not anonymous and that involves minimal risk to subjects. On average, 30 percent of submission to the UCF IRB call under this category. Expedited only means that the research proposal is done by one designated reviewer. The decisions of the designated reviewer include approval, approval after required modifications and deferral to Full Board.

Full IRB Review: Research that does not fall into any of the federally-defined categories for Expedited Review or that has been deferred must seek Full Board review. On average, 10 percent or less of submissions will need full board review.

Top 10 errors to Avoid & Speed Up IRB Review

- Not responding to IRB comments and requests in a timely manner. The ideal time it should takes applicants to respond to IRB requests is one week. Active communication in the review process is highly encouraged.

- The protocol submitted requires the approval of another party (dean, department chair or faculty advisor) or is missing from the appropriate forms.
- Research team members have not completed the appropriate CITI training - Group 1 or Group 2
- Consent or participant materials not written in layman's language or includes coercive language.
- Multiple typographical and grammatical errors. Red lines and draft version submitted as final.
- Information is not consistent from section to section within forms. For example, the list of investigators, sample size, duration and description of risks are different in the protocol and consent forms.
- Recruitment and the informed consent process are not fully explained in the protocol narrative or show discrepancies.
- In the protocol narrative, probable risks to the participants are not adequately justified and potential societal benefits are not mentioned. Often the record keeping policy is missing.
- Safeguards to protect personal health information and research data from potential computer breach are inadequate.
- Document required when research is to be conducted at non-UCF sites is missing from the application.