What is an Institutional Review Board (IRB)?

An Institutional Review Board (IRB) is a committee established to formally review and oversee biomedical and behavioral research involving human subjects to ensure compliance with federal, institutional, and ethical guidelines. The overall goal of the IRB is to protect the rights, welfare and safety of all human subjects. The Vice Chancellor for Research and Innovation (or his/her designee) signs a Federalwide Assurance to ensure human subject research is conducted following ethical standards and to maintain eligibility for federal funding for research.

The University of Massachusetts Lowell IRB strives to work closely with faculty, staff, and students to ensure that all research studies involving human studies are in compliance with ethical standards and local, state, and federal regulations. The UMass Lowell IRB aims to provide support for all researchers to successful obtain approval for human subject research. In accordance with regulations by the Department of Health and Human Services and the Food and Drug Administration, the IRB can decide to approve, require modifications prior to approval or disapprove any human subject research projects.

What to Expect When You Submit an IRB Protocol

- At UMass Lowell, only full-time faculty, with some exceptions, may serve as the Principal Investigator (PI) of a research study or project.

- IRB protocols should be clearly written and describe all aspects of the research in detail (including objectives, methods, types of date to be collected or evaluated, types of interactions with participants, how recruitment will occur, incentives, risks, consent, data privacy and security processes, etc.).

- All materials should be submitted at the same time for review to irb@uml.edu.

- All materials are “pre-reviewed” for accuracy and completeness by the IRB Administrator to facilitate reviews by the IRB members. Pre-reviews typically are returned within a day or two to the Principal Investigator (PI), depending on work load.
  - If concerns are identified, they must be addressed and all documents revised as necessary prior to being sent for formal IRB review. Once the pre-review concerns are addressed and materials resubmitted, the application and all supporting documentation are then sent for review.

- Protocol review time estimates vary depending on the category of review. (Every IRB member has the authority and responsibility to request a full board review for any protocol they perceive to be of risk or include vulnerable populations). Estimates by category are as follows:
  - Exemption request determinations are made by the IRB Administrator or Director of Institutional Compliance. PIs are not authorized to make this decision.
  - Expedited protocols are reviewed by two IRB committee members (on a rotating basis) and the reviewers are requested to provide feedback within 10 business days of receipt.
  - Full review protocols are sent to the entire IRB committee for review after all pre-review concerns have been addressed by the PI. Materials must be submitted in time to allow members to have all of the materials at least one week before the scheduled meeting.

- All protocol reviews completed by the IRB members assigned are returned to the IRB Administrator, who compiles a concerns memo to be sent to the PI.

- To respond to and address the IRB’s concerns, a PI should use the “track changes” function in Word documents. This should be completed for all documents requiring revision. If there are specific reasons for not making a requested revision, provide justification within the concerns memo.

- After all materials are resubmitted for review, the IRB Administrator will review the revisions and compare the final resubmitted materials to the concerns memo. If all of the concerns have been addressed satisfactorily, the IRB Administrator will send an approval memo to the PI through email. No research may begin until the PI receives the official approval from the IRB Administrator.