LECOM Institutional Review Board
Instructions for Submission of Research Protocols

An investigator may request IRB review of a proposed research activity by submitting a research protocol to the IRB Secretary. While no specific format is specified, a complete research protocol includes the items listed below. Investigators are encouraged to familiarize themselves with the "LECOM IRB Protocol Review Form" to ensure that their submissions have appropriately addressed all items that will be reviewed by the IRB:

1. The name, institutional affiliation, title, and contact information of a single Principal Investigator. A LECOM student may not serve as Principal Investigator (except for students in the M.S. in Medical Education program who are also LECOM faculty members or resident physicians at Millcreek Community Hospital).
2. A statement describing the qualifications of the Principal Investigator demonstrating his or her ability to conduct or oversee the particular research activity. The qualifications of other study personnel may also be described to demonstrate that needed attributes not embodied in the Prinicipal Investigator are available.
3. Documentation that the Principal Investigator has completed, within the prior three years, the on-line training for Principal Investigators provided by the Collaborative Institutional Training Initiative, www.citiprogram.org.
4. The names, institutional affiliations, titles, and roles in the research project (i.e. co-investigator, research assistant, etc.) of all additional research project personnel.
5. Documentation that all research project personnel have completed, within the past two years, the on-line CITI training appropriate to their roles.
6. The title of the research project.

7. A description of the research question to be addressed (including the specific hypotheses to be tested, if applicable) and a brief review of the relevant literature.
8. A specific description of the research methodology, including subject selection and recruitment procedures, potential risks/discomforts and benefits to subjects or others, procedures planned to minimize risks/discomforts, planned interventions or observations, instrumentation, plans for data collection and analysis (including plans for protecting the privacy of subjects). If an investigational drug or device is to be used, the FDA-issued IND or IDE number must be included and so must be a copy of the sponsor's "Investigator's Brochure".
9. A description of the procedures to be used to obtain informed consent of subjects (or assent of subjects who are children and permission of their parents), including a copy of the Consent Form (or the script for the informed consent discussion if the "short form" consent is used).
10. Any requests by the Investigator for alteration or waiver of any of the required elements of informed consent, or for waiver of the requirement for informed consent, or for waiver of the requirement that informed consent be documented, or for waiver or alterations of the HIPAA authorization requirement.