Institutional Review Board (IRB) Requirements for Global Short-Term Training Program (GSTTP) Students

In addition to contacting your mentor(s), please feel free to contact Rachel Abbott (REAbbott@mednet.ucla.edu) or Dr. Daniel DeUgarte (DDeugarte@mednet.ucla.edu) with any questions.

GSTTP requires that proof of UCLA IRB and local bioethics committee approvals be submitted to Rachel Abbott (REAbbott@mednet.ucla.edu) prior to your departure. UCLA IRB approval can generally take several months, depending on the type of approval needed (exempt and non-human subjects can be as short as 2-3 weeks, with full committee review taking 2 months or longer). Local bioethics committee approval can sometimes take 3-6 months, or longer. In general, you should initiate submissions immediately (if you haven’t already). Even if you are performing a quality improvement project that is either 1) not considered human subjects research or 2) exempt from review, please submit to the UCLA IRB and provide confirmatory notification from the IRB that the project meets these criteria (see attached IRB Activities Requiring Review to facilitate discussion with IRB). If no local IRB is considered necessary, we require a letter or e-mail from the local investigator and/or mentor acknowledging their agreement, stating that local IRB is not required for the project. Be aware that prior to any publication, most journals require that bioethics approval is obtained from the country regulatory body where the research has taken place, as well as from collaborating institutions.

In order to initiate the UCLA IRB process, your mentor will need to request a web account for you and you will need to complete the required IRB training. For a UCLA IRB web account, your mentor can email webirbhelp@research.ucla.edu with your name, UCLA logon, UCLA ID number, email, and your affiliation/department (DGSOM). Access is generally granted within 24 hours of the request. You will be required to register and go through CITI online training (it takes about 30-60 minutes). Most GSTTP Projects are reviewed by the South General IRB (SGIRB), which reviews social-behavioral research from the Schools of Public Health, Nursing, and Medicine. Your mentor should advise you on the correct IRB and we are available to assist, as needed.

The protocol you submit may be assessed as:

1. **Exempt**—technically exempt from IRB review but requires submission of an application.
2. **Expedited**—No more than minimal risk defined as “…the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life…”
3. **Full Committee**—more than minimal risk to subjects, including randomized clinical trials of investigational drugs or other interventions; one-on-one interviews with vulnerable populations about sensitive topics, etc.

IRB approval may fall under the scenarios below:

1. **You are conducting research where your protocol is part of a larger project and the principal investigator (PI) already has UCLA IRB approval**: The PI needs to add your name to the investigator list. In order to be added, you must complete CITI training. The UCLA IRB staff have access to the results of CITI training and can verify that you have completed this requirement.
2. **You are conducting research, but the work that you are doing is an expansion of work that already has UCLA IRB approval:** The PI can submit an amendment to an existing protocol to get approval for the expanded scope of work. Amendments are typically approved in 2-4 weeks, unless they represent complex changes.

3. **You are conducting work that has not been approved by the UCLA IRB:** You must submit a new protocol with a faculty member as your sponsor. This process requires more work, and you should start as soon as possible to allow for enough time for approval. Typically the IRB will not approve an initial submission. They will ask for questions and clarifications. It can take 3-4 rounds of responses before final approval, depending on the complexity of the project.

4. **You are conducting work where the PI is based at another institution and has obtained IRB approval to do that work from this institution, but UCLA approval has not been obtained:** You and your UCLA faculty mentor must submit the letter of approval from the PI’s IRB to the UCLA IRB and request that UCLA allow the PI’s institution to be the IRB of record. In some instances, UCLA IRB will contact the other institution and make all of the arrangements for the PI’s institution to be the IRB of record. If not the case, the UCLA IRB should guide you accordingly.

   Please note the UCLA IRB staff are extremely helpful. You should have a low threshold for reaching out to an IRB contact for advice about which IRB is appropriate for your study, and with any questions about completion of the actual application.

**To obtain a copy of an approved IRB, please follow these steps (from UCLA WebIRB):**

1) Select the Study
2) Click on “Notices” on the Bottom Horizontal Tab
3) Click on “view Approval Notice”
4) Print as PDF (or print document and scan)
5) Email to Rachel Abbott (REAbbott@mednet.ucla.edu)

**Local IRBs:**

There can be a high level of complexity when submitting to local IRBs. Please work with your UCLA and in-country mentors to ensure a local IRB application is completed, if necessary. Some IRBs only meet every few months and can take several months to respond, so timing is critical. Start early! If you are concerned by the IRB process timeline, please reach out to us as soon as possible, so we can help you troubleshoot and/or revise your project to be feasible within local and UCLA regulations. **Send proof of local IRB approval or a letter from your mentor explaining why it is not required to REAbbott@mednet.ucla.edu.**