Institutional Review Board (IRB) Requirements

The primary goal of any IRB body is to protect human subjects and minimize risk. As a researcher, it is essential that you gain familiarity with how the IRB approval process works.

Work directly with your mentor(s) for all IRB preparations, submissions, and questions. If you still have questions, please reach out to the Global Health Research Director, Dr. Kate Dovel (kdovel@mednet.ucla.edu) to discuss any remaining concerns that were not answered by your mentor.

UCLA IRB approval can 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). In-country ethics approval can take 3-6 months, or longer. In general, you should initiate submissions as soon as the methodology for your project is developed. Even if you are performing a quality improvement (QI) project that is either (1) not considered human subjects research or (2) exempt from review, you still need to submit to the UCLA IRB in order to receive exempt status (see *IRB Activities Requiring Review* and *CITI Training Guide* on page 5 to facilitate discussion with IRB). Please provide this confirmatory notification from UCLA IRB that the project meets criteria as non-human subjects research. If in-country ethics approval is considered unnecessary, we **still require a letter or email** from the local investigator and/or mentor acknowledging that in-country approval is not required for the project. Please note that prior to any publication, most journals require that ethics approval be 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 by emailing webIRBHelp@research.ucla.edu with your (1) name, (2) UCLA logon, (3) UCLA ID number, (4) mednet email, and (5) your affiliation/department (i.e. DGSOM). Access is generally granted within 24 hours of the request. You will be required to register and go through CITI online training (see below for more information about CITI training). Most 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 GHP is available to assist, as needed.

The protocol you submit may be assessed as (see *Levels and Types of IRB Review* for more information):

(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.

In terms of your IRB protocol, you will likely fall under one of the following scenarios:

(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, which can take 3-4 rounds of responses (and 1-4 months in total) 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 their institution, but UCLA approval has not been obtained:** You and your UCLA faculty mentor must submit the letter of approval from the PI's institutional IRB to the UCLA IRB as part of your application 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. We encourage you to reach out to them (webIRBHelp@research.ucla.edu) if you have questions regarding which IRB is appropriate for your study, and with any questions about completion of the actual application.

In-country ethics committee

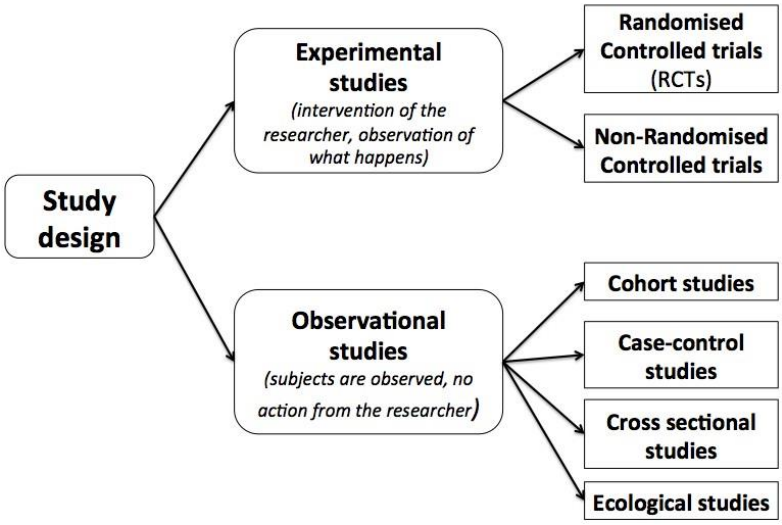
Submitting to an in-country ethics committee can often be complex, given that some committees only meet every few months and can take several months to respond. We encourage you to work with your UCLA and in-country mentors to ensure an ethics committee application is completed, and to start early! **Please send proof of local IRB approval or a letter from your mentor explaining why it is not required to Vijeta (VVaswani@mednet.ucla.edu) prior to departure (if traveling in-country) or before data collection begins, whichever comes first.**

Helpful hints

If you are going through this process for the first time, please note that different types of research/QI projects will have different requirements. For example, your summer research project may fall into any of several different categories. In general, the two aspects that will dictate your IRB process the most are (1) **study design** and (2) **target population**.

(1) Clearly defined study design is essential for IRB approvals. Examples of study designs and how they might impact IRB include:

- **Quality improvement (QI)**: Review this document to determine whether your project falls under the category of "research", as you may qualify for exemption (but are still required to go through IRB process)
- **Observational** (cross-sectionals/surveys/questionnaires/interviews/focus groups, cohorts, case-control, ecological/population-based): All require IRB, although they generally present less risk to participants as there is no direct intervention
- **Experimental** (RCTs, non-randomized controlled trials, clinical trials): All require IRB, and tend to present the most risk and require very clear design and planning



Source: https://www.masc.org.au/stats/Guides/StudyDesign

(2) Examples of target populations (human subjects – participants in a research project/study) and how this might impact IRB include:

- **Adults only** (not including pregnant women): Vulnerable to the least amount of risk and therefore most expedited subject group in terms of IRB approvals
- **Pregnant women only**: Require additional safeguards to ensure research presents no additional risk or potential harm to the mom or baby, therefore requiring more justification and time for IRB approval
- **Adults, including pregnant women**: Same as above

- **Children (<18) only**: Also require additional steps and safeguards, as children are unable to provide their own consent; assent and/or parental consent may be required (see image below for an explanation of assent vs. consent)
- **Adults (not including pregnant women) and children (<18)**: Same as above
- **Other protected groups** include fetuses, neonates, prisoners (may require special consent)

Assent vs Consent

Comparison Table

Characteristics	Assent	Consent
Meaning	Agreeing with something, a request, or to participate in an activity	Giving permission to be involved in an activity
Age	Obtained from people who are not of legal age to give a consent	Obtained from adults (people above the legal age)
In research	Willingness to participate in a study	Legally entered agreement for a subject to participate in a study
In law	Not a legally binding permission	Legally binding permission

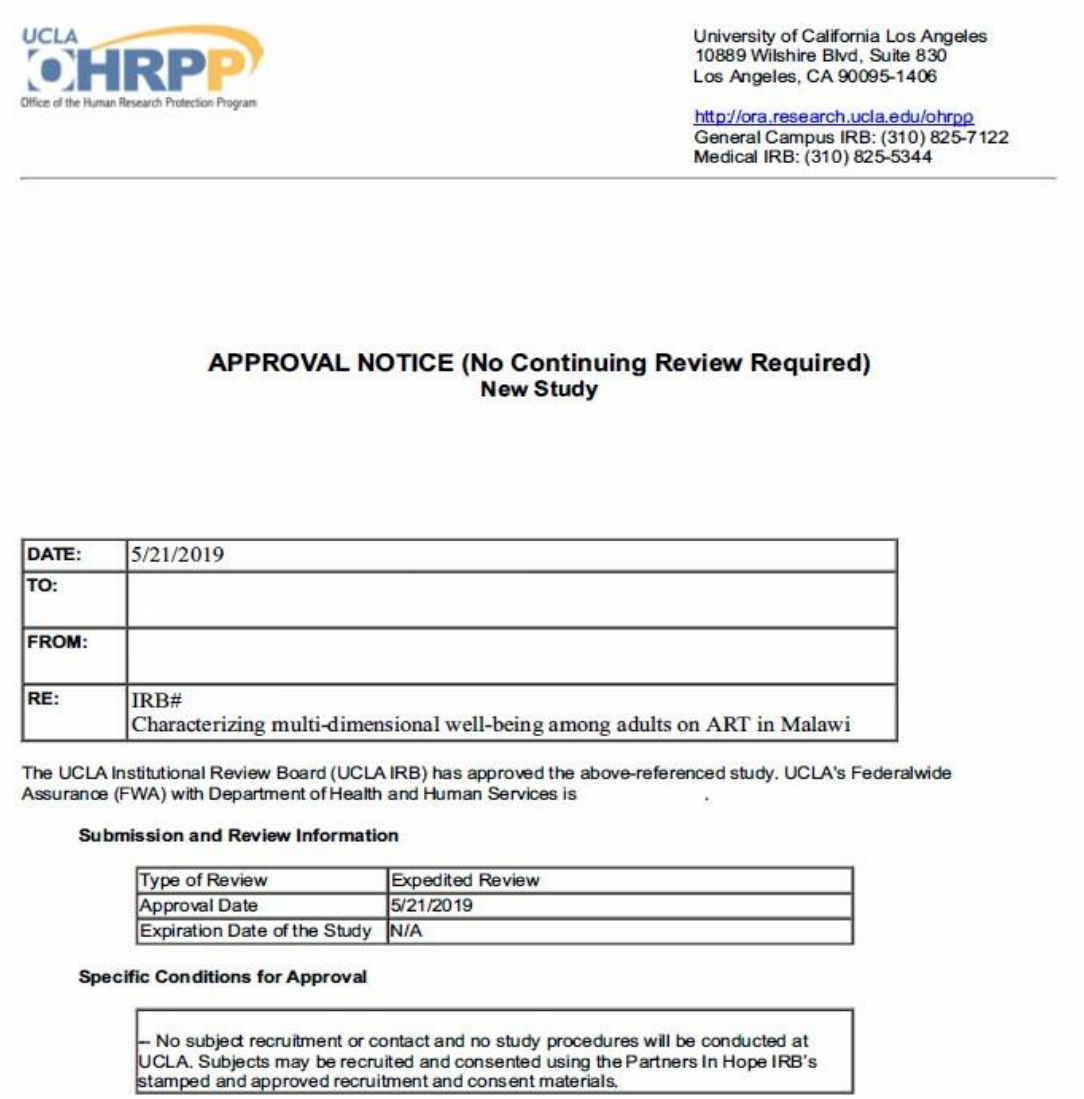
Source: https://www.masc.org.au/stats/Guides/StudyDesign

Step-by-step Guide to Obtaining a Copy of IRB Approval

To obtain a copy of your 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 **Vijeta (VVaswani@mednet.ucla.edu)**

Your approval letter will look something like this:



UCLA OHRPP
Office of the Human Research Protection Program

University of California Los Angeles
10889 Wilshire Blvd, Suite 830
Los Angeles, CA 90095-1406

http://ora.research.ucla.edu/ohrpp
General Campus IRB: (310) 825-7122
Medical IRB: (310) 825-5344

APPROVAL NOTICE (No Continuing Review Required)
New Study

DATE:	5/21/2019
TO:	
FROM:	
RE:	IRB# Characterizing multi-dimensional well-being among adults on ART in Malawi

The UCLA Institutional Review Board (UCLA IRB) has approved the above-referenced study. UCLA's Federalwide Assurance (FWA) with Department of Health and Human Services is .

Submission and Review Information

Type of Review	Expedited Review
Approval Date	5/21/2019
Expiration Date of the Study	N/A

Specific Conditions for Approval

-- No subject recruitment or contact and no study procedures will be conducted at UCLA. Subjects may be recruited and consented using the Partners In Hope IRB's stamped and approved recruitment and consent materials.

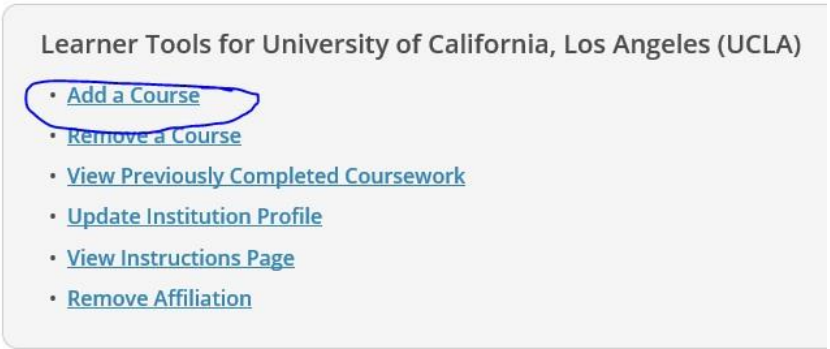
Step-by-Step CITI Training Guide

(1) Go to: https://www.research.ucla.edu/CITIProgram/ and login using mednet credentials (after your mentor has helped you to create an account, which is described on page 1)

(2) Select:

(3) Scroll down, and add recommended courses:

a. Human Research – Biomedical Researchers & Staff
b. Human Research - Social & Behavioral Researchers & Staff
c. UCLA HIPAA
d. Biomedical Responsible Conduct of Research (Optional)
e. Good Clinical Practice (Optional)



We suggest that you complete all of the recommended courses and modules to learn about how to perform different types of research to the highest ethical standards.