



UNIVERSITY OF CALIFORNIA, SAN DIEGO HUMAN RESEARCH PROTECTIONS PROGRAM

Human Subject Protection Training

A. General Information

As part of continuing education efforts in the area of human research protection and as a requirement to ensure more consistent and documented training of those involved in human research and/or the review of such research, UCSD faculty, staff, and students (undergraduate and graduate), who are conducting research as Principal Investigators or key personnel, must take the research-appropriate course on the Collaborative Institutional Training Initiative (CITI) Program's website.

As of November 13, 2009, the UCSD Human Research Protections Program (HRPP) required that all Principal Investigators and key personnel listed on an IRB application to be reviewed by a UCSD IRB or that is found to be exempt from IRB review complete the appropriate CITI training. The CITI home page is at <http://www.citiprogram.org/>.

Some researchers may have already completed the CITI training as a VA or another institution's requirement. Section E (see below) includes information on how to apply some or all of that completed training to meet this requirement.

If the Principal Investigator and all key personnel have not completed this training, research projects may be subjected to the following actions:

- *Documents provided for initial review of projects may not be placed on an agenda until training is completed.*
- *Initial and Continuing Review approval may not be granted until training is completed.*
- *Amendment requests associated with a change in PI and/or addition of key personnel may not be approved until training is completed.*

B. Background on CITI Training Modules and Benefits

What does the CITI Course in the Protection of Human Research Subjects Cover?

The CITI training includes basic courses in the following:

- Biomedical Research
- Social and Behavioral Research
- Good Clinical Practice
- Clinical Research Coordinator

What are the Benefits of Taking CITI Training?

The CITI Certification is accepted at hundreds of universities, hospitals and research facilities throughout the country. Acceptance of the CITI Training Courses by other institutions, allows a researcher or key personnel who has completed training through affiliation with UCSD or the VA to have their CITI training accepted by other institutions.

The CITI Basic/Refresher Course certification is good for three (3) years at which time the course may be re-taken.

You may print out your own completion certificate at any time. Anyone who has registered and completed a CITI Program Training Course can print out their own Completion Report when they need to do so, for example, to meet another institution's human subjects protection training requirement and to provide to the HRPP office (see Section F below).

C. Eligibility and Applicability of CITI Training

Who Needs To Take The CITI Program Training?

All Principal Investigators and "Key Personnel" who are engaged in research with living human beings, human tissue samples or identifiable private information, or conducting research under the review of UCSD IRBs are required to take the CITI Training Program. Other support staff may take this training as well.

Who are Key Personnel?

Key Personnel who are engaged in research with human subjects are UCSD faculty, staff or students who:

- Enroll individuals;
- Obtain subjects' informed consent by doing more than handing out or collecting forms or telling subjects how to get in touch with the Investigators;
- As part of the research team intervene or interact with subjects by performing invasive (e.g., drawing blood) or non-invasive (e.g., survey) procedures on them (excludes UCSD Medical Center workforce members performing services on behalf of UCSD Medical Center);
- Collect data directly from or follow-up directly with participants;
- Collect identifiable private information from participants;
- Have access to information that links participants' names or other identifiers with their data or;
- Act as authoritative representatives for the investigators.

Do Students Need to Take the CITI Training?

Graduate and undergraduate students that serve as a Principal Investigator (PI) or co-PI need to complete the same basic CITI Training course as a faculty member.

If the student is not a PI, co-PI or key personnel, it is up to the faculty member that teaches or supervises a course to instruct the students in the ethical practice of research and human subject protections. Faculty members, however, may use all or part of the CITI Training program for the protection of human subjects.

D. Determining Which CITI Course Applies and Must Be Completed

What CITI Course Must be Completed?

The Basic Course (if taking the course for the first time) or the Refresher Course (if “renewing” your CITI training), in either Biomedical or Social and Behavioral Research, is required in order for a protocol to be reviewed by the IRB and to verify training in research ethics to sponsors.

The other CITI courses, however, may be considered optional and may be found beneficial to those conducting research. Should you conduct research involving patient populations or conditions and drugs, devices, or agents, it is also strongly suggested that you complete the Good Clinical Practice Course that is extremely helpful in providing an excellent foundation for research and may be required by a study sponsor.

To determine which CITI course to complete, please review the following:

- If the **research involves direct or indirect patient populations; accesses medical records/tissues; is being conducted at UCSD Medical Centers; Rady Children’s Hospital – San Diego;** and the Biomedical Research Application form will be submitted — Complete the CITI Biomedical Research – Basic/Refresher Course.
- If the **research does not involve the above and is being conducted in general campus areas such as (but not limited to) History, Ethnic Studies, Education, Communication, Linguistics, and Economics** and the Social and Behavioral Sciences Application form will be submitted — Complete the Social and Behavioral Research – Basic/Refresher Course.
- If an Exemption of IRB Review is being requested and the Biomedical Standard Face Sheets and appropriate Research Plan will be submitted — Complete the CITI Biomedical Research – Basic/Refresher Course.
- If an Exemption of IRB Review is being requested and the Social and Behavioral Face Sheet and appropriate Research Plan will be submitted — Complete the Social and Behavioral Research – Basic/Refresher Course.

Because some areas of Psychology and Cognitive Science may cross-over research areas, contact the HRPP office should there be any confusion regarding which module to take or which application form to submit.

E. Specific Date and Time Requirements

By When must CITI Training be completed?

The Principal Investigator and all key personnel must complete their CITI training before the review of documents submitted to the HRPP may be done including initial review, continuing review and amendment requests. *Please note that by signing the current Application Facesheets and/or Continuing Review Facepages, the PI is certifying that the key personnel associated with the study have completed the appropriate CITI training.*

What if Current CITI Training is Valid?

If you have taken the CITI Protection of Human Research Subjects training before for another institution or as part of VA requirements, just log in on the CITI website at <http://www.citiprogram.org/> and add “UCSD” to your affiliate institutions. The credit for modules taken will automatically transfer over for most, if not all modules. In most cases, CITI will indicate there is no need to re-take if status is still valid.

How long will it take to complete the CITI Training?

The time required to complete each of the basic courses varies between 10 minutes and 30 minutes. The total time required is estimated to be 2 to 3 hours. It is strongly suggested that the entire course not be taken in one sitting, and individuals may enter the course at any time. Courses are designed to be taken sequentially.

F. Obtaining Certificate of Completion Report

When completing the course, select "View Completion Report" at the top or the bottom of the Grade Book and print it for your record. Currently, responses must be 75% correct to obtain completion. The completion report will remain on the CITI database and may be accessed by you or by the UCSD Human Research Protections Program and Research Compliance Program.

If a study is amended to change PI or co-investigators or add other "key personnel," the PI must ensure training is completed.

G. Other Training Requirements

The CITI course is intended to provide a training opportunity and resource. And, because it is used and accepted by hundreds of domestic and international organizations, it reduces the requirement for duplicative training in most cases. However, some sponsors, departments, and other entities may require additional training, such as NIH. Please check with the appropriate administrative authority as CITI does not replace training requirements beyond the purview of the IRB.

Private Health Information (PHI) Training Requirements

For the researchers potentially using Private Health Information (PHI) or related data, completion of the HIPAA tutorial on the UCSD website is also requested. For example, if you conduct research involving medical records or patient populations you would complete:

- 1) UCSD's HIPAA tutorial (a short, site-specific tutorial) available on our website at <https://irb.ucsd.edu/hipaatutorial/login.shtml>, and;
- 2) The appropriate CITI Course as noted in item D above.

H. Further Information

General Technical Questions about CITI Training:

For technical questions or help, please see the CITI Support Center at <https://support.citiprogram.org/>

For UCSD Specific Questions about CITI Training:

If you experience problems or have questions about your CITI training for the modules related to UCSD IRBs, please direct your questions to the HRPP Office at (858) 246-4777 or email hrpp@ucsd.edu.