



UNIVERSITY OF CALIFORNIA, SAN DIEGO HUMAN RESEARCH PROTECTIONS PROGRAM

Introduction of New Training for Human Research Protections Collaborative Institutional Training Initiative (CITI) Programs

A. GENERAL INFORMATION

New Training Available Now

UCSD Institutional Review Board (IRB) human subject protection training has expanded to include the Collaborative Institutional Training Initiative (CITI) Program's Human Subject Protection Course. 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 investigators or key personnel, may now take the research-appropriate course on the CITI website.

The UCSD IRB tutorial currently available on our website will be taken down in September 2009, as it will no longer meet training requirements. It will be replaced by the CITI training module. Completion of the appropriate CITI training module will be required effective November 13, 2009. The CITI home page is at <http://www.citiprogram.org/>.

CITI training is considered a national best practice for those involved with research and review. This additional IRB training effort is supported by the Collaborative Institutional Training Initiative (CITI) out of the University of Miami for baseline human research protection education and follows the introduction of UCSD's Research Compliance CITI efforts and activities.

Is this Training a New Requirement?

Currently, investigators and research personnel must comply with all external research training requirements including those requested by the VA. As of November 13, 2009, the UCSD Human Research Protections Program (HRPP) will require that all 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 training.

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

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 course modules in the following:

- Biomedical Course in the Responsible Conduct of Research Protection of Human Research Subjects
- Social-Behavioral Research Course in the Responsible Conduct of Research
- Good Clinical Practice Course

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 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 with the IRB application.

C. ELIGIBILITY AND APPLICABILITY OF CITI TRAINING

Who Needs To Take The CITI Program Training?

All 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 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 MODULE APPLIES AND MUST BE COMPLETED

What CITI Module Must be Completed?

For UCSD, the Basic Course, Protection of Human Research Subjects, in either Biomedical or Social-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 modules, however, are 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.

To determine which CITI module 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; VA, San Diego Healthcare System, Rady Children's Hospital – San Diego;** and the Biomedical Research Application form will be submitted—Complete the CITI IRB Biomedical, Protection of Human Research Subjects module
- 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 CITI IRB Social-Behavioral, Protection of Human Research Subjects module.
- 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 IRB Biomedical, Protection of Human Research Subjects module.
- 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 CITI IRB Social-Behavioral, Protection of Human Research Subjects module.

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?

▪ **If Current HRPP/IRB Training Status is Valid**

As of November 13, 2009, UCSD will require that all UCSD/VA faculty, staff, students and researchers and VA personnel listed on an application to be reviewed by a UCSD IRB must complete this CITI Protection of Human Research Subjects training. Go to the CITI home page to begin your training at <http://www.citiprogram.org/>.

- **If Current HRPP/IRB Training Status is Not Valid (expired or not completed)**

Completion of CITI training is requested **prior to submission** of an application to the IRB and the training certificate should be valid. PIs are responsible for ensuring training is completed and valid prior to submission. Completion of training may be verified prior to release of initial or continuing approvals, including amendment requests.

The IRB reserves the right to require that an investigator complete any or all of the optional training modules before approving a protocol.

What if Current CITI Training is Valid?

- **If CITI Module Has Already Been Completed for Another Institution or for the VA**

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 modules 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. Modules 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 the certificate. The completion will remain on the CITI database and may be accessed by you or by the UCSD Human Research Protections Program, and Research Compliance.

A copy of the completion report from the CITI site will need to be filed for the PI and the PI must retain copies of other completion reports for all co-investigators and other "key personnel" listed on each protocol. A copy of each of these reports must be provided along with initial and continuing review submissions.

Further, if a study is amended to change PI or co-investigators or add other "key personnel," the PI must ensure training is completed and maintain this record. A copy of the CITI completion report for each of these individuals must be provided along with the amendment request submission.

Please do not indicate, "Copy of report already on file at IRB" as the reports will need to be submitted and verified with each review.

UCSD will be working CITI to enhance our database to allow for this information to be downloaded automatically in the near future.

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 and the VA. 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 required. 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 <http://132.239.155.52/hipaatutorial/login.html>, and
- 2) CITI IRB training module for either Biomedical (research under review by IRB "A", "B", "C" or "D" committees) or Social and Behavioral Sciences module (research under review by the IRB "S") committee. If you conduct research reviewed by all IRBs, complete the Biomedical module.

UCSD's HIPAA tutorial can be verified by HRPP staff; however, documentation of CITI training must be retained by the PI and submitted as requested with the research application.

Eventually the CITI module will be developed to incorporate the HIPAA tutorial and it is anticipated that only one tutorial will be needed to meet UCSD's IRB training requirements.

H. FURTHER INFORMATION

General Technical Questions about CITI Training:

For technical questions or help, please contact CITI at: citisupport@med.miami.edu

CITI maintains a "Frequently Asked Questions" list available at:

<http://www.citiprogram.org/citidocuments/faq.htm>

For UCSD Specific Questions about CITI Training:

During the introductory period, 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) 455-5050 or email hrpp@ucsd.edu, subject line "CITI".