

#### **1.4 Human Research Institutional Review Board CITI Training Requirement**

The *Faculty Handbook* charges the Human Research Institutional Review Board (IRB) with “The formulation of guidelines and policies that meet federal regulations, incorporate the ethical concerns of the entire Saint Mary’s community, and reflect the particular needs of the College researchers.” Oversight of the IRB rests with the President and Provost, in that “guidelines and policies are to be approved by the President of the College in consultation with his designee and the College’s General Counsel,” and “The committee reports to the Provost or the Provost’s designee.” (1.7.3.8)

Consistent with this responsibility, as well as the increasing scholarly activity on campus and pursuit of external resources, the IRB has charted a process for achieving a federal-wide assurance (FWA). FWA status, held by many of our peer institutions, is important for researchers on campus who wish to apply for federal funding for their research involving human subjects, either on their own or together with collaborators at other institutions. Definitions of human subjects research can be found on the IRB can be found on their website: <http://www.stmarys-ca.edu/institutional-review-board>.

FWA certification requires the establishment of a training program for all human subjects researchers on campus. The IRB recognizes that completion of the training is an investment by our researchers to honor our commitment to safeguard human subjects, protect the institution from undue liability, and uphold our mission respecting the freedom and dignity of all persons. In discussion of adopting a human subjects protection training program, the IRB considered both the Collaborative Institutional Training Initiative (CITI), founded in March 2000 as a collaboration between the University of Miami and the Fred Hutchinson Cancer Research Center, and National Institutes of Health (NIH) training programs. The IRB adopted the online CITI program because it contains separate modules focused on either biomedical or social/behavioral research. As of 2011, there were approximately 1130 institutions and organizations with access to the CITI course site, including the 10 campuses of the University of California, most campuses of the California State University, and many of our peer institutions (e.g., Brigham Young University, Loyola Marymount, Pepperdine University, Santa Clara University, University of Portland, University of San Diego, Seattle University, Boston College, Mills College, Chapman University, and Pacific Lutheran University).

The IRB requires that all faculty, staff, and students conducting research with human participants complete the relevant CITI program modules for CITI certification. Once obtained, CITI certification is valid for four years.

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## **CITI Training and the Institutional Review Board**

**What is CITI training?** The Collaborative Institutional Training Initiative (CITI) was established in 2000 with the mission of *"providing high quality, peer reviewed, web based, research education materials to enhance the integrity and professionalism of investigators and staff conducting research."* In other words, CITI is a set of online modules detailing the complex aspects of conducting research with human participants. It provides an historical context including research that occurred before human subjects protection (e.g. Yale's Milgram experiment, the Tuskegee Syphilis experiment and the Stanford Prison Experiment). It then provides up-to-date information using the Belmont Report and federal guidelines to give information in an accessible way through modules and quizzes. It is currently used by over 2000 institutions including both highly prestigious research institutions and comparable teaching-focused institutions.

**Why is Saint Mary's College of California requiring anyone doing human participant research to complete CITI training?** In order to insure the protection of all individuals who are participants in Saint Mary's research endeavors, it is essential that researchers have a standard set of background knowledge for the benefit and protection of all. This on-line method is the most logistically realistic way to insure that all researchers have this information. Every module is followed by a brief quiz and all quizzes must be passed with at a rate of 80% or better. CITI is the best fit in terms of a program that insures this information has been communicated to everyone who takes the course. It also serves as an on-line resource for researchers who want to double check that they are within the boundaries of ethical research. Finally, this type of standardized training is essential for Saint Mary's College of California to procure Federal Wide Assurance (FWAs), giving the college the opportunity to compete for federal grant money.

**How long is it and how long will it take to complete the training?** The number of modules depends on the research type (Social/ Behavioral or Biomedical) and level of risk of research, but it is around 16 modules. The IRB committee is in the process of reducing the number of modules for student researchers to make the process as efficient as possible without sacrificing effectiveness. The amount of time it will take to complete CITI training will vary with reading speed and familiarity with research practices, but it is the contention of the IRB committee that if an individual is willing to commit solely to completing the training (e.g. ignoring email and letting calls go to voicemail, etc...) that it can be completed in less than three hours. Individuals also have the opportunity to log in and log back out without losing their progress so it could also be done in shorter increments, at the discretion of the learner.

**How often will I have to complete the training?** At SMC, we consider the CITI certification to be valid for four years.

## **How to Navigate to and Complete CITI Training**

1. **Begin at the Saint Mary's College IRB page (<http://www.stmarys-ca.edu/institutional-review-board>)**
2. **On the side of the screen are a series of links in blue boxes, the third to the last blue box is labeled CITI Training. Click on that one.**
3. **Assuming you do not have CITI certification from another institution, click on the link [www.citiprogram.org](http://www.citiprogram.org)**
4. **You have now navigated away from the Saint Mary's website**
5. **Click on the button Create an Account on the right hand side of the page**
6. **Go to the first box "Participating Institutions" Scroll to Saint Mary's College of California**
7. **Continue to Step 2 on the CITI website.**
8. **Complete "Personal Information" fields**
9. **Continue to Step 3 on the CITI website.**
10. **Enter your name, and email address**
11. **Create a user name and password (remember that passwords are case sensitive)**
12. **Continue to Step 4 on the CITI website.**
13. **Enter gender, race, ethnicity (please refer to the question bubble on screen to learn why CITI is asking for this demographic data). You will notice that you have an option to click "I would rather not disclose this" for all three questions**
14. **Continue to Step 5 on the CITI website.**
15. **Decide whether or not you would like to receive Continuing Education Units (CEUs) for completing the program and whether you would like CITI to send you other surveys, etc...**
16. **Continue to Step 6 on the CITI website.**
17. **Please provide the information requested by Saint Mary's College of California (for "Role in Research" you will most likely choose either Clinical Researcher or Co-Investigator)**

18. Continue to Step 7 on the CITI website.

19. Choose your role for Human Subjects Research (Biomedical Research Investigators, Social & Behavioral Research Investigators, Students conducting no more than minimal risk research, Research with data or laboratory specimens- ONLY: No direct contact with human subjects.).

Please note that if you are a student who is unsure of whether or not you conduct no more than minimal risk research, please consult with your instructor or sponsoring faculty member (e.g. thesis chair) to determine your status.

Faculty assigning the CITI course to students: For faculty doing research in a course, you should already have obtained from the IRB a "Course Notice of Exemption" for your course research. The IRB strongly recommends that you assign the "Students conducting no more than minimal risk research" CITI course for your students prior to beginning your course research project. Faculty should consider asking students to complete the CITI training outside of the classroom, because they can submit their completion forms to you for your records.

If you are conducting non-exempt research in your course, your students must complete the Basic/Refresher course for your research discipline.

Faculty supervising graduate research should assign the "Students conducting no more than minimal risk research" to their students only if the research is exempt. Otherwise, your students must complete the Basic/Refresher course for your research discipline.

For both prompts on this page, you are most likely to choose either Biomedical Basic/ Refresher Course or Social and Behavioral Basic/ Refresher Course depending on your discipline.

The Responsible Conduct of Research (RCR) courses are not required by the IRB. However, some funding agencies do require research ethics training, which the RCR courses are designed to meet.

20. Congratulations! Click Complete Registration

21. Now navigate to Main Menu and click Saint Mary's College of California as your institution affiliation.

22. You are now ready to begin your CITI training. For example, if you clicked Social and Behavioral Responsible Conduct of Research Course, you will complete: Social and Behavioral Research- Basic/ Refresher (16 modules).