

CITI Training Guide for Research with Human Participants

Fitchburg State University
Institutional Review Board (IRB)

Overview of CITI Training Guide

Members of the Fitchburg State community who conduct teaching laboratories, research, and/or supervise student researchers or post-docs are responsible for ensuring all work is done in compliance with Fitchburg State University and governmental compliance policies. This includes ensuring that all personnel are given proper training in the responsible and ethical conduct of research. In addition, three committees provide oversight over the use of human subjects, vertebrates, and biohazards. The Human Subjects Committee was established as an Institutional Review Board in order to protect the rights and welfare of human subjects on campus. The Institutional Animal Care and Use Committee (IACUC) assures that live vertebrate animals are cared for and used in ways that are scientifically, technically, and humanely appropriate. The Institutional Biosafety Committee (IBC) oversees the use of recombinant DNA (rDNA), microbes, biological toxins, plant and animal tissues, including human and nonhuman primate materials on campus. The IRB, IACUC, and IBC have jurisdiction over all activities on campus whether they be for teaching, scholarly activities, or staff activities.

Fitchburg State University uses the Collaborative Institutional Training Initiative Program (about.citiprogram.org), a division of BRANY, to help satisfy the education and training requirements for research compliance. The web-based courses are open to all faculty, staff, researchers, committee members, and students. **All faculty members, undergraduate, and graduate students are expected to complete training in the responsible and ethical conduct of research (RCR).** In addition, Fitchburg State requires that all individuals conducting human subjects research, utilizing vertebrates or biohazards, and/or serving on a compliance committee complete the appropriate training prior to the submission of a proposal to the appropriate governing committee.

New Users

New users should start here. If you have completed the RCR training, you may skip to the Human Subjects Training section below.

Adding Additional Courses

Once you have logged into your account, go to the page that lists your courses. At the bottom of the page that lists Go to the CITI Program web page at citiprogram.org. Create an account by selecting “Register” in the upper right-hand corner. (Figure 1)

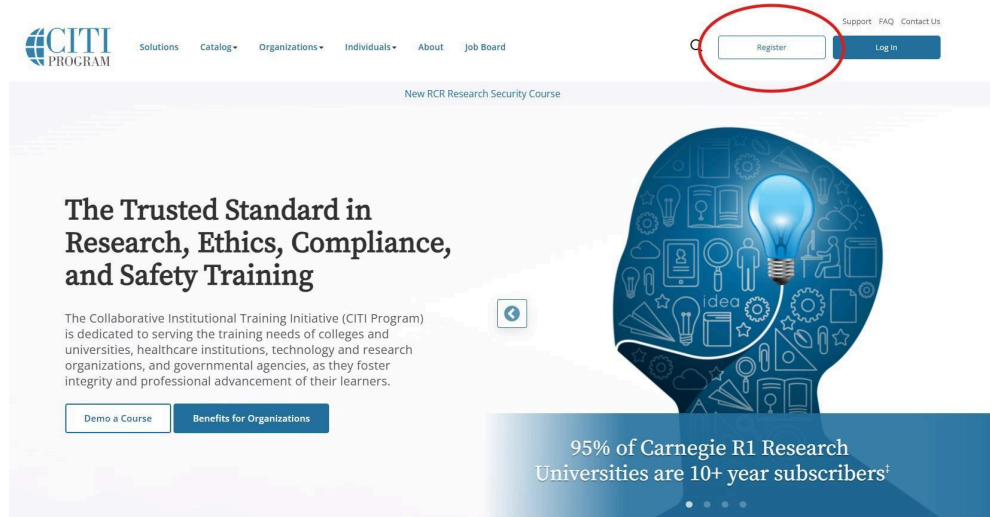


Figure 1. Screenshot of CITI website showing where to select "Register" to create a new CITI account

Information on getting started may be found at this link on the CITI website: support.citiprogram.org/s/article/updated-guide-to-getting-started

The registration process will present the user with a series of menus in order to collect basic information and establish a log-in with a password. On the page where it asks for a role at the university, select the one that best fits your status.

The organization affiliation is Fitchburg State University. The user will be asked to select their role in research. Select the appropriate choice: student or faculty/staff. The training requirements differ between the two groups.

Course Selection for Faculty/Staff/Administrators

There are two basic courses that are required of all faculty/staff/administrators need to complete to be eligible to conduct research with human participants:

- **Responsible Conduct of Research**
- **Conflicts of Interest**

If you need to complete training in more than one area, you will be able to add additional courses under a different training area once you are fully registered. The site will present the user with a series of questions or options that enable them to enroll in the correct compliance training. After selecting faculty/staff and selecting “Next”, the following learner groups will be listed:

- Human Subject Course
- Animal Care and Use
- Responsible Conduct of Research
- Good Clinical Practice Course
- Health Information Privacy and Security (HIPS)
- Biosafety and Biosecurity

Select **Responsible Conduct of Research**. (Figure 2) Next, select the specific course according to your learner group: Faculty/Researchers/Staff/Administrators (and others) RCR. (Figure 3) Anyone may take *Communicating Research Findings*. (Not required by Fitchburg State University)

Select Curriculum
Fitchburg State University

Please choose one learner group below based on your role and the type of research.

This question is required. Choose one answer.

- Human subject course
- Animal Care and Use
- Responsible Conduct of Research
- Good Clinical Practice course
- Health Information Privacy and Security (HIPS) optional
- Biosafety/Biosecurity

[Start Over](#) [Next](#)

Figure 2. Screenshot of CITI website showing list of "Learner Groups"

Select Curriculum

Fitchburg State University

If you want to take the Responsible Conduct of Research (RCR) course, please make your selection below.

This question is required. Choose one answer.

- Students Responsible Conduct of Research Course
- Faculty/Researchers/Staff/Administrators (and others) RCR
- Communicating Research Findings

Start Over

Next

Figure 3. Screenshot of CITI website showing the RCR courses for all "Learner Groups"

The appropriate course will be added to the learner's account. When enrolled in the Responsible Conduct of Research Course, the user will automatically be enrolled in the **Conflicts of Interest** course.

After selecting the course, the user is given the opportunity to enroll with another institution if needed. When the registration is complete, click on **Finalize Registration**.

The learner account registration is complete.

Course Selection for Students

In general, there is one basic course that are required of students to be eligible to conduct research with human participants:

- ***Students Responsible Conduct of Research***

Depending on your role on the research team and type of research being conducted, you may need to complete additional training in more than one area. The faculty advisor and/or IRB Chair can help determine if additional training is required. You will be able to add additional courses under a different training area once you are fully registered. The site will present the user with a series of questions or options that enable them to enroll in the correct compliance training. After selecting student and selecting "Next", the following learner groups will be listed:

- Human Subjects Research
- Animal Care and Use
- Responsible Conduct of Research
- Biosafety and Biosecurity

Select **Responsible Conduct of Research**. (Figure 4) Next, select the specific course according to your learner group: Students Responsible Conduct of Research. (Figure 5) Anyone may take *Communicating Research Findings*. (Not required by Fitchburg State University)

Select Curriculum
Fitchburg State University

Please choose one learner group below based on your role and the type of research.

This question is required. Choose all that apply.

- Human Subjects Research
- Animal Care and Use
- Responsible Conduct of Research
- Biosafety/Biosecurity

[Start Over](#) [Next](#)

Figure 4. Screenshot of CITI website showing "Types of Research" for student users

Select Curriculum

Fitchburg State University

If you want to take the Responsible Conduct of Research (RCR) course, please make your selection below.

This question is required. Choose one answer.

- Students Responsible Conduct of Research Course
- Faculty/Researchers/Staff/Administrators (and others) RCR
- Communicating Research Findings

Start Over

Next

Figure 5. Screenshot of CITI website showing the RCR courses for all "Learner Groups"

The appropriate course will be added to the learner's account.

After selecting the course, the user is given the opportunity to enroll with another institution if needed. When the registration is complete, click on **Finalize Registration**.

The learner account registration is complete.

Accessing the Course

The user will now be able to access the **Main Menu** of their account. This page lists the course the user has chosen. The Main Menu also provides **Learner Tools** designed to help in the completion of course. Each course is composed of multiple modules which may be completed over time.

Click the **Title of the Course** to begin or continue a course. The user can complete the modules at their own pace. In order to complete the training, you must first complete the "Integrity Assurance Statement." Complete the **Required Modules** and associated quizzes. Depending on the discipline specific requirements the user may need to complete several Optional Modules. The IRB Chair or the campus CITI administrator may assist in determining which optional modules should be completed, if any.

When all required modules are completed successfully, print the completion report.

The RCR Training is now complete and additional training for human subjects, animal care and use, or biosafety may now be completed. See the appropriate training document for further information.

Returning Users

Users with an account and completed RCR training may begin here.

Adding Additional Courses

Once you have logged into your account, go to the page that lists your courses. At the bottom of the page that lists your courses, you will see the following menu. (Figure 6) Click on **Add a Course** and identify whether you are a student or faculty/staff. (Figure 7)

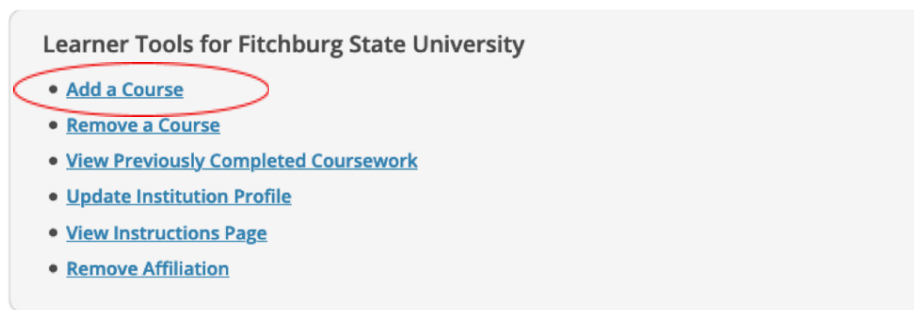


Figure 6. Screenshot of CITI website showing the "Learner Tools" for Fitchburg State University menu

Question 1

Please make your selection below. You will be enrolled in courses based on your role in research.

This question is required. Choose one answer.

Students

Faculty/Staff

Figure 7. Screenshot of CITI website showing selection for role in research

Faculty/staff will be presented with the following:

- Human Subject Course

- Animal Care and Use
- Responsible Conduct of Research
- Good Clinical Practice Course
- Health Information Privacy and Security (HIPS)
- Biosafety and Biosecurity

Select **Human Subject Course**. (Figure 8)

Select Curriculum
Fitchburg State University

Please choose one learner group below based on your role and the type of research.

This question is required. Choose one answer.

- Human subject course
- Animal Care and Use
- Responsible Conduct of Research
- Good Clinical Practice course
- Health Information Privacy and Security (HIPS) optional
- Biosafety/Biosecurity

[Start Over](#) [Next](#)

Figure 8. Screenshot of CITI website showing "Human Subject Course" option for faculty/staff

Students will be presented with the following:

- Human Subjects Research
- Animal Care and Use
- Responsible Conduct of Research
- Biosafety and Biosecurity

Select **Human Subjects Research**. (Figure 9)

Select Curriculum

Fitchburg State University

Please choose one learner group below based on your role and the type of research.

This question is required. Choose all that apply.

- Human Subjects Research
- Animal Care and Use
- Responsible Conduct of Research
- Biosafety/Biosecurity

Start Over

Next

Figure 9. Screenshot of CITI website showing "Human Subject Course" option students

Once the user has selected their area of training, the user will be asked to select the appropriate course defined by their role at the university and the type of research being conducted. (Figure 10)

Select Curriculum

Fitchburg State University

Please choose one learner group below based on your role and the type of human subjects activities you will conduct. You will be enrolled in the Basic Course for that group.

This question is required. Choose one answer.

- Biomedical Research Investigators:** Choose this group to satisfy CITI training requirements for Investigators and staff involved primarily in Biomedical research with human subjects.
- Social & Behavioral Research Investigators:** Choose this group to satisfy CITI training requirements for Investigators and staff involved primarily in Social and Behavioral research with human subjects.
- IRB Members:** This Basic Course is appropriate for IRB or Ethics Committee members.
- Students conducting no more than minimal risk research**
- Research with data or laboratory specimens- ONLY:** No direct contact with human subjects.
- IRB Chair member
- Institutional Official

Start Over

Next

Figure 10. Screenshot of CITI website showing course selection based on role and type of research to be conducted

Course Selection

Your position with the university, role in the research project, and type of research being conducting with human participants will all factor in to which training course(s) must be completed. The following information can be used to help guide you as to which Human Subject Training is required. The IRB Chair or campus CITI Administrator can also assist you in determined which training in required.

Student Course Selection

In general, Student users should complete the following:

- ***Students Responsible Conduct of Research***
- ***Students- Class Projects***

Depending on the nature of and the role of the student in the research project, different and/or additional training may be required. This could include completing training as outlined in the

Faculty/Staff Course Selection section. The IRB Chair or campus CITI Administrator, in collaboration with the faculty advisor, can assist with determining what training is required.

Faculty/Staff Course Selection

There are two basic courses that are required of all faculty/staff/administrators need to complete to be eligible to conduct research with human participants:

- ***Responsible Conduct of Research***
- ***Conflicts of Interest***

Depending on your role at the university and/or the type of research you will be conducting, you may need to complete one or more than one of these courses. The IRB Chair or campus CITI Administrator, in collaboration with the faculty advisor, can assist with determining what training is required.

1. Biomedical Research
 - a. Involves projects that examine biological processes, diseases, or medical interventions in humans
 - b. Includes, but is not limited to:
 - i. Collection of physical data (e.g., blood samples, tissue, physiological measurements)
 - ii. Testing of drugs, medical devices, or clinical treatments
 - iii. Projects related to diagnosis, prevention, or treatment of diseases
2. Social & Behavioral Research
 - a. Involves projects focused on understanding human behavior, attitudes, or interactions
 - b. Includes, but is not limited to:
 - i. Surveys, questionnaires, and/or interviews
 - ii. Observations of individuals or groups
3. Biomedical Data or Specimens ***ONLY*** Research
 - a. Involves projects using existing data or biological specimens ***without*** direct interaction with participants
 - b. Includes, but is not limited to:
 - i. Analysis of previously collected medical records or datasets
 - ii. Projects using stored blood, tissue, or DNA samples
 - iii. Secondary analysis from prior studies
4. IRB Member
 - a. Must be completed by each IRB Member
 - b. Must also complete the 2 basic required courses
 - c. Must also complete trainings listed in 1 through 3
5. IRB Chair
 - a. Must be completed by the IRB Chair
 - b. Must also complete the 2 basic required courses

- c. Must also complete trainings listed in 1 through 4
- 6. Institutional Official
 - a. Must be completed by the Institutional Official

When all required modules are completed successfully, print the completion report.

External Collaborators

Individuals who are not current students or faculty/staff/administrators at Fitchburg State University may still be involved as co-investigators on a research project that includes human participants where the principal investigator is affiliated with Fitchburg State University. These individuals will need to complete the same CITI training as a current employee. Further, the individual or their institution's IRB will need to enter into a "Reliance Agreement". Please contact the IRB Chair for additional information.