

Instructions to complete CITI Human Subjects Training - New User

To ensure compliance with federal regulations that all personnel engaged in research or advising research involving human subjects receive specialized training in human subject protection, Marian University has subscribed to the Collaborative Institutional Training Initiative (CITI), which is maintained at the University of Miami.

The Institutional Review Board (IRB) will only approve protocol submissions from researchers who have successfully completed the appropriate web-based CITI training course. All faculty, staff and students involved either as a researcher or as a research advisor must complete human subject training before the IRB will review the protocol submissions. Research involving human subjects may not begin until IRB approval has been received.

Training certification is **valid for three years** after the date of successful completion of the training program.

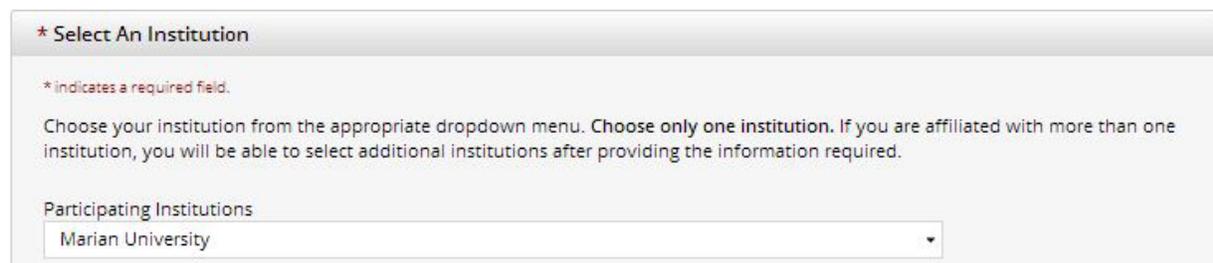
Step 1: Log on to the CITI website: <http://www.citiprogram.org>

Step 2: Click on: “Register”



The screenshot shows the CITI PROGRAM website. The header includes the logo and the text "Collaborative Institutional Training Initiative at the University of Miami". A search bar is located in the top right. Below the header is a navigation menu with links: Home, About Us, Courses, Become a Subscriber, CE Credits, News and Events, Resources, and Contact Us. The main content area features two images: one of a large blue structure and another of a computer monitor displaying the CITI PROGRAM logo. To the right of the images is a registration form with fields for Username and Password, a Log In button, and a link for "Forgot Username or Password?". Below the form is a "Create an account" section with a "Register" button, which is highlighted by a yellow arrow. A note below the button states: "Access requires registration as an affiliate of a subscribing CITI institution or as an unaffiliated learner."

Step 3: Select An Institution. Go to the drop down box entitled, “Participating Institutions.” Click on the arrow and select **Marian University**; leave the remaining items blank. Click “Continue”.



The screenshot shows a form titled "* Select An Institution". Below the title is a note: "* indicates a required field." The main instruction reads: "Choose your institution from the appropriate dropdown menu. Choose only one institution. If you are affiliated with more than one institution, you will be able to select additional institutions after providing the information required." Below this is a dropdown menu labeled "Participating Institutions" with "Marian University" selected.

Step 4: Personal Information. Enter the requested information, noting that you are not required to include a second Email Address. Click “Continue”.

Personal Information

* indicates a required field.

* First Name * Last Name

* Email Address * Verify email address

If you have a secondary email address that can be used in case your preferred email address changes, enter it below.
If you forget your username or password, it will be mailed both to your preferred email address and your secondary email address.

Secondary email address Verify secondary email address

Step 5: Create your Username and Password. Enter a username and password meeting the posted requirements, as well as a security question. Click “Continue”.

Create your Username and Password

* indicates a required field.

Your username should consist of 4 to 50 characters. Your username is not case sensitive; "A12B34CD" is the same as "a12b34cd". Once created, your username will be part of the completion report.

* User Name

Your password should consist of 8 to 50 characters. Your password IS case sensitive; "A12B34CD" is not the same as "a12b34cd".

* Password * Verify Password

Please choose a security question and provide an answer that you will remember. **NOTE: If you forget your login information, you will have to provide this answer to the security question in order to access your account.**

* Security Question

* Security Answer

Step 6: Gender, Ethnicity, and Race. Complete the page, including only the personal information you wish to reveal. Click “Continue”.

Gender, Ethnicity and Race

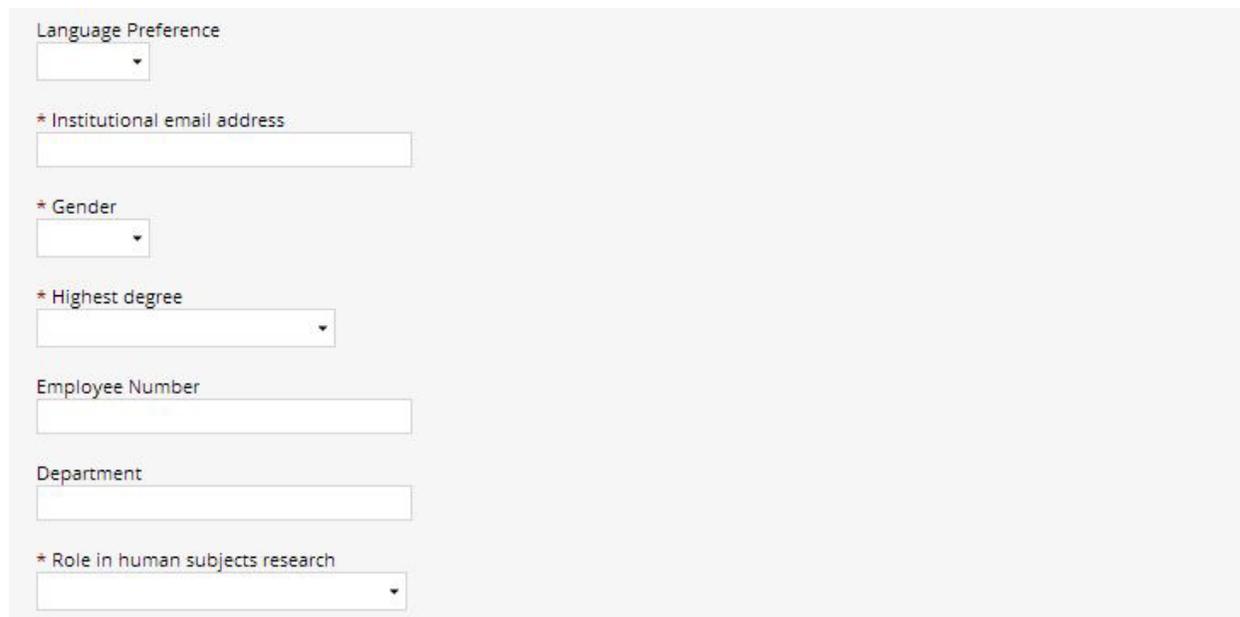
Why does CITI Program ask about your gender, race and ethnicity? ⓘ
Why does CITI Program use these categories? ⓘ
Why does CITI Program ask about your gender? ⓘ

Step 7: CEU Credits and Survey Participation. Please note that while you need to answer the questions, you do NOT need to sign up for the CME/CEU credits or future research surveys. Click “Continue”.

* Are you interested in the option of receiving Continuing Education Unit (CEU) credit for completed CITI Program courses?

* Can CITI Program contact you at a later date regarding participation in research surveys? 

Step 8: Additional Information. Please complete at minimum the required fields.



Language Preference

* Institutional email address

* Gender

* Highest degree

Employee Number

Department

* Role in human subjects research

Note: In the field, “Role in Human Subjects Research” –

Clinical Researcher
Interviewer
IRB administrator
IRB Chair
IRB Member
Pharmacist
Principal Investigator
Co-Investigator
Recruiter
Statistician
Study nurse
Study Coordinator
Site Coordinator
Social Worker
Research Assistant
Data manager

This field is for record-keeping purposes only. It will not affect the courses that you take, nor will an inaccurate entry require future changes. The IRB recommends:

- a. Graduate students may choose “*Student Researcher - Graduate Level*” or, if acting as the primary investigator for a culminating activity, such as action research, master’s theses, master’s project, or action research, choose “*Principal Investigator*.”
- b. Undergraduate researchers should choose “*Student Researcher – Undergraduate*.”

Note: In the field, “What course do you wish to take?”

- 1) Students, Faculty, Staff from all majors should choose “Basic Human Subjects - Social and Behavioral Focus”
- 2) Only researchers engaged in medical and/or biomedical research should select “Basic Human Subjects –Biomedical.”

Students should confirm the appropriate course with their research advisor/instructor before.

- Basic Human subjects - Biomedical
- Basic Human Subjects - Social & Behavioral Focus** ←
- Basic Human Subjects - Biomedical & Social & Behavioral Focus
- Biosafety / Biosecurity
- Good Clinical Practice
- Health Information Privacy and Security (HIPS)
- Laboratory Animal Welfare
- Responsible Conduct of Research
- Refresher Course - Biomedical Research
- Refresher Course - Social and Behavioral Research
- Other

Click “Continue”.

Step 9: Select Curriculum: Using the information above, select the appropriate learner group. For new users, you should select an option from ONLY Question 1 , as shown in the image below, unless directed by the ORSP or, for students, by your research advisor.

Human Subjects Research

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.

Choose one answer

- Social and Behavioral Research ←
- Biomedical Research Only
- IRB Board Members Only
- Biomedical Data or Specimens Only Research
- Undergraduate Students (Non-McNair)
- I have completed the Basic Course.

Please go to Question 2.

Question 2

If you have completed the Basic Course portion, 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 Refresher Course for that group.

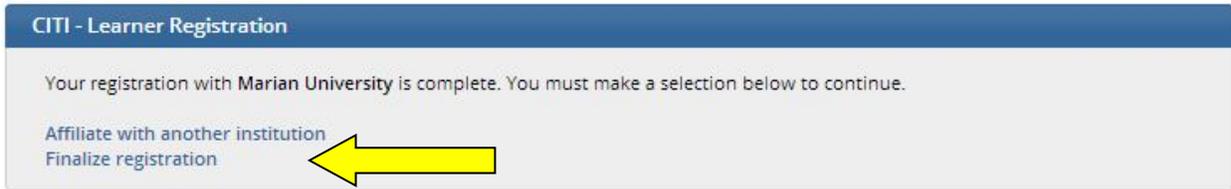
Choose one answer

- Social and Behavioral Research
- Biomedical Research Only
- IRB Board Members Only
- Biomedical Data or Specimens Only Research
- I have not completed the Basic Course. ←

Please go to Question 1.

Click “Continue”.

Step 10: Confirm your account. You will now receive a confirmation page; click on “Finalize registration” to proceed.

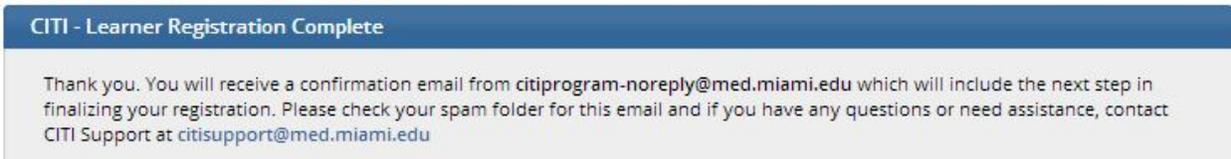


CITI - Learner Registration

Your registration with Marian University is complete. You must make a selection below to continue.

[Affiliate with another institution](#)
[Finalize registration](#)

When you do so, you will receive a confirmation message similar to the one below.



CITI - Learner Registration Complete

Thank you. You will receive a confirmation email from citiprogram-noreply@med.miami.edu which will include the next step in finalizing your registration. Please check your spam folder for this email and if you have any questions or need assistance, contact CITI Support at citisupport@med.miami.edu

An email will be sent to the primary email account you listed during the registration process. Navigate to your email account, open the message from CITI, and click on the link included in the email to confirm your account. This will bring you to a webpage confirming your registration; follow the link to log into your account using the username/password you have created.

✔ Thank you. Your email has been validated and your registration complete. [Click here to log into your CITI account.](#)

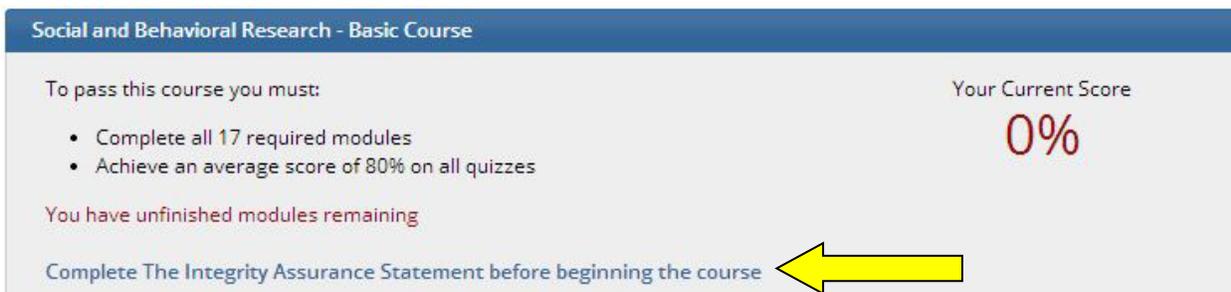
Step 11: Beginning your courses. You'll now be at your main screen, as shown below. Under “Marian University Courses”, you'll see the selection you made for curriculum. To begin your training, click on the course name (in the example's case, “Social and Behavioral Research”).



| Course | Status | Completion Report | Survey |
|--------------------------------|-------------|-------------------|--------|
| Social and Behavioral Research | Not Started | Not Earned | |

You now are seeing your Gradebook, which lists each training module required. Each training module has reading material followed by a short quiz. A successful score is 80% correct answers for the training as a whole. You may retake any module's quiz until you have achieved 80% or better.

The first step is to complete the “Integrity Assurance Statement” by clicking the blue link, as shown below.



Social and Behavioral Research - Basic Course

To pass this course you must:

- Complete all 17 required modules
- Achieve an average score of 80% on all quizzes

You have unfinished modules remaining

Your Current Score
0%

[Complete The Integrity Assurance Statement before beginning the course](#)

You then can begin each item by clicking on the top module marked as “Incomplete”, as shown below.

| Required Modules | | |
|--|----------------|----------|
| | Date Completed | Score |
| Belmont Report and CITI Course Introduction (ID: 1127) | Incomplete | 0/0 (0%) |
| Students in Research (ID: 1321) | Incomplete | 0/0 (0%) |
| History and Ethical Principles - SBE (ID: 490) | Incomplete | 0/0 (0%) |
| Defining Research with Human Subjects - SBE (ID: 491) | Incomplete | 0/0 (0%) |
| The Regulations - SBE (ID: 502) | Incomplete | 0/0 (0%) |
| Assessing Risk - SBE (ID: 503) | Incomplete | 0/0 (0%) |
| Informed Consent - SBE (ID: 504) | Incomplete | 0/0 (0%) |
| Privacy and Confidentiality - SBE (ID: 505) | Incomplete | 0/0 (0%) |
| Research with Prisoners - SBE (ID: 506) | Incomplete | 0/0 (0%) |
| Research with Children - SBE (ID: 507) | Incomplete | 0/0 (0%) |
| Research in Public Elementary and Secondary Schools - SBE (ID: 508) | Incomplete | 0/0 (0%) |
| International Research - SBE (ID: 509) | Incomplete | 0/0 (0%) |
| Internet Research - SBE (ID: 510) | Incomplete | 0/0 (0%) |
| Research and HIPAA Privacy Protections (ID: 14) | Incomplete | 0/0 (0%) |
| Vulnerable Subjects - Research Involving Workers/Employees (ID: 483) | Incomplete | 0/0 (0%) |
| Conflicts of Interest in Research Involving Human Subjects (ID: 488) | Incomplete | 0/0 (0%) |
| Marian University (ID: 12867) | Incomplete | 0/0 (0%) |



As you complete modules, the date of completion and score will be listed, with the next available module becoming available to complete.

| | | |
|--|------------|------------|
| Belmont Report and CITI Course Introduction (ID: 1127) | 09/09/13 | 3/3 (100%) |
| Students in Research (ID: 1321) | Incomplete | 0/0 (0%) |



You do not have to complete the entire course at one time. When you come back to the training site, you will be asked for your user name and password, which will bring you back to your Main Menu (see Step 11), and you may continue the course at the point you left it.

Once all modules are passed, CITI notifies you of successful completion. We recommend that you print the certification for your records. Students may be required to submit a copy to their research advisors.

It is not necessary for you to submit documentation that you have completed the course with the IRB Protocol Submission Forms. Notification of training completion is sent to the IRB Administrator within 24 hours of completing the course.

If you have any questions concerning the training, please contact the IRB at 920-923-7632 or email irb@marianuniversity.edu.