Mandatory Training

Purpose

The purpose is to outline the policies and procedures for mandatory educational training in human research.

Definitions | Chart of Courses | Additional Courses | International Research | Professional Services | Unaffiliated Investigators | Policies | Procedures

Definitions

CITI is the Collaborative Institutional Training Initiative (www.citiprogram.org). Established in 2000 by the University of Miami and currently operated by the Biomedical Research Alliance of New York (BRANY), it is the provider of high quality, peer-reviewed, and web-based educational courses in research ethics, regulatory oversight, research administration, and other topics pertinent to the interests of member organizations and individual learners.

A **clinical trial** is a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on biomedical or behavioral health-related outcomes.

To be **engaged in research** activities, an institution's employees or agents, for the purposes of research must obtain: (1) Data about the subjects through intervention or interaction with them; (2) identifiable private information about the subjects; or (3) The informed consent of human subjects for the research.

A **Human Subject (Participant)** is a living individual about whom an investigator (whether professional or student) conducting research:

1. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
2. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

International Research is research which is proposed to take place outside of the United States. It may involve activities which take place on foreign soil, which access foreign human subjects remotely (e.g., Internet), or which access data about human subjects from the foreign location.

Research is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge; a project designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge, which may be expressed in theories, principles, and statements of relationships.

Chart of Available CITI Courses

Once registered at the CITI Program's site at www.citiprogram.org, CITI users may add a training course or learner group to their account at any time. Marywood University's available courses will be shown under a series of five questions, as shown in this table. Investigators should take note of where to submit their completion reports, also indicated in the table.

Available Courses	Learner Groups within Courses	Complete If	Where to Submit Report	Expiration Date
Question 1 at CITI HUMAN RESEARCH	Social/Behavioral Biomedical Clinical Trial/GCP	Working with human subjects or identifiable human subject data or specimens in research	ERC or IRB via IRBNet	3 years

	Staff & Members			
Question 2 at CITI RESPONSIBLE CONDUCT OF RESEARCH	N/A	Involved in a federally funded research project	ERC or IRB via IRBNet	3-4 years or at certain career stages (refer to funding source)
Question 3 at CITI INFORMATION PRIVACY SECURITY	N/A	A student in the School of Social Work (prior to field placement)	SSW Staff	None
Question 4 at CITI ANIMAL RESEARCH	Non-Vertebrate Animal Vertebrate Animal Vertebrate Animal-Student Teaching Demonstrations	Working with animals in research or during class activities	IACUC via IRBNet Sponsored Programs	None
Question 5 in CITI BLOODBORNE PATHOGEN	N/A	A student in the Physician Assistant Program	PA Professor	1 Year

Policies

Educational training in the protection of human subjects is required of all investigators who are engaged in such research. This includes all members of the research team, such as co-investigators and research assistants, but may extend to others who will work directly with subjects, such as live interpreters, or those who may perform data analysis of identifiable records. Research advisors

(formerly called sponsors) and IRB staff and members must also complete this training.

Educational training is conducted online through the CITI Program at www.citiprogram.org, with each basic course taking approximately two to four hours to complete. Courses are comprised of modules followed by brief quizzes. Completing a set number of core modules, each learner must also select a minimum number of electives based on the learner's research activities and/or interests. Learners are free to complete additional electives or supplemental modules.

Completion of the human training course is good for **three years**, at which time a refresher course must be completed.

Investigators must submit evidence of human research training to the Exempt Review Committee or Institutional Review Board online in the form of completion reports, which show all transcripts (modules and grades). Completion certificates will not be accepted.

Besides human research, several other training courses are available through Marywood University's CITI account, some of which are offered by other campus departments. See the complete list in the above chart and described in more detail, below.

HUMAN RESEARCH COURSE (HRC) – Required of All Engaged in Human Research Presenting topics such as history and ethical principles, regulations, informed consent, risk, privacy and confidentiality, etc., this course is required of <u>all</u> investigators engaged in human research. Learners must earn a minimum passing score of eighty (80) percent. Learners must select one or more of the following groups according to their primary discipline or role. Those involved in FDA-covered clinical trials must take both the Biomedical and Clinical Trial group courses. Only IRB members or office staff must complete the Staff & Members learner group.

- Social/Behavioral learner group
- Biomedical learner group
- Clinical Trial /Good Clinical Practice learner group (if this applies, must also take Biomedical)
- Staff & Members learner group

Additional Courses or Modules

1. Responsible Conduct of Research Course (RCR) – For Federally Funded Projects

   Presenting topics such as authorship, collaborative research, conflict of interest, peer review, research misconduct and responsible mentoring, this course is required only if certain Federal funding will be awarded (e.g., NSF, NIH, USDA, etc.). Learners must earn a minimum passing score of eighty (80) percent for this course. Completion reports are to be submitted to the IRB or ERC, if the course applies. The Office of Research and Sponsored Programs should also be sent a copy. The course must be renewed at intervals set by Federal funding agencies (e.g. four years for NIH clinical trials; three years or at specific career intervals for some awards). Due to the variable timetables, the CITI site does not establish expiration dates. It is an investigator's responsibility to ensure that training is kept up to date.

2. Information Privacy and Security Course - For School of Social Work Students

   Presenting the basics of health privacy and information security, this four-module course is required by the School of Social Work (SSW), which uses the CITI site to meet its own requirements for field placements. Completion reports are to be submitted directly to the department, not to the ERC or IRB. Learners must earn a minimum passing score of eighty (80) percent for this course. Optional modules are available as part of the course.

3. Animal Research Course(s) - For Vertebrate or Invertebrate Research or Class Demonstration Projects

Presenting such topics as animal care and use, lab procedures, or classroom activities, this course and the learner groups within it are required and managed by the Institutional Animal Care and Use Committee (IACUC). Learners must earn a minimum passing score of eighty (80) percent for this course. Completion reports are to be submitted directly to IACUC via IRBNet. When funding is involved, the Office of Research and Sponsored Programs should also be sent a copy.

4. Bloodborne Pathogen Course - For PA Program Students

Presenting such topics as Hepatitis B vaccination, engineering controls, universal precautions and work practices, and emergency response, this five-module course is required by the Physician Assistant (PA) Program, which uses the CITI site to meet its own requirements. Completion reports are to be submitted directly to the requesting professor, not to the ERC or IRB. Learners must earn a minimum passing score of eighty (80) percent for this course.

International Research - Module Required

Available within the human research course, this module used to be optional, but is now required as part of the basic course.

Professional Services (Interpretation, Transcription, etc.)

Because they interact with participating subjects and are often engaged in the informed consent process, live interpreters must complete the Human Research course. Transcriptionists, document translators, interpreters of de-identified audio recordings, or other hired professionals performing a specific skill (e.g., X-ray technician) are usually not considered to be engaged in research activities so long as they are not interpreting or analyzing results, and therefore may not be required to complete online training. Decisions about training for these individuals will be made on a case-by-case basis.

Unaffiliated Investigators

Training evidence provided by investigators who are not affiliated with Marywood University will be evaluated on a case-by-case basis. Unaffiliated investigators must supply evidence of completed training with clear indication of topics covered, not just a certificate of completion. If such investigators have completed training through CITI, they must provide their full, basic course reports (showing modules and grades) in additional to any refresher course reports or certificates of completion. Refresher courses are abbreviated courses that are retaken at intervals specified by the institution, such as every two to three years.

Procedures (Instructions)

How to Register and Select Courses at CITI:

1. Visit the Collaborative Institutional Training Initiative (CITI) at www.citiprogram.org.
2. If new to the website, click Register in the upper right corner of the page. If already registered, click *Login* and skip to step 9.
3. CITI's Step 1:
    1. Under Select Your Organization Affiliation, type Marywood University into the search box.
    2. Click the checkbox agreeing to the Terms of Service.
    3. Click *Continue.*
4. CITI's Steps 2, 3 and 4: Supply your name, email address, username, password and country of residence. If you have a secondary email account, add it. If not, leave it blank.
5. CITI's Step 5: Click yes or no to indicate if you will purchase continuing education credits. This involves a fee and is optional.
6. CITI's Step 6: Indicate language preference and other institution-specific questions.
7. CITI's Step 7: Enroll in required courses by checking the appropriate boxes under the below sections. You can also return later to add them by selecting your institution and then scrolling to the bottom of the page to click *Add a course.*
    1. Question 1 - Human Research Course: Those working with human subjects will typically select one learner group. The Social/Behavioral course is most common. Those working on an FDA-monitored clinical

trial (e.g. drugs, biologics, devices) must take both the Biomedical and Clinical Trial (Good Clinical Practice) courses. Only those serving on the IRB or working in the IRB office should select the IRB Members and Staff course. It contains both Social/Behavioral and Biomedical course modules, including one module specific to members.

2. Question 2 - Responsible Conduct of Research Course: Those working on a federally funded project requiring this basic, RCR course will choose this selection in addition to the human research course or courses. It is most common for NIH, NSF and USDA. Refer to the funding agency for requirements.

3. Question 3 - Information Privacy and Security Course: Students in the School of Social Work (SSW) involved in field placements may be asked by the SSW to select this course. IT IS NOT REQUIRED BY THE IRB/ERC. Do not submit this report to the IRB or ERC. The SSW uses CITI for its own purposes. Submit your report directly to the SSW only.

4. Question 4 - Animal Research Course: Those working with animals will select the appropriate course. Do not submit this report to the IRB or ERC unless it asks. Submit your report directly to the IACUC via IRBNet and/or the Office of Research & Sponsored Programs.

5. Question 5 - Bloodborne Pathogen Course: Those in the Physician Assistant (PA) Program may be asked by a professor to select this course. IT IS NOT REQUIRED BY THE IRB/ERC. Do not submit this report to the IRB or ERC. The PA Program uses CITI for its own purposes. Submit your report directly to your requesting professor only.

8. Click Finalize Registration. You will now be able to access the Main Menu of your account. Learners do not have to complete training in one sitting and may sign in any time to view their progress.

9. To begin a course, after logging in, click *View Courses* next to Marywood University. Under *Active Courses,* click on *Continue Course.* Then, click the blue *Start* button for the first module.

10. If you need to change your course registration, click on *Add a Course* at the bottom of the page when viewing the courses for you institution.

11. After each course is completed, the CITI system will make its completion report available for downloading. See *How to Access Your Completion Report* below to retrieve it.

How to Access Your Completion Report at CITI:

1. Visit the Collaborative Institutional Training Initiative (CITI) at www.citiprogram.org and log in.
2. Next to Marywood University or your home institution, click the blue *View Courses* button
3. Under Completed Courses, locate the course you wish to access. Note that if you have taken the human course's social/behavioral learner group, it will be labeled as "Social Behavioral Research Researcher, Student or Sponsor." The SSW's Information Privacy Security course is labeled here as either "Researcher" or "Clinicians."
4. Click the gold *View-Print-Share Record* button for the appropriate course.
5. On the left under *Completion Report*, click the blue *View/Print* button. This will access the full transcript (modules and grades). DO NOT click the button under *Completion Certificate* on the right.
6. Save the .pdf document to your device or computer.
7. If submitting to the ERC or IRB, continue with step 8, below. If you have taken an Information Privacy Security, Animal (IACUC), or Bloodborne Pathogen course, submit to the appropriate department as outlined in the above chart.
8. Log in to IRBNet at www.irbnet.org and then upload and submit the training reports in **ONE** of the following ways (see our IRBNet Instructions for Researchers document or tutorial videos under Helpful Tools). DO NOT use IRBNet's "External Account" transfer feature. Marywood University does not subscribe to it, so it will not function.
   1. Upload the report to the project package with other application materials. Submitting reports in this manner will require the action to be repeated with each new project that you may create or have shared with you in IRBNet.
   2. Upload the report directly to your IRBNet user profile (must be your own profile, not another profile). Submitting the reports in this manner will take place one time (as long as there's no expiration date) and carry across multiple IRBNet projects. You do not need to link training reports to a particular study, as staff will see them so long as they have been uploaded into your IRBNet user profile.

How to Add a Course after Registration:

1. Visit the Collaborative Institutional Training Initiative (CITI) at www.citiprogram.org and log in.
2. Next to Marywood University or your home institution, click the blue *View Courses* button.
3. Scroll to the bottom of the page, and click *Add a Course.*
4. Choose the appropriate course(s). If you add the wrong course, choose *Remove a Course,* which is also listed on the screen described in step 3.
5. Complete the course(s) at your leisure. After completion, the CITI system will make its completion report available for downloading. See the below steps to retrieve it.

How to Affiliate with Marywood if Unaffiliated:

If you are not affiliated with Marywood University and the ERC or IRB determines that your institution is missing some required modules, it may ask you to affiliate with Marywood to select those modules. If you affiliate with Marywood and select a course that you have already taken, any previously taken modules should automatically carry over, so long as the course numbers are exactly the same and the course completion hasn't expired. This should leave you with only outstanding modules to complete.

1. Visit the Collaborative Institutional Training Initiative (CITI) at www.citiprogram.org and log in.
2. On the main screen under Institutional Courses, select the *Add Affiliation* button.
3. Type in Marywood. Once located, click on its name.
4. Read the information provided, check the boxes, and then click *Continue.*
5. Supply requested information and finalize your affiliation. When it asks you to select courses, select the appropriate ones based on the above chart and policies.

How to Merge Duplicate CITI Accounts

It is recommended to only have one CITI Program account to keep accurate completion records and to avoid duplicating previously completed coursework.

Duplicates cannot be deleted, but if you would like to merge accounts, please send an email to support@citiprogram.org and include the following information:

1. Your first and last name
2. The name of your institution
3. The username or member ID for the account to keep
4. The username(s) or member ID(s) for the account(s) to merge

Questions:

Questions about online training requirements or the CITI website should be directed to irbhelp@marywood.edu or 570-348-6211, x. 2418.

Related Institutional Policies

- Educational Training in Human Participants Protection for Investigators
- Educational Training in Human Participants Protection for IRB Members and IRB Administrative Personnel
- Educational Training in Responsible Conduct of Research
- Educational Training in Animal Research

History

08/30/2013 - Updated

07/07/2014 - Updated with the word biologics; chart adjusted

04/10/2015 - Updated with additional information on Information Privacy and Security

07/31/2015 - Updated procedures and contact information for questions

12/14/2016 - Updated to include new contact information and Animal policy link (related policies)

02/28/2017 - Updated instructions about full completion report with modules instead of general certificate

06/09/2017 - Updated CITI definition and added link

09/14/2017 - Updated procedures to match revised CITI site

03/15/2018 - Updated NIH-related definition and training requirements; updated procedures section

05/14/2018 - Updated RCR content, per a change approved by Marywood University's Policy Committee

05/23/2018 - Added that IPS course report should be submitted to the SSW

09/06/2018 - Updated how to submit reports

09/20/2018 - Updated additional courses for clarity

12/12/2018 - Updated procedures to reflect updates to CITI's website

07/05/2019 - Updated as a result of the Revised Common Rule

08/25/2020 - Updated the CITI instructions for learner group selection

10/19/2020 - Clarified the RCR training renewal requirement

04/21/2021 - Updated definitions, course information, chart, and procedures

11/18/2021 - Updated to add expiration information for the human research course

01/25/2022 - Added procedures for duplicate accounts and clarified definitions