

UMSON Human Subjects Research Training Guide

When conducting human subjects research at the University of Maryland School of Nursing (UMSON), you are required to complete:

1. [Collaborative Institutional Training Initiative \(CITI\)](#) - Group 1 (Biomedical) or Group 2 (Social Behavioral) Protection of Human Subjects Training
2. [Health Insurance Portability and Accountability Act \(HIPAA\) trainings](#) –HIPAA 201 and HIPAA 125
3. Good Clinical Practice (GCP) training through the National Institute on Drug Abuse Clinical Trials Network (NIDA CTN), the Society of Behavioral Medicine, or CITI. *Please note that the CITI Social and Behavioral GCP training and the Society of Behavioral Medicine GCP are the same course.*
4. **All** University of Maryland, Baltimore (UMB) employees (including faculty, staff, post-docs, and students) participating in the design, conduct, or reporting of research funded by **Public Health Service (PHS) agencies** (including National Institutes of Health [NIH], Centers for Disease Control and Prevention [CDC], Substance Abuse and Mental Health Services Administration [SAMSHA], Food and Drug Administration [FDA], Agency for Health Care Research and Quality [AHRQ], Health Resources & Services Administration [HRSA], Agency for Toxic Substance and Disease Registry [ATSDR], and Indian Health Service [HIS]) are required to complete PHS Conflict of Interest (COI) training through the [CITI](#) program. Individuals who have previously completed the training will receive notification from the UMB Office of Accountability and Compliance (OAC) when they are due for training. If you have not previously completed the training and are engaging in research funded by a PHS agency, you must complete this training **immediately** and submit an [SFI disclosure](#) to OAC. Training is required every four years, and SFI disclosure forms are required annually. Questions related to this policy and COI should be sent to Alison Watkins, UMB COI officer, athom001@umaryland.edu, or Shilene Johnson, research compliance specialists, shilene.johnson@umaryland.edu. Additional information regarding this policy can be found on the OAC [website](#).

Research team members must keep Basic CITI, HIPAA, and GCP completion reports/certificates on file along with any other protocol-specific training documentation. This documentation should be placed in appropriate study binders, if applicable.

Students involved in human subjects research are required to submit completion reports to the principal investigator of the study and to the associate dean of their degree program. All individuals must submit **GCP certificates** to the Office of Research and Scholarship at NRSResearch@umaryland.edu.

UMSON employees and affiliates actively engaged in human subjects research are required to submit documentation of GCP training to the UMSON Office of Research and Scholarship at NRSResearch@umaryland.edu and to the UMB Human Research Protections Office (HRPO) at hrpo@umaryland.edu, when applicable.

All employees who work in a laboratory **or** who have potential exposure to blood-borne pathogens are required to complete [Environmental Health and Safety \(EHS\)](#) training.

Training Descriptions

1. CITI Training for Protection of Human Subjects (required every three years)

All individuals engaged in human subjects research at UMB are required to complete the UMB-specific CITI training for protection of human subjects. Every three years, a refresher course is required. All individuals are required to complete either Group 1 or Group 2 training below, based on which is more aligned with the type of research they are engaged in. To complete CITI training, visit www.citiprogram.org.

Group 1: Biomedical Research Investigators and Key Personnel

This is most appropriate for researchers involved in clinical drug or device trials or other biomedical research. Biomedical studies include studies on human physiology or the treatment or understanding of the disease; however, not all biomedical studies include the administration of a drug or use of a device.

OR

Group 2: Social/Behavioral Research (SBR) Investigators and Key Personnel

This is most appropriate for researchers who specialize in the social and behavioral sciences. Data collection methods commonly include surveys, interviews, focus groups, observations, and other noninvasive measures. SBR tends to focus on attitudes, beliefs, and behaviors.

If you have questions about UMB CITI training, contact the UMB HRPO at 410-706-5037. If you have questions about the Veterans Affairs CITI training, contact Yolanda Gayden at 410-605-7130 or yolanda.gayden@va.gov.

2. HIPAA Training (required once)

UMB policy requires that all individuals complete **HIPAA 125**, regardless of whether or not they are engaging in research. All individuals engaging in research must also complete **HIPAA 201**. This applies to all faculty, staff, and students engaged in human subjects research.

To complete this training, login at <http://issomvweb4.som.umaryland.edu/hipaa/quiz/index.asp>. Your username is your six-digit UMB employee ID number, and your password is your first name.

If you have questions about accessing the HIPAA training, contact the University of Maryland School of Medicine Help Desk at 410-706-3998.

3. Good Clinical Practice course (required every three years)

All individuals engaged in human subjects research at UMB are required to complete a GCP course every three years. This is consistent with the UMB HRPO policy for National Institutes of Health (NIH)-funded investigators.

Option 1 – NIDA CTN: To complete this training, visit <https://gcp.nidatrain.org>.

Option 2 – GCP-SBR eLearning Course: To complete this training, visit <http://www.sbm.org/training/good-clinical-practice-for-social-and-behavioral-research-elearning-course>

Option 3- CITI GCP- Social and Behavioral Research Best Practices for Clinical Research training (Please note that the CITI Social and Behavioral GCP training and the Society of Behavioral Medicine GCP are the same course). To complete this training, visit <https://about.citiprogram.org/en/homepage/>

Email your GCP completion certificate to the UMSON Office of Research and Scholarship at NRSResearch@umaryland.edu. If conducting NIH-funded research, you should also email your certificate to HRPO at hrpo@umryland.edu.

4. Environmental Health and Safety Training (EHS) (See required training frequency below.)

All employees that work in a laboratory are required to take laboratory safety training.

- New employees who work in a laboratory must take the classroom course prior to working in a laboratory.
- All employees who work in a laboratory must take the online laboratory safety training on an annual basis.
- Employees with potential exposure to blood-borne pathogens must take the blood-borne pathogens training annually.
- Employees who work with radioactive material must take radiation safety training, which is only offered in a classroom setting.
- Employees who ship biological material must take the Department of Transportation Infectious and Biological Material Shipping training either online or in the classroom. Training is required every two years.

Additional EHS training may be required depending on your job duties.

- To determine what training you need to complete for your job-specific duties and to register, visit www.umaryland.edu/ehs/training. Trainings may include:
 - Blood-borne Pathogens
 - Laboratory Chemical Safety
 - Hazardous Waste
 - Radiation Safety Training
- To view the training schedule, visit www.umaryland.edu/ehs/training/classroom-in-person-training-schedule-and-registration.
- To complete online training you will need to create an account at [MyEHS](#).

For questions about biosafety, blood-borne pathogens, recombinant DNA registration, etc., contact Melissa Morland at 410-706-7845 or mmorland@af.umaryland.edu.

For questions about radiation safety training, contact Nick Wellnitz at 410-706-7055 or nwellnitz@umaryland.edu.

5. PHS Conflict of Interest Training (required every four years)

All UMB employees participating in the design, conduct, or reporting of research funded by PHS agencies (including NIH, CDC, SAMHSA, FDA, AHRQ, HRSA, ATSDR, IHS) will complete their online PHS Conflict of Interest Training through the CITI program at <https://about.citiprogram.org/en/homepage>. Access to the CITI COI module is outlined below for UMB employees with and without current CITI accounts.

Non-UMB employees, which include sub-award recipients, consultants, or other collaborators without a UMB account, will continue to take the training through the [NIH website](#). It is recommended non-UMB employees contact their respective institutions for additional guidance.

If you have any questions, contact Shilene Johnson at shilene.johnson@umaryland.edu or Erin Burch, accountability and compliance specialists, at erin.burch@umaryland.edu. Both are in the COI Office.

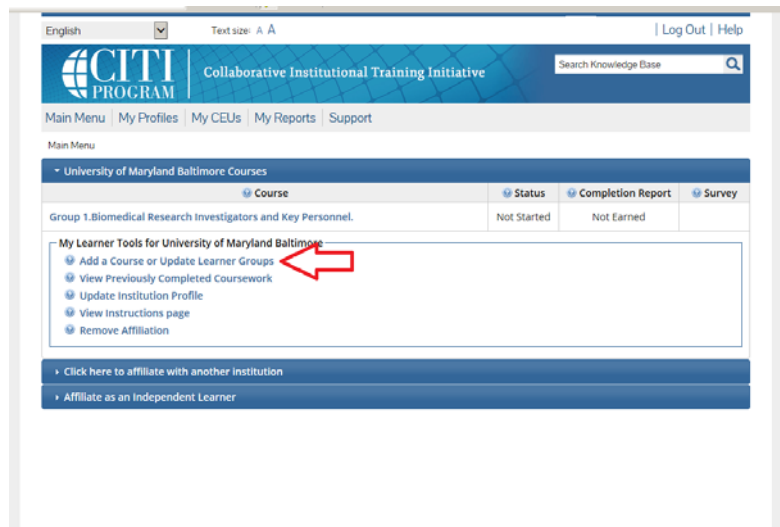
Accessing CITI for Protection of Human Subjects Training (Basic or Refresher Course), Conflict of Interest, and Good Clinical Practice Training

Step 1: Visit www.citiprogram.org.

Step 2: Log in or register (if you do not have an existing account).

If you don't already have a CITI account, you will need to create one. When creating your account you **MUST** affiliate with the **University of Maryland, Baltimore**.

Step 3: Once you are logged in to your account, your screen should look like the image below. Select “Add a Course or Update Learner Groups.”



Step 4: For Question 1, if you have never completed any trainings, select “Protection of Human Subjects,” “Conflicts of Interest,” and “Good Clinical Practice.” Otherwise, only select those courses you need to complete at this time.

Select Curriculum

University of Maryland Baltimore

Question 1

Please make your selection below according to your role or interests.

This question is required. Choose all that apply.

☐ Protection of Human Subjects

CITI

☐ Lab Animal Welfare

☐ Responsible Conduct of Research

☐ Conflicts of Interest

COI

GCP

☐ Good Clinical Practice

☐ Good Laboratory Practice (GLP)

☐ Practice-Based Research Network

☐ Revised Common Rule

Start Over
Next

Step 5: For Question 2, if you have never completed CITI human subjects basic training, you will need to be enrolled in the Basic Course. To enroll in the Basic Course, select “Yes.” If you have taken the CITI basic training (through UMB) previously and need to take the refresher course, select “No.”

Select Curriculum

University of Maryland Baltimore

Question 2

Are you here to take a Basic Course?

This question is required. Choose one answer.

- ☒ **Yes** : Please select this option if you are taking this course for the first time, you will be enroll to the **Basic Course**.
- ☐ **No**: Please select this option if you had completed basic course before, you will be enroll to the **Refresher course**.

Start Over

Next

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Step 6: For Question 3, select either the Biomedical or Social/Behavioral group. Most UMSON faculty, staff, and students should select Group 2.

Select Curriculum

University of Maryland Baltimore

Question 3

Please select the group appropriate to your research activities.

Choose one answer.

- ☐ **Group 1**: Biomedical Research Investigators and Key Personnel.
- ☒ **Group 2**: Social / Behavioral Research Investigators and Key Personnel
- ☐ **Group 3**: IRB Member Module - ONLY
- ☐ **Clinical Research Coordinator (CRC)**
- ☐ **Lab Animal Welfare**: Select this response to bypass the Human Subjects Course [Go to Question 3](#) for the Lab Animal Course and select the appropriate response.

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Step 7: For Questions 5-9, you can select “Not at this time.” Some individuals may choose to complete additional trainings, such as Responsible Conduct of Research. Completing additional trainings is encouraged but not required. If you wish to complete additional trainings you can self-select those courses by changing your answers to Questions 5-9.

CITI PROGRAM Collaborative Institutional Training Initiative

Home > Add a Course

Select Curriculum - University of Maryland Baltimore (ID: 411)

* Indicates a required field.

* Please select appropriately if you wish to enroll in the courses below.
Choose all that apply

☐ IRB Administration

☐ Institutional Official: Human Subjects

☐ Not at this time.

Next Start Over

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Step 8: For Question 10, if you have never taken the GCP course, select “Please Show me the **Basic** GCP courses.” If you have taken a previous GCP through CITI, select “Please show me the **Refresher** GCP courses.”

Select Curriculum

University of Maryland Baltimore

Question 10

Good Clinical Practice (GCP)

Would you like to enroll in the **Basic** stage of the GCP or the **Refresher** stage? (Only select refresher if you have completed the basic previously)

This question is required. Choose one answer.

☐ Please show me the **Basic** GCP courses

☐ Please show me the **Refresher** GCP courses

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CITI PROGRAM

Step 9: For Question 11, all UMSON staff, faculty, and students engaged in human subjects research should select “GCP - Social and Behavioral Research Best Practices for Clinical Research.”

Select Curriculum

University of Maryland Baltimore

Question 11

Basic - Good Clinical Practice (GCP)

Make your selection below to be enrolled in the **basic stage** of the following GCP courses:

Choose all that apply.

- ☐ Good Clinical Practice and ICH
- ☐ Good Clinical Practice Course (US FDA focus)
- ☒ **GCP - Social and Behavioral Research Best Practices for Clinical Research**

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Step 10: You will now be at your “home” screen. On this screen you will see active courses (those in progress), course ready to begin (those you need to take), and complete courses.

Active Courses

[Learner Tools](#)

University of Maryland Baltimore

Social and Behavioral Responsible Conduct of Research

Stage 1 - RCR

3 / 8 modules completed



Continue Course

Courses Ready to Begin

[Learner Tools](#)

University of Maryland Baltimore

Good Clinical Practice and ICH

Stage 1 - Basic Course

0 / 13 modules completed



Start Now

University of Maryland Baltimore

Group 1.Biomedical Research Investigators and Key Personnel.

Stage 3 - Refresher Course

0 / 14 modules completed



Start Now

University of Maryland Baltimore

Group 2.Social / Behavioral Research Investigators and Key Personnel

Accessing HIPAA

Step 1: Go to <http://issomvweb4.som.umaryland.edu/hipaa/quiz/index.asp>.

Step 2: Log in using your UMB employee ID Number and your first name as your password.

Step 3: If you do not have an account, follow the instructions for creating a new account.

If you cannot remember your login, select “Look UP/Request a Login.”

If you do not have an account, select “Create an ID.”

Step 4: Complete HIPAA 125 and 201.

Accessing GCP Course through NIDA CTN

Step 1: To access the GCP course, visit <https://gcp.nidatrain.org>.

Step 2: Create an account.

Welcome

The Good Clinical Practice (GCP) course is designed to prepare research staff in the conduct of clinical trials with human participants. The 12 modules included in the course are based on ICH GCP Principles and the Code of Federal Regulations (CFR) for clinical research trials in the U.S. The course is self-paced and takes approximately six hours to complete.

To preview the new enhanced features, please [click here](#).

To begin, please *sign in* using the link to the right if you have already created an account. If you do not have an account, click [here](#) to register.

Login

|

password

[Forgot password?](#)

Sign in

Need an account?
[Sign up here!](#)

Create an Account

Please enter your first and last name as you would like it to appear on your certificate. You will **NOT** be able to change your name later.

First Name*

Last Name*

Node/University Name

Staff Number

Protocol Role(s)*

☐ IN - Investigator

☐ QA - QA Staff

☐ RS - Research Staff

☐ RG - Regulatory Staff

Step 3: Complete modules.

Overview
My Progress
Resources
Certification

You have successfully logged in!

Overview of Good Clinical Practice Training

The Good Clinical Practice (GCP) online training consists of 12 modules. Each module discusses a specific GCP standard. General conduct of research standards are also presented.

Modules

The 12 modules may be completed one at a time or in one sitting as users may login and logout, as needed. Users have the option to complete module quizzes after reviewing the instructional material, or choose to complete the module quizzes only, particularly for returning users. Accessing quizzes is easy. Select the **Take the Quiz** button in each module or choose one of the links on the **My Progress** page.

Introduction
Institutional Review Boards
Informed Consent
Confidentiality & Privacy
Participant Safety & Adverse Events
Quality Assurance

The Research Protocol
Documentation & Record-Keeping
Research Misconduct
Roles & Responsibilities
Recruitment & Retention
Investigational New Drugs

Step 4: Complete quizzes.

Overview
My Progress
Resources
Certification

My Progress

Module	Score
Introduction	N/A
Institutional Review Boards	Take the Quiz
Informed Consent	Take the Quiz
Confidentiality & Privacy	Take the Quiz
Participant Safety & Adverse Events	Take the Quiz
Quality Assurance	Take the Quiz
The Research Protocol	Take the Quiz
Documentation & Record-Keeping	Take the Quiz
Research Misconduct	Take the Quiz
Roles & Responsibilities	Take the Quiz
Recruitment & Retention	Take the Quiz
Investigational New Drugs	Take the Quiz

Step 5: Print the certificate.

My Progress

Module	Score
Introduction	N/A
Institutional Review Boards	100%
Informed Consent	80%
Confidentiality & Privacy	80%
Participant Safety & Adverse Events	80%
Quality Assurance	100%
The Research Protocol	100%
Documentation & Record-Keeping	80%
Research Misconduct	80%
Roles & Responsibilities	100%

Folder for Jessica Rowe

Good Clinical Practice

<https://gcp.nidastraining.org/certification>

is hereby granted to
Jessica Rowe

to certify your completion of the six-hour required course on:

GOOD CLINICAL PRACTICES

MODULE:	STATUS:
Introduction	N/A
Institutional Review Boards	Passed
Informed Consent	Passed
Confidentiality & Privacy	Passed
Participant Safety & Adverse Events	Passed
Quality Assurance	Passed
The Research Protocol	Passed
Documentation & Record-Keeping	Passed
Research Misconduct	Passed
Roles & Responsibilities	Passed
Recruitment & Retention	Passed
Investigational New Drugs	Passed

Course Completion Date: 4 January 2017
CTN Expiration Date: 4 January 2020

Tracee Williams, Training Coordinator
NIDA Clinical Coordinating Center

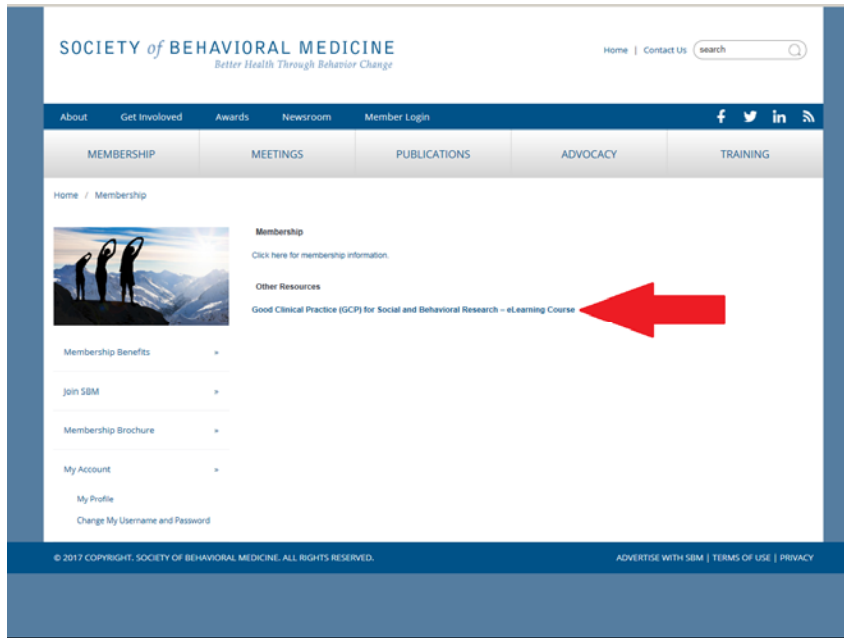
This training has been funded in whole or in part with Federal funds from the National Institute on Drug Abuse, National Institutes of Health, Department of Health and Human Services, under Contract No. HHSN27201201000024C.

Print Certificate

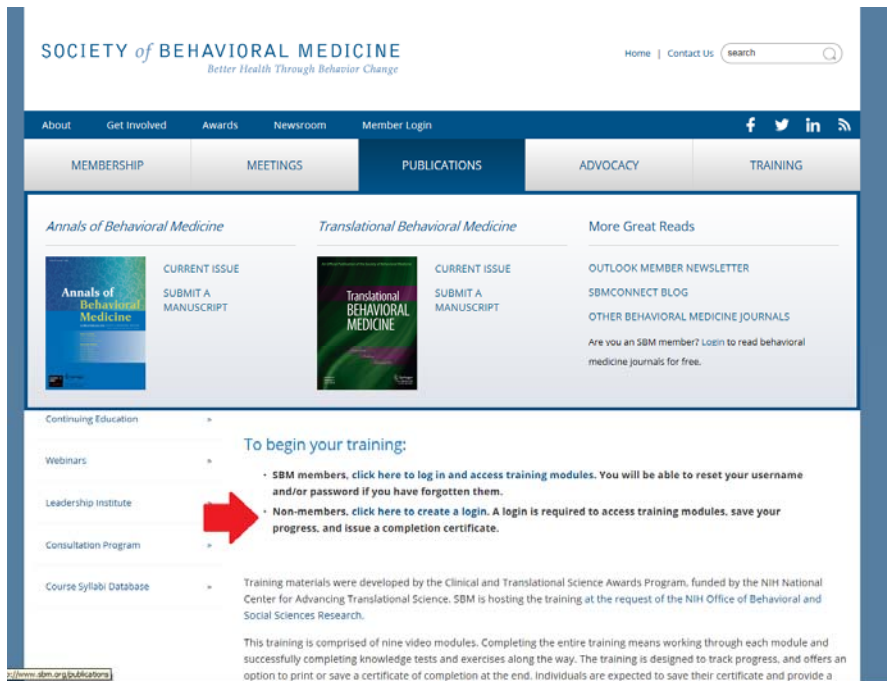
Accessing GCP Course through the Society of Behavioral Medicine*

*This same course is available through CITI, and it is recommended that you access the course through CITI.

Step 1: Go to <http://www.sbm.org/training/good-clinical-practice-for-social-and-behavioral-research-elearning-course>.



Step 2: Create a Non-member account.



Step 3: Log in and select “Good Clinical Practice (GCP) for Social and Behavioral Research – eLearning Course” and complete the modules. You must achieve a score of 100 percent on each module assessment to continue to the next module.

Step 4: Download and print your certificate.

