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 UMSON 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.nidatraining.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 very 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.

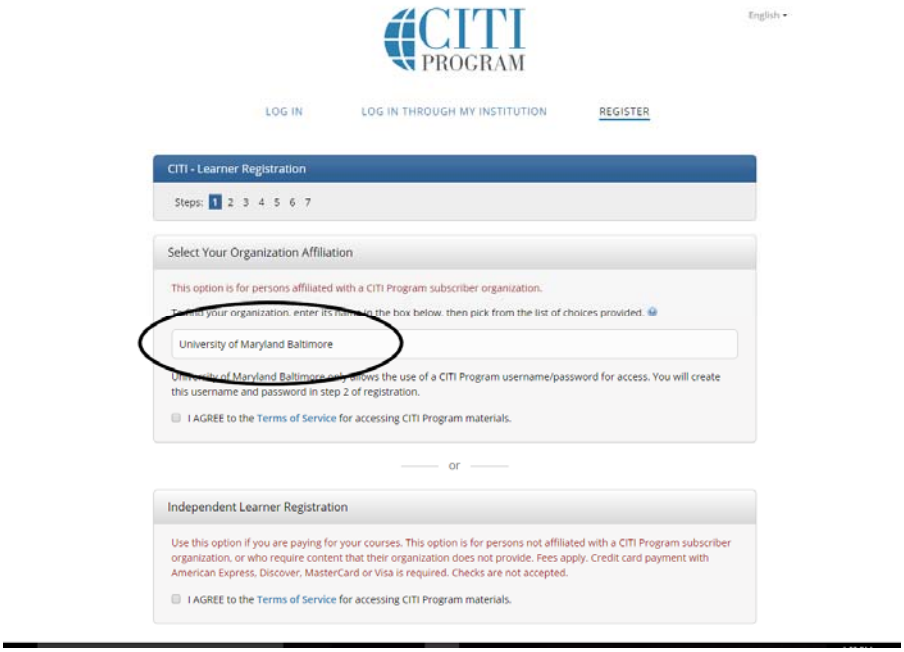
If you have any questions, contact Shilene Johnson at shilene.johnson@umaryland.edu or Erin Burch, accountability and compliance specialists, at erin.burch@umaryland.edu. Both are in the COI Office.

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

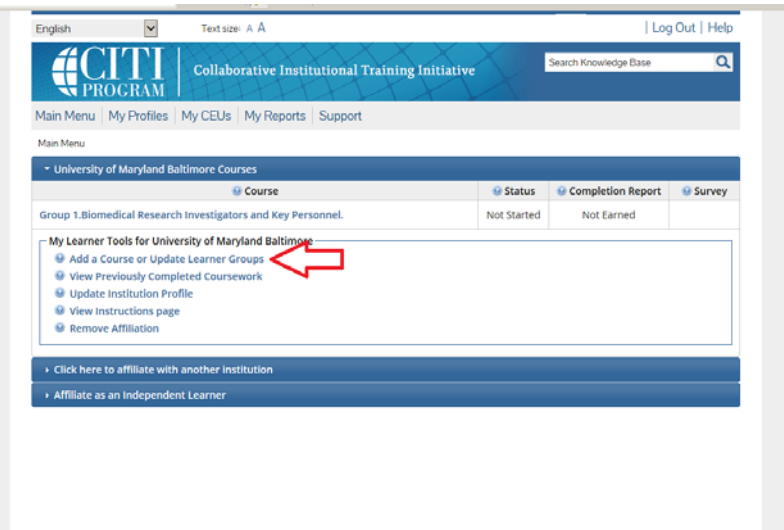
Step 1: Visit www.citiprogram.org.

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

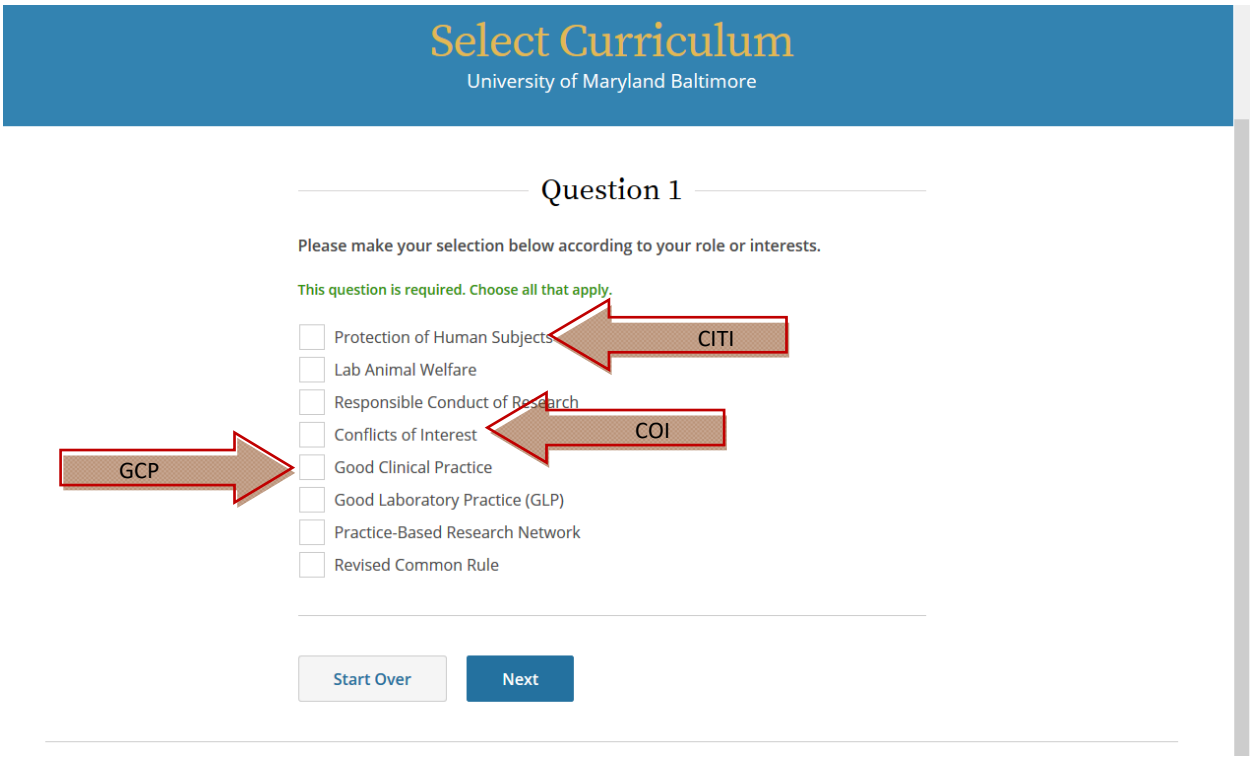
If you don't already have a CITI account, you will need to create one. When creating your account you **MUST affiliate with the University of Maryland, Baltimore**.



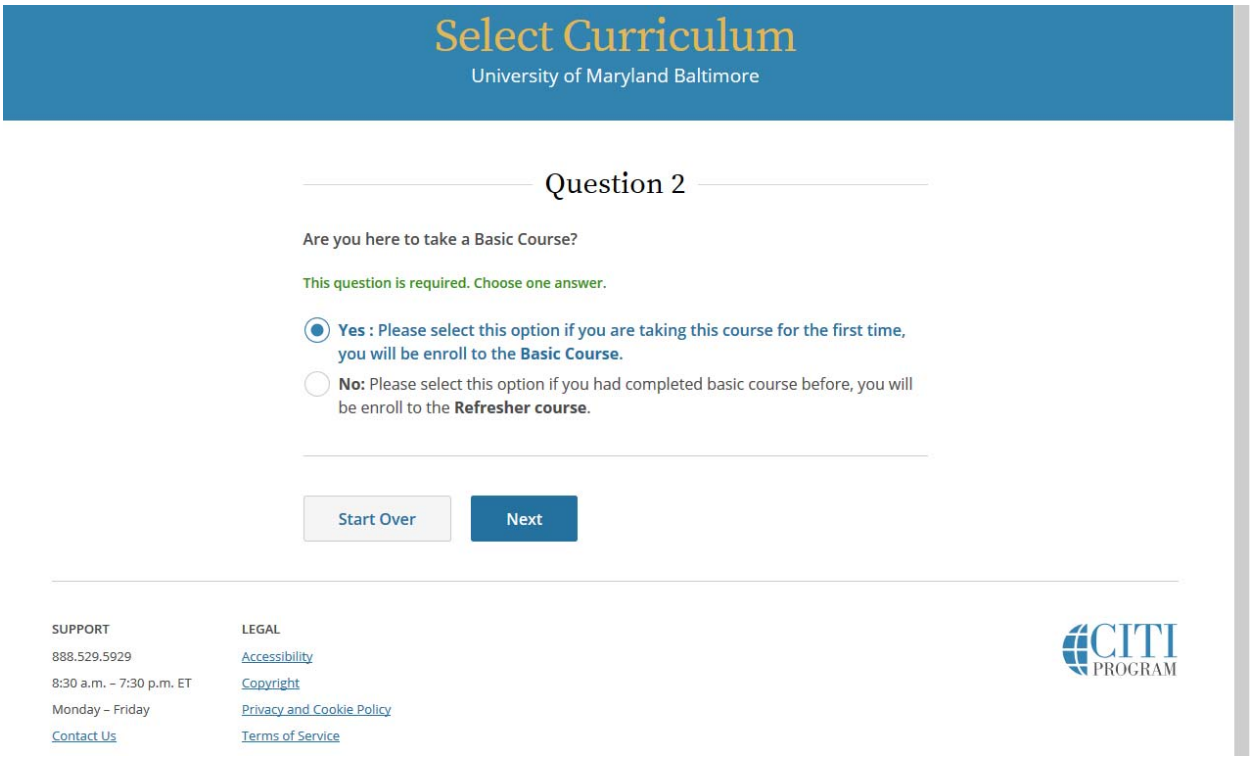
Step 3: Once you are logged in to your account, your screen should look like the image below. Select "Add a Course or Update Learner Groups."



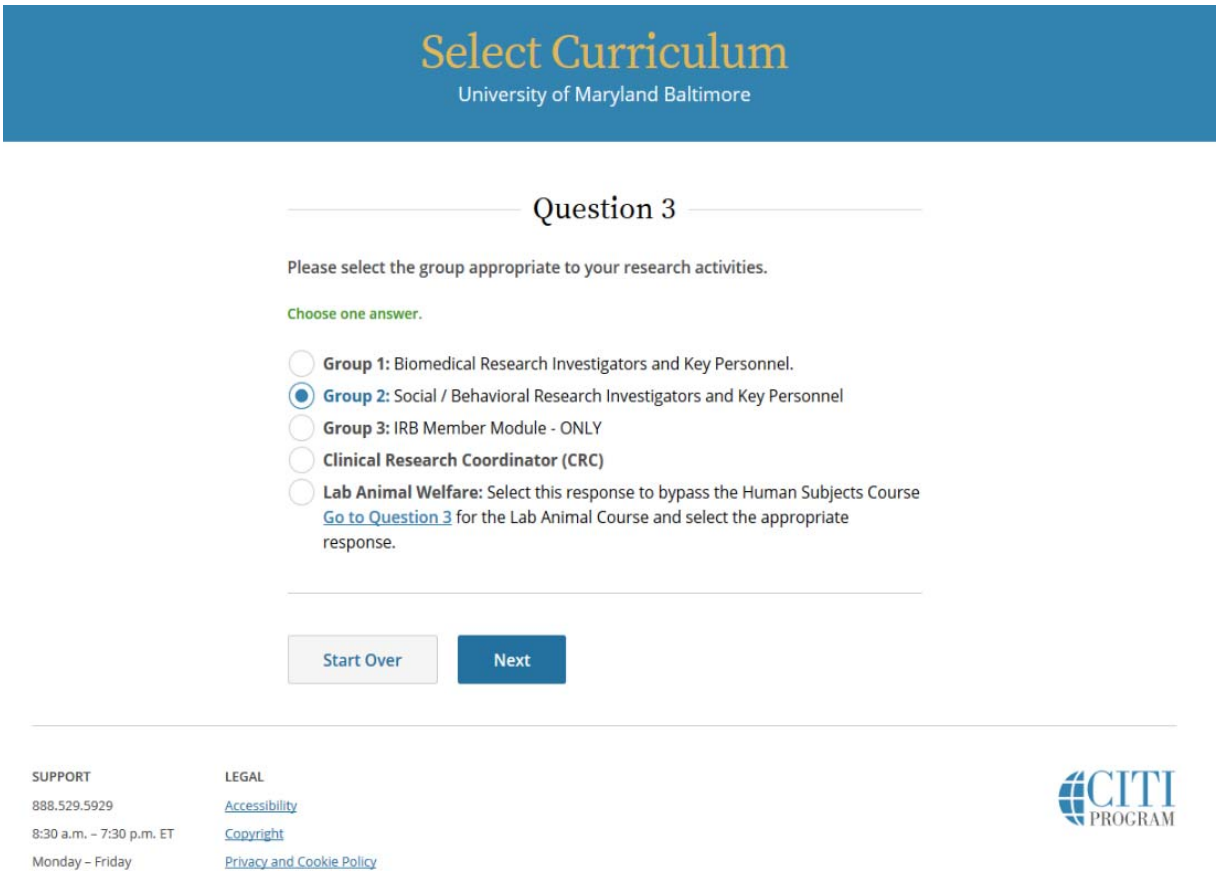
Step 4: For Question 1, if you have never completed any trainings, select "Protection of Human Subjects," "Conflicts of Interest," and "Good Clinical Practice." Otherwise, only select those courses you need to complete at this time.



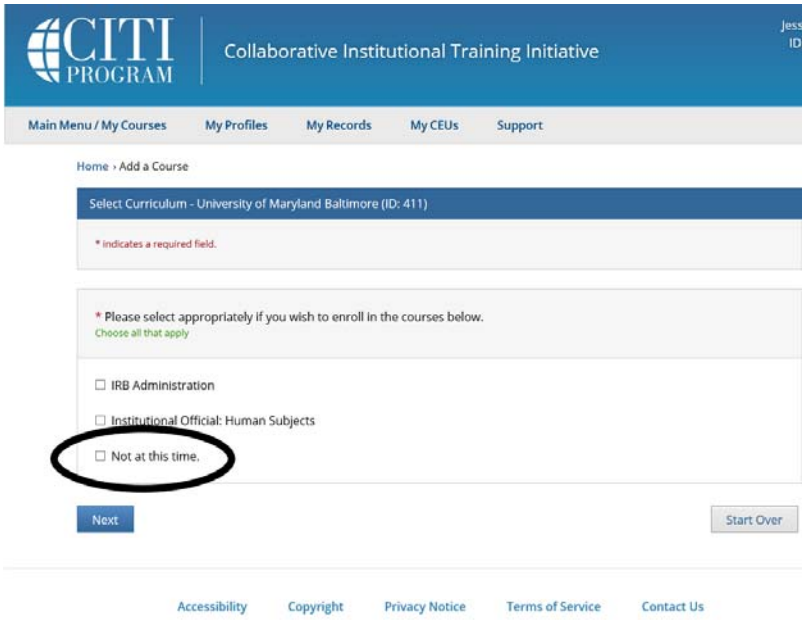
Step 5: For Question 2, if you have never completed CITI human subjects basic training, you will need to be enrolled in the Basic Course. To enroll in the Basic Course, select "Yes." If you have taken the CITI basic training (through UMB) previously and need to take the refresher course, select "No."



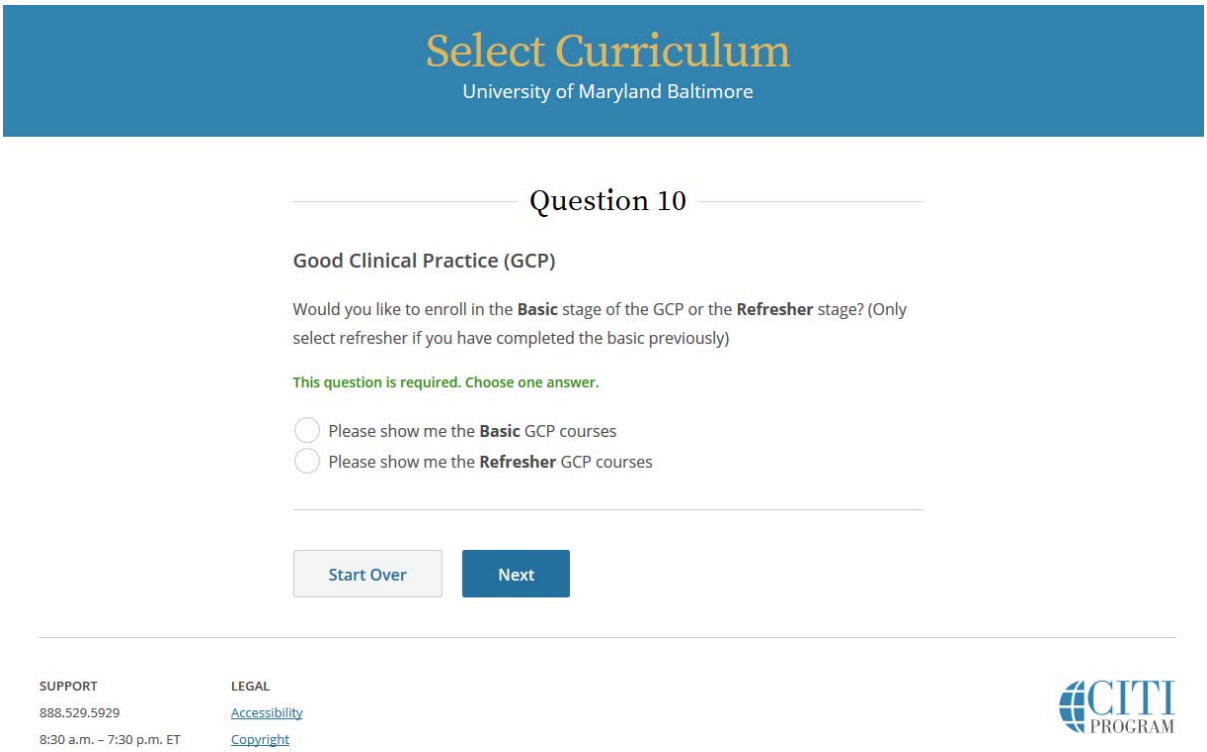
Step 6: For Question 3, select either the Biomedical or Social/Behavioral group. Most UMSON faculty, staff, and students should select Group 2.



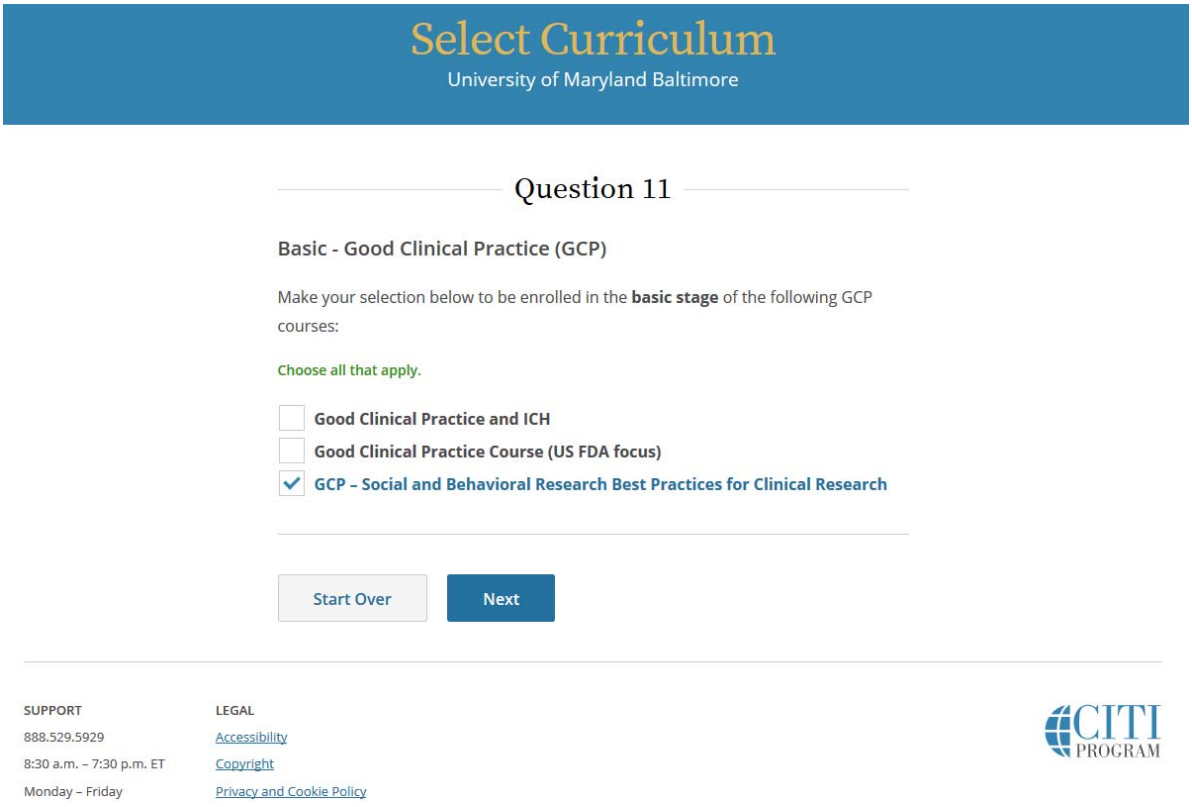
Step 7: For Questions 5-9, you can select "Not at this time." Some individuals may choose to complete additional trainings, such as Responsible Conduct of Research. Completing additional trainings is encouraged but not required. If you wish to complete additional trainings you can self-select those courses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



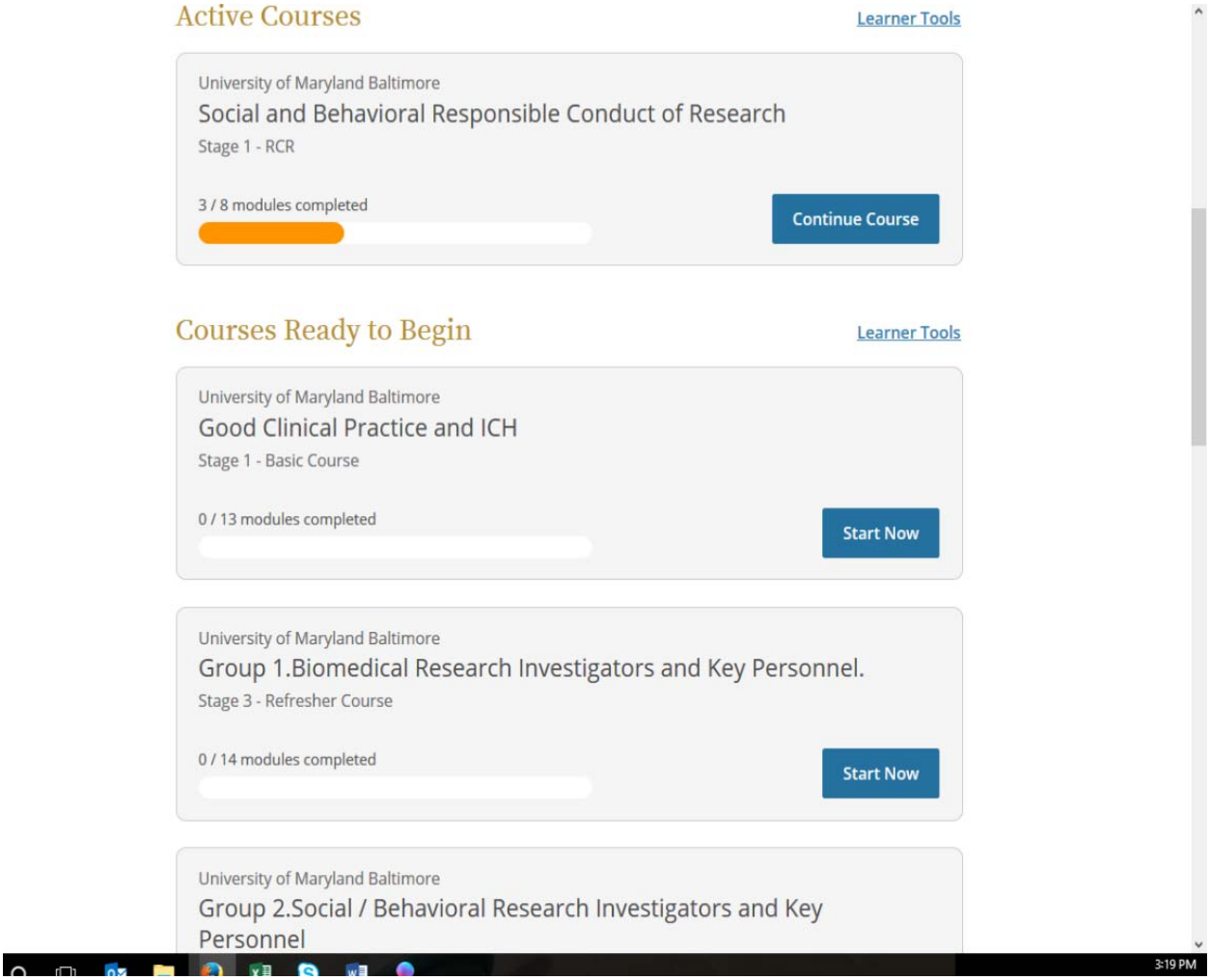
Step 8: For Question 10, if you have never taken the GCP course, select "Please Show me the **Basic** GCP courses." If you have taken a previous GCP through CITI, select "Please show me the **Refresher** GCP courses."



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."



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.



Accessing HIPAA

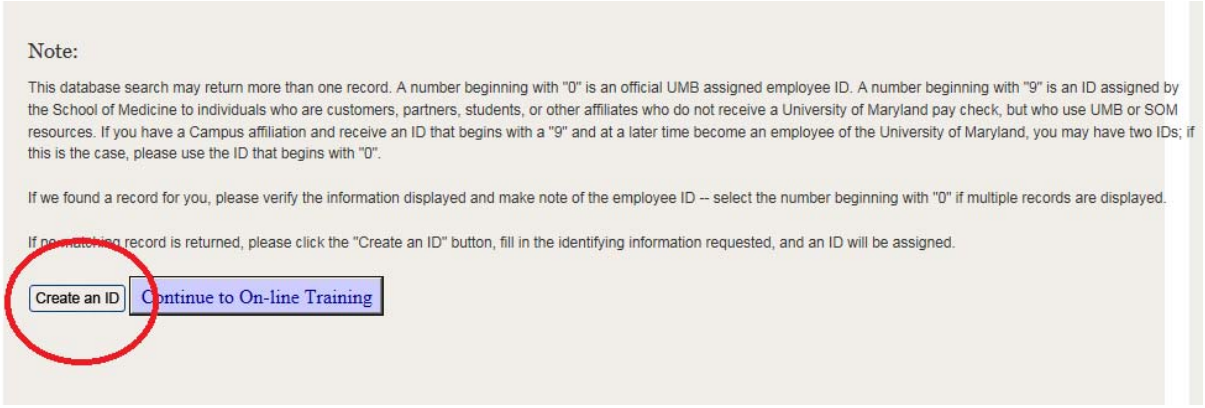
Step 1: Go to http://issomvweb4.som.umaryland.edu/hipaa/quiz/index.asp.

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."

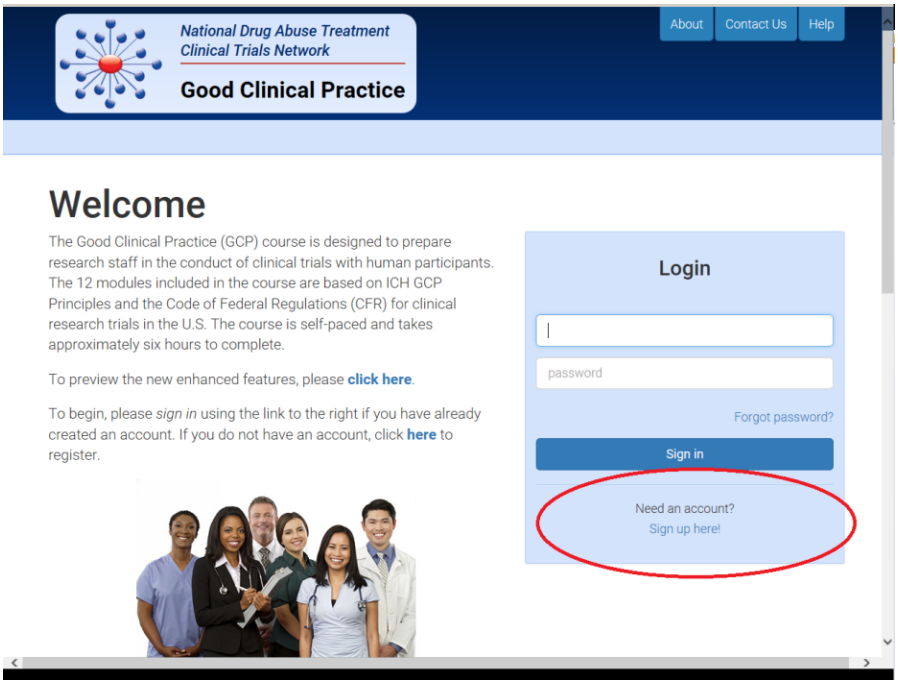


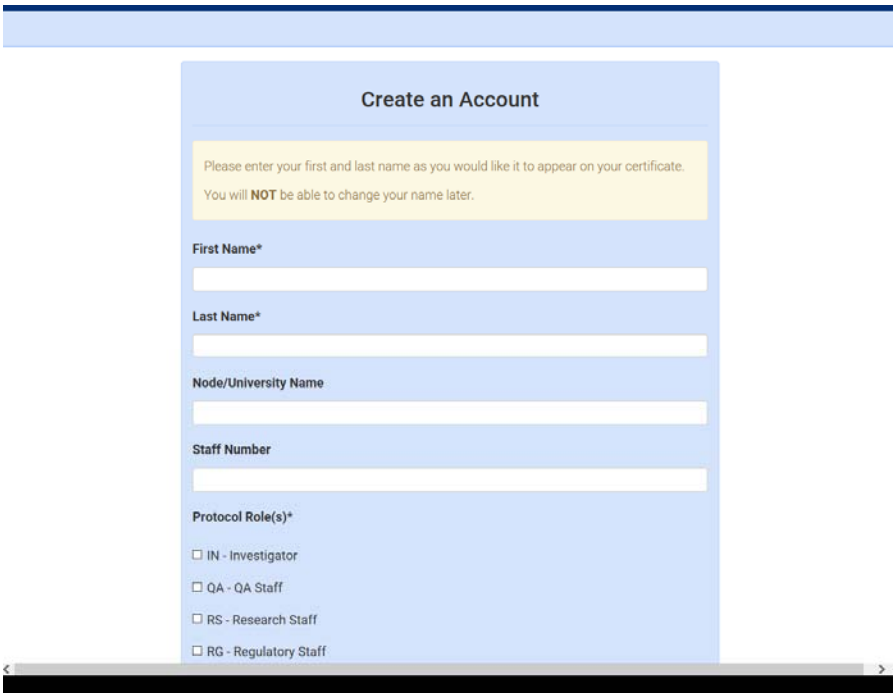
Step 4: Complete HIPAA 125 and 201.

Accessing GCP Course through NIDA CTN

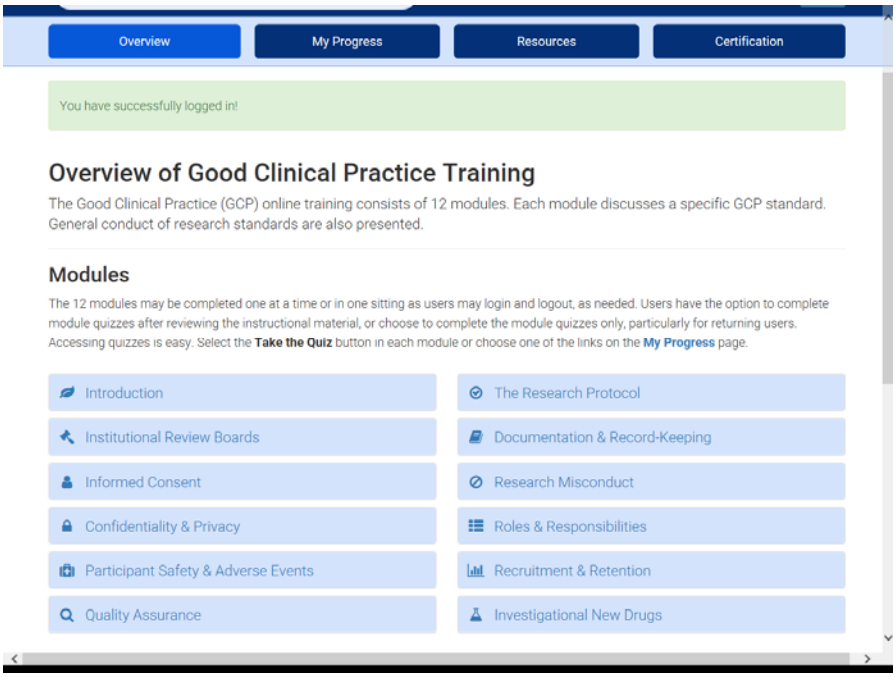
Step 1: To access the GCP course, visit https://gcp.nidatraining.org.

Step 2: Create an account.

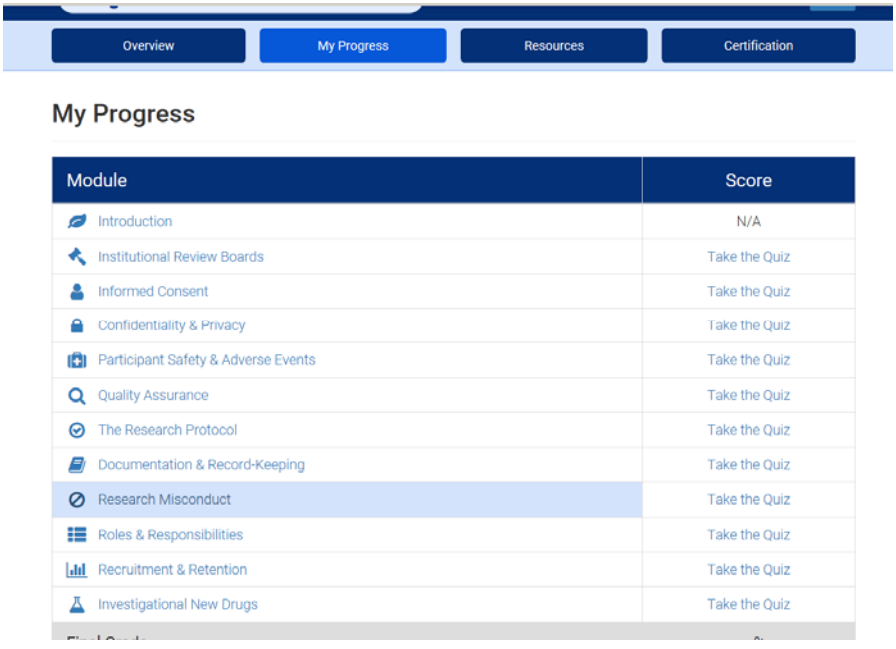




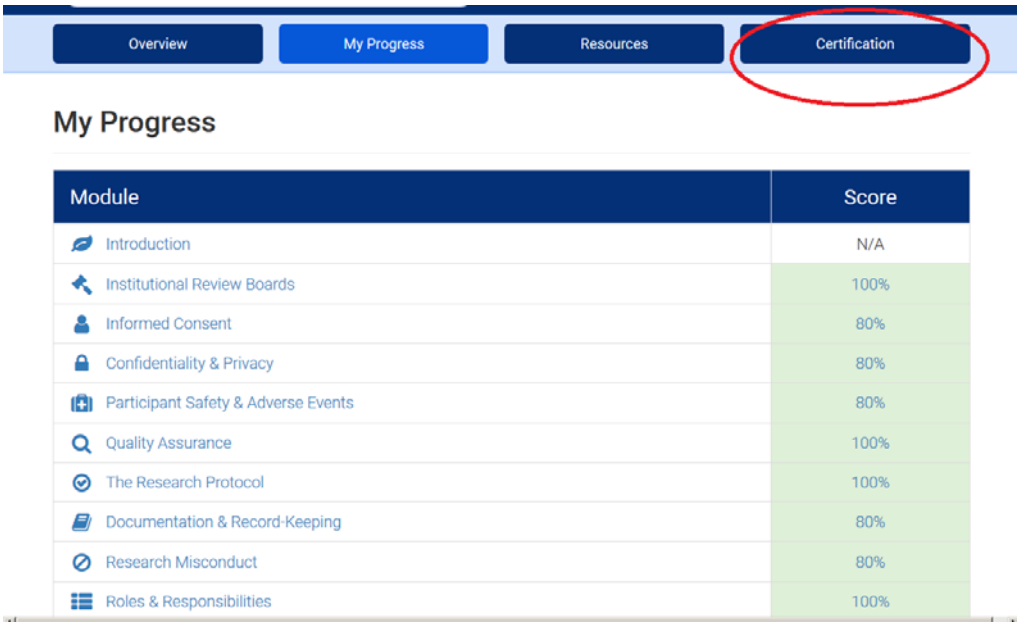
Step 3: Complete modules.

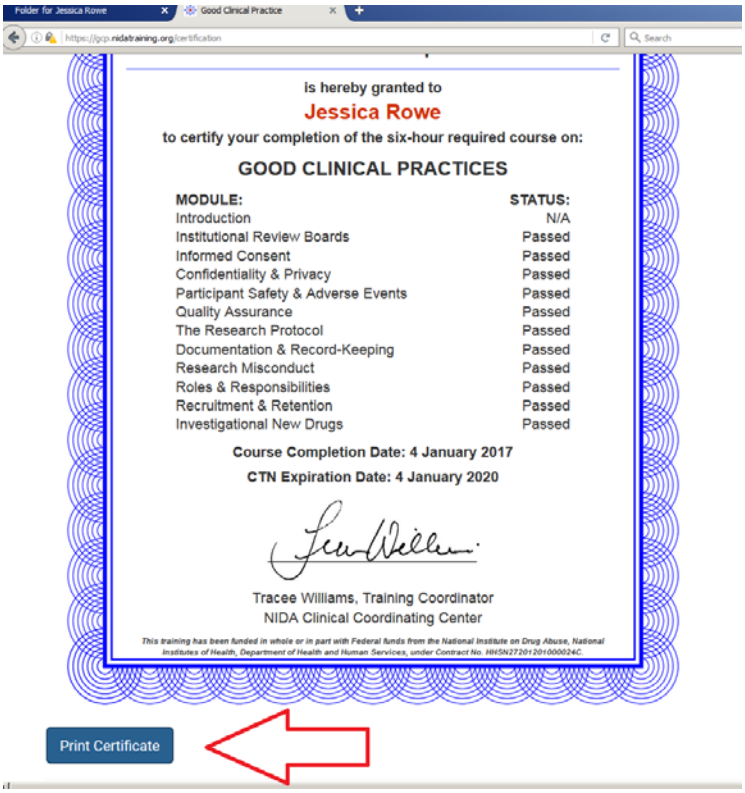


Step 4: Complete quizzes.



Step 5: Print the certificate.

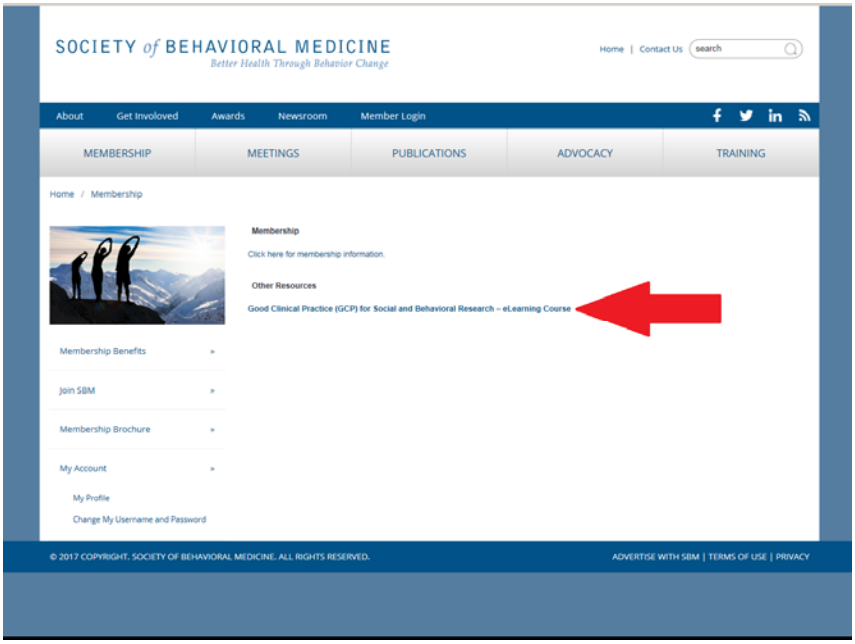

Overview
My Progress
Resources
Certification
My Progress
Module
Score
Introduction
N/A
Institutional Review Boards
100%
Informed Consent
80%
Confidentiality & Privacy
80%
Participant Safety & Adverse Events
80%
Quality Assurance
100%
The Research Protocol
100%
Documentation & Record-Keeping
80%
Research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


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
Print Certificate

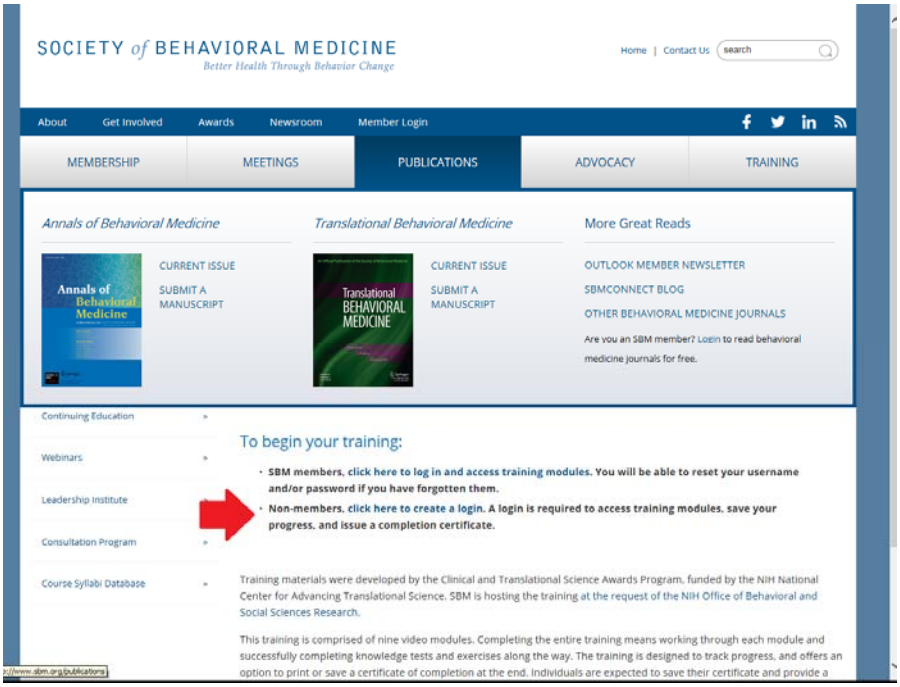
Accessing GCP Course through the Society of Behavioral Medicine*

*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.