

Adding a GCP course in CITI (www.citiprogram.org)

From the Main Menu, select “University of Maryland Baltimore Courses.” Within the drop down, select “Add a Course.”

▼ University of Maryland Baltimore Courses			
🔍 Course	🔍 Status	🔍 Completion Report	🔍 Survey
Conflicts of Interest	Passed 11/19/2014	View/Print Share	Post-course evaluation
Good Clinical Practice Course (US FDA focus)	Not Started	Not Earned	
My Learner Tools for University of Maryland Baltimore			
🔍 Add a Course 🔍 Remove a Course 🔍 View Previously Completed Coursework 🔍 Update Institution Profile 🔍 View Instructions page 🔍 Remove Affiliation			

Select “Protection of Human Subjects” and click “Next.”

Select Curriculum - University of Maryland Baltimore (411)

* Indicates a required field.

* Please make your selection below according to your role or interests.
Choose all that apply

☐ Protection of Human Subjects

☐ Lab Animal Welfare

☐ Responsible Conduct of Research

☐ Conflicts of Interest

NextStart Over

If you have not previously taken the Good Clinical Practice course, select “Yes.” Otherwise, select “No,” and click “Next.”

Select Curriculum - University of Maryland Baltimore (411)

* indicates a required field.

* Are you here to take a **Basic Course**?
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**.

Next

Start Over

Select the Good Clinical Practice course that is most relevant to the research being conducted and click “Next.”

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)**

☐ **Good Clinical Practice and ICH:** This course consists of 13 modules on GCP and ICH E6 for investigators. This Basic GCP course should not be attempted until the Basic Human Subjects Course is completed. Choose this learner group and follow the link to the Basic Course.

☐ **Good Clinical Practice (US FDA Focus)**

☐ **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.

There will be several additional pages related to optional courses. You may select “Not at this time” and “Next” for the remaining pages.

CITI will then return to the Main Menu.

Select “University of Maryland Baltimore Courses” and then click on the title of the course from the drop down to begin the course.

Accessing NIH GCP training (GCP.NIHtraining.com)

Create an account



**National Drug Abuse Treatment
Clinical Trials Network**
Good Clinical Practice

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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

[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

Complete modules

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	The Research Protocol
Institutional Review Boards	Documentation & Record-Keeping
Informed Consent	Research Misconduct
Confidentiality & Privacy	Roles & Responsibilities
Participant Safety & Adverse Events	Recruitment & Retention
Quality Assurance	Investigational New Drugs

Complete quizzes

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

Print Certificate and email to hrpo@umaryland.edu



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%