

Questions?

- For questions about accessing CITI for GCP and human subjects training, please see:

[http://
www.umassmed.edu/
ccts/irb/citi/](http://www.umassmed.edu/ccts/irb/citi/)

or contact

irb@umassmed.edu

- For general questions relating to this policy, please contact:

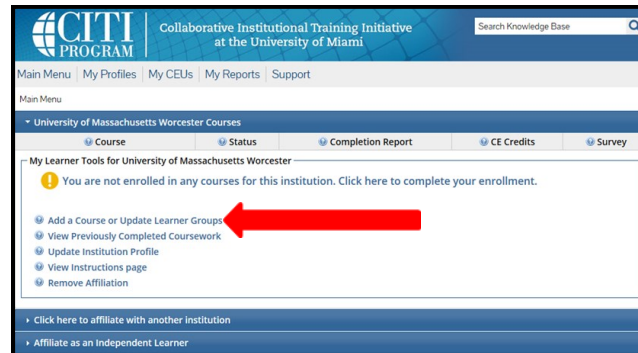
Dr. Margaret Koziel or
hrp@umassmed.edu

Where do I find GCP training in CITI?

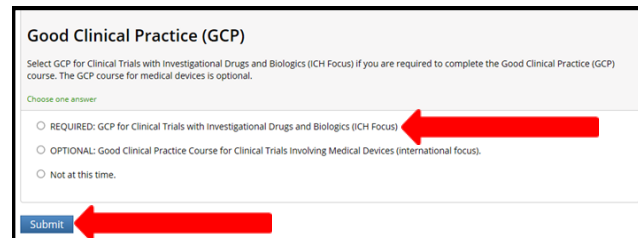
- 1) [Log in](#) to your CITI account.
- 2) From the Main Menu screen, select *University of Massachusetts Worcester Courses*.



- 3) Next, select *Add a Course or Update Learner Groups*.



- 4) Click on the *Required* option.
- 5) Click on *Submit*.

A screenshot of the 'Good Clinical Practice (GCP)' selection screen. The title is 'Good Clinical Practice (GCP)'. Below the title is a paragraph: 'Select GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus) if you are required to complete the Good Clinical Practice (GCP) course. The GCP course for medical devices is optional.' Below this is a section for 'Choose one answer' with three radio button options: 'REQUIRED: GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus)' (selected and highlighted with a red arrow), 'OPTIONAL: Good Clinical Practice Course for Clinical Trials Involving Medical Devices (international focus)', and 'Not at this time.' At the bottom left is a 'Submit' button (highlighted with a red arrow).

Good Clinical Practice (GCP) Training at UMMS

2016



University of Massachusetts
Center for Clinical and
Translational Science

What?

Good clinical practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects.

GCP requirements are common to drug and device trials, but GCP principles apply to other types of research as well.

Who?

All investigators and study staff who are involved in the conduct of *clinical trials** as defined by NIH.

Why?

Common GCP training helps to:

- Protect the rights and welfare of subjects
- Ensure data integrity
- Meet Sponsor requirements
- Address investigator and study staff requests for training
- Facilitate audit preparation and improve outcomes

How?

UMMS will offer GCP training through the **Collaborative Institutional Training Initiative (CITI)**.

GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus)

- Includes references to FDA regulations and guidance
- Meets the *Minimum Criteria* for ICH GCP training as recognized by **TransCelerate BioPharma** to allow mutual recognition of GCP training among trial sponsors.

(See the back panel for further CITI instructions.)

Note: If you have previously completed the ICH-focused Basic CITI GCP training module or refresher course, you do not need to repeat the training. However, you need to stay up-to-date with both human subjects and GCP refresher courses in CITI **every 3 years**.

* NIH definition of a clinical trial:

“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 health-related biomedical or behavioral outcomes.”

When?

New clinical trial* IRB submissions effective **May 1, 2016**

Continuing Review submissions effective **May 1, 2017**

Exceptions at Reapproval:

- In data analysis only
- In long-term follow-up only

FAQs

Q: Do I have to take CITI GCP if I already have GCP training from a Sponsor or another source?

A: Yes. The goal is for all UMMS investigators and staff to receive common GCP training in a system that notifies the institution when users complete the requirement and notifies users when their training is due to expire.

Q: I am only involved in social or behavioral research. I do not do studies with drugs or devices. Am I subject to this requirement?

A: Possibly. Some social and behavioral studies meet the NIH definition of a clinical trial. Please see the NIH definition of a clinical trial in the center column or visit the link provided.

Q: Will eIRB track training dates?

A: Yes, eIRB will be updated soon to show expiration dates for CITI GCP and for CITI IRB human subjects training.