

**CITI Human Subject Protection (HSP) Training and Good Clinical Practice (GCP) Training**

All WMed Center for Clinical Research (CCR) investigators and research team members engaged in human subjects research must be trained in the **protection of human subjects** prior to IRB approval of protocols or continuing review applications. All WMed CCR investigators and research team members engaged in clinical research must be trained in **good clinical practices (GCP)** prior to performing any required protocol tasks.

WMed employs the **Collaborative Institutional Training Initiative (CITI)** for these training courses. CITI is an online tutorial and testing site offering education on the basic principles and procedures related to the protection of human research subjects and GCP.

If you **have not** trained in the **protection of human subjects** in the last 4 years, you need to complete the appropriate learner group modules and/or appropriate Refresher Courses.

**Guide to Identify Appropriate Training Modules**

Please see examplesbelow to help you determine which learner group is most appropriate for you to select (for **Question # 1**) once you log on to [www.citiprogram.org](http://www.citiprogram.org) (whether you are a new or existing CITI user).

**Social & Behavioral Research examples include:**

* Epidemiology
* Database – not a medical or clinical PHI database
* Ethics
* Surveys, Questionnaires
* Studies that utilize medical student records

**Biomedical Research examples include:**

* Clinical Trials
* Clinical Investigations
* Typical studies in Pediatrics, Internal Medicine, Orthopedics and other specialty offices
* Studies that utilize clinical or medical records with PHI

**If you are a new CITI User**

* Log on to [www.citiprogram.org](http://www.citiprogram.org)
* Select “Register” to create an account (remember to save your Username and Password)
* Affiliate with WMed by searching for “Western Michigan University Homer Stryker M.D. School of Medicine” from the Participating Institutions drop-down menu
	+ Follow the prompts to determine your requirements
	+ Add the additional **Good Clinical Practice** Courseif you need GCP Training
	+ Your required courses will be listed at the Main Menu page. Select the applicable curriculum associated with:
		- **Question # 1** **Human Subjects Research -** (Select Biomedical Research Investigators or Social & Behavioral Research Investigators – see above examples)
		- **Question # 2 IRB Chair** (NA unless you are an IRB member)
		- **Question # 3** **Good Clinical Practice (GCP)**
		- **Question # 4 Responsible Conduct of Research** (Mandated if receiving National Institutes of Health (NIH) or National Science Foundation (NSF) funding)
		- **Question # 5 Laboratory Animal Research** (NA unless requested by IACUC)
		- **Question # 6** **Biosafety/Biosecurity** (NA unless you have been requested by Institutional Biosafety Committee (IBC) to take a Biosafety/Biosecurity course)

 **If you are an Existing or Current CITI User with another Institution**

* Log on to [www.citiprogram.org](http://www.citiprogram.org)
* Enter your existing Username and Password
* At the Main Menu page, choose “Click here to affiliate with another institution”
* Affiliate with Western Michigan University Homer Stryker M.D. School of Medicine from the Participating Institutions drop-down menu
* Follow the prompts to determine your requirements
* Add the additional **Good Clinical Practice** Courseif you need GCP Training
* Your required courses will be listed at the Main Menu page. Select the applicable curriculum associated with:
* **Question # 1** **Human Subjects Research -** (Select Biomedical Research Investigators or Social & Behavioral Research Investigators – see above examples)
* **Question # 2 IRB Chair** (NA unless you are an IRB member)
* **Question # 3** **Good Clinical Practice (GCP)**
* **Question # 4 Responsible Conduct of Research** (Mandated if receiving National Institutes of Health (NIH) or National Science Foundation (NSF) funding)
* **Question # 5 Laboratory Animal Research** (NA unless requested by IACUC)
* **Question # 6 Biosafety/Biosecurity** (NA unless you have been requested by Institutional Biosafety Committee (IBC) to take a Biosafety/Biosecurity course)

If you are a user who works with both **Biomedical and Social & Behavioral** studies, both of these categories may be marked; however, the system may initially reflect duplicate training modules that will need to be completed. Once a module has been completed, all subsequent duplicates of that module will be removed by the system. You do not have to complete a module more than once as the system will identify duplicate modules and adjust the documentation accordingly.

It is not necessary to complete all the modules in one sitting – you can return to the website anytime and pick up where you left off.  **However, don’t log off in the middle of an exam or you will lose it!** A minimum “passing” aggregate score of 80% is required for each course.  A grade book is provided to help you track your progress.  You may repeat any module quiz to improve your score.

When you have finished the required CITI Training modules:

1. Print or download a Course Certificate Report for your records
2. Forward your certificate(s) to your Regulatory Specialist, if applicable (i.e. industry-sponsored studies)
3. Forward your certificate(s) to Quality Control at Marissa.Mattox@med.wmich.edu if applicable (i.e. industry-sponsored studies)
4. Include your certificate(s) in the IRB Application Submission Process

Completion of the appropriate HSP & GCP courses will be required every 4years (every 3 years for IRB members) from the date of completion listed on the previous CITI Certificate documentation of training. A reminder from CITI will be emailed to you 30 days prior to expiration of your course certificate.

**Further Information**

For frequently asked questions and general support inquiries
please visit the CITI Program Support Center - Knowledge Base at:

[http://citiprogram.desk.com](http://citiprogram.desk.com/)

or contact:

Julie Bouma, QA and Education Coordinator ׀ 337-4322 ׀ Julie.bouma@med.wmich.edu

Jacob Holloway, QA Analytics Coordinator ׀ 337-4323 ׀ jacob.holloway@med.wmich.edu