CITI Human Subject Protection (HSP) Training and Good Clinical Practice (GCP) Training
For New to CITI Users

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. In addition to **HSP** Training, all WMed CCR investigators and research team members engaged in clinical research involving drug and/or device must be trained in **GCP** Training prior to performing any required protocol tasks. **GCP** Training is required every **3** years.

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.

Guide to Identify Appropriate Training Modules

Please see examples below 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 (whether you are a new or returning CITI user).

Social & Behavioral Research examples include:

- Epidemiology
- Database – not a medical or clinical protected health information database
- Ethics
- Surveys, Questionnaires
- Studies that utilize medical student records (may also include records with personal information)

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 protected health information

Research with data or laboratory specimens ONLY: No direct contact with human subjects (or identifiable data)

- Statisticians
- Epidemiologists
- Data Technicians

If you are a new to CITI User

1. Log on to www.citiprogram.org
2. Select "Register" to create an account (remember to save your Username and Password)
3. Affiliate with WMed by searching for "Western Michigan University Homer Stryker M.D. School of Medicine" NOT "Western Michigan University" from the Participating Institutions drop-down menu
4. Follow the prompts to determine your requirements
5. Add the additional **Good Clinical Practice** Course if you need GCP Training
6. The 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)** (NA unless clinical trial or industry sponsored studies involving human subjects)
    - **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)

- **Question # 7 Clinical Trial Billing Compliance (**NA unless your focus is on research billing compliance)
- **Question # 8 IRB Administration (**NA, unless affiliated with IRB)

If you are a user who works with both **Biomedical** and **Social & Behavioral** Research studies, both of these learner courses may be selected. Please Note: The CITI System will ensure that any identical modules would not have to be completed more than once.

If you are involved in both Biomedical and Social & Behavioral studies the IRB may require training for both areas.

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. You can re-enter each module and re-take each quiz to achieve a passing score as necessary.

When you have finished the required CITI Training modules:

1. Print or download a CITI Course Completion Report for your records. To Print your report, go to the main menu and select "View-Print-Share" from the Completion Record.
2. Include your CITI Course Completion Report(s) in the IRB Application Submission Process
3. Forward your CITI Course Completion Report(s) to your Regulatory Specialist, if applicable (i.e. industry-sponsored studies)
4. Forward your CITI Course Completion Report(s) to Quality Control at Marissa.Mattox@med.wmich.edu if applicable (i.e. industry-sponsored studies)

Completion of the appropriate **HSP** courses will be required every 4 years (every 3 years for IRB members) from the date of completion listed on the previous CITI Completion Report documentation of training. Completion of the appropriate GCP courses will be required every 3 years (if applicable).

An expiration reminder from CITI will be emailed to you 90, 60, 30 and 7 days prior to expiration and 1-day post expiration.

Further Information

For frequently asked questions and general support inquiries
please visit the CITI Program Support Center - Knowledge Base at:
http://citiprogram.desk.com , telephone support 1-888-529-5929
or contact:

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