

BRI IRB Ethics and GCP Training

Instructions for completing CITI training requirements

BACKGROUND

The BRI Clinical Research Program has limited the requirements for Ethics and GCP* training to one program, the Collaborative Institutional Training Initiative (CITI), for the following reasons:

- To ensure standardized training,
- It is a web-based program, accessible 24/7,
- The CITI modules provide electronic documentation of completion directly to the IRB,
- The CITI Developers Group meets semi-annually to review and update the courses and to develop new initiatives for the program, and
- Approximately 1130 institutions and facilities around the world currently use the CITI program.

You will need to score 80% or better on each module to fulfill your requirement. If you do not score 80%, you can back up and take the test as many times as you need with no penalty. When you have completed all required modules, a certificate of completion will be automatically emailed to you and the IRB.

During the course of completing the modules, if you need assistance, contact the IRB at (206) 341-1346 for guidance. You may also contact the CITI Office at the University of Miami at 305-243-7970 or by e-mail at citisupport@med.miami.edu.

WHAT DO I NEED TO COMPLETE?

1. All VM/BRI researchers considered “***key personnel***” are required to complete the “***Basic CITI Course in the Protection of Human Research Subjects***” (Basic Course) and ***GCP modules****.
2. VM/BRI researchers having completed the “Basic Course”, must complete the “***Refresher Course in the Protection of Human Research Subjects***” (Refresher Course) and ***GCP modules**** every 2 years.
3. Researchers not directly affiliated with VM/BRI (e.g. UW, SCH, FHCR) may qualify for an exception if they have completed training at their own institution (see “***DO I QUALIFY FOR AN EXCEPTION?***”)

WHO IS CONSIDERED KEY PERSONNEL?

Persons responsible for one or more of the following:

- a. Day-to-day protocol decision-making related to the study conduct;
- b. Participant recruitment, selection and eligibility;
- c. Clarification of the complexities of the protocol to the participant and others;
- d. Collecting participant information and entering data using procedures to maintain privacy and confidentiality;
- e. Ensuring that the rights and welfare of participants are monitored throughout the study.

NOTE: For more details see: http://www.benaroyaresearch.org/bri/files/webfm/investigatortwo/Key_Personnel_Defined.doc

**As of November 2010, completion of the Good Clinical Practices (GCP) modules will be required through the CITI training web-site. You are required to complete GCP modules every 2 years with your “Refresher Course”. An alternative course is available for outside researchers that qualify for an exception and have not taken the CITI ethics course (see “DO I QUALIFY FOR AN EXCEPTION?”).*

HOW DO I REGISTER?

1. Go to www.citiprogram.org
2. Click **[Register Here](#)** next to where it indicates “New Users”.
3. Under “**[Participating Institutions:](#)**” choose “**Virginia Mason (VM)/ Benaroya Research Institute at Virginia Mason (BRI)**” and then click the **[Submit](#)** button.
4. After you have entered your basic user information, you will be prompted with these options/questions to determine which modules you’ll need to complete:
 - a) Please select the groups related to your research activities to view available courses. (**[Human or Lab Animal Research Courses](#)**)
 - b) Do you need to complete a basic or a refresher course? (**[Basic Course or Refresher Course](#)**)
[Note: You must first complete an approved basic course to receive credit for completing a refresher course]
 - c) Will you ever view or have access to subject Protected Health Information (PHI) for ANY research conducted at VMMC/BRI? (**[YES or NO](#)**) [Note: If you choose NO, you will not be able to take GCP training. As well, you will not be allowed to view BRI/VMMC patient PHI in research.]
 - d) Select the group appropriate to your research activities or for which you have previously completed an institutionally approved Basic Course in the Protection of Human Research Subjects. [There are 4 learner’s “groups”, each focused on a different aspect of bioethics and human subjects research. You only need to complete one of the four “groups”].
 - [Group 1 - Biomedical Research Personnel](#)** - This course is suitable for Students, Investigators and staff conducting BIOMEDICAL RESEARCH with human subjects. The VA module must be completed if you plan to work with subjects at a VA facility.
 - [Group 2 - Social & Behavioral Research Personnel](#)** - This course is suitable for Students, Investigators and staff conducting Social & Behavioral Research with human subjects.
 - [Group 3 - Data or Specimens Only Research Personnel.](#)**
 - [Group 4 - BRI IRB Members.](#)** (Only if you are a member of the BRI IRB)
5. Once registered, you will be taken to the “**[Main Menu](#)**”.
6. Go down the page to “My Courses”. Under “Status” you will see **[Not Started – Enter](#)** for each course you still need to take. To begin, click on **[Enter](#)** to start the course.
7. You will be directed to the “Human Research Grade Book” page. A list of the required modules will appear. Click on **[Take the next required module](#)** or the highlighted link in red to start each module.
8. Follow the instructions to complete each module. Tests are located at the bottom of each module.

HOW DO I COMPLETE THE “REFRESHER” COURSE?

Recertification for CITI training must be completed every 2 years. If you received notification as "key personnel" on one or more research studies at VM and/or BRI, you will need to take the CITI “refresher course” and “GCP” at this time:

1. Go to www.citiprogram.org
2. Under “**Login**” enter your username and password. If you don’t have these, see section (WHAT IF I LOST MY USERNAME AND PASSWORD?)
3. Once registered, you will be taken to the “**Main Menu**”.
4. Go down the page to “**My Courses**”. Under “**Status**” you will see **Not Started – Enter**. To begin the “Refresher Course” and “GCP”, you need to click on **Enter** to start.
5. You will be directed to the “Human Research Grade Book” page. A list of the required “refresher” modules will appear. Click on **Take the next required module** or the highlighted link in red to start each module.
6. Short “refresher” tests are located at the bottom of each module.

ADDING GCP MODULES AFTER YOU HAVE ETHICS TRAINING AT CITI?

If you have already completed CITI ethics training and would like to add GCP modules to your account, follow these steps:

1. Go to www.citiprogram.org
2. Under “**Login**” enter your username and password. If you don’t have these, see section (WHAT IF I LOST MY USERNAME AND PASSWORD?).
3. Once registered, you will be taken to the “**Main Menu**”.
4. Go down the page and click the link “**Add a course or update your learner groups...**”
5. You will be prompted with the same questions when you originally registered (see HOW DO I REGISTER? #4 [a-d]). You will need to answer all questions consistent with your current Basic/Refresher group (*i.e. if you completed Group 1 already, choose Group 1 again*). When asked “**Will you ever view or have access to subject Protected Health Information (PHI) for ANY research conducted at VMMC/BRI?**”, you must answer “**YES**”.
6. You will be directed to the “**Main Menu**” again. Go down the page to “**My Courses**”. Under “**Status**” you will see **Not Started – Enter**. To begin the “CITI Good Clinical Practices, GCP” course you’ll need to click **Enter** to start.

DO I QUALIFY FOR AN EXCEPTION?

An exception is available for “[key personnel](#)” completing ethics training at another institution (i.e. outside VM/BRI). The institution must have a current Federalwide Assurance (FWA) and documentation of training for each person must be provided to the BRI IRB office. Documentation via hardcopy or e-mail is acceptable, or you may provide a web-link to your institution's ethics training listing.

An exemption to the GCP training requirement may be available for “[key personnel](#)” that do not work with VM/MC/BRI patients or subjects directly, their records or identifiable information, or samples. Please email CRP@benaroyaresearch.org with your request for exemption. Be sure to include the IRB number of the study you wish to be exempted from and clearly state will not work with VM/MC/BRI patients or subjects directly, their records or identifiable information, or samples.

WHAT IF I LOST MY USERNAME AND PASSWORD?

If you do not remember your username and/or password, follow these steps:

1. Go to www.citiprogram.org. Click on [Forgot Login Information?](#)
2. Once there, you will be asked “**If you forgot your username:**” to enter your email and request your username be emailed to you.
3. You have the option to request your password as well by answering the questions under “**If you forgot your password:**”

NOTE: Your **username** and **email address** used to complete the Basic CITI ethics course is located on the top of your original course completion certificate. Contact the IRB office at: IRB@benaroyaresearch.org if you need assistance.

HOW DO I OBTAIN CME CREDITS?

Six (6) Category I CME credits are available for Physicians, Physician's Assistants, Nurse Practitioners and Psychologists who complete the "Basic Course". The credits are available through the University of Miami Office Continuing Medical Education for a handling fee of \$60.00.

Two (2) Category I CME credits are available for Physicians, Physician's Assistants, Nurse Practitioners and Psychologists who complete the “Refresher Course”, for a handling fee of \$30.00.

Please call (305) 243-6716 for information specific to CME credits or see the CITI web-site link <https://www.citiprogram.org/citidocuments/cme/index.htm> for additional instructions.

Frequently Asked Questions:

<https://www.citiprogram.org/announcementview.asp?strKeyID=A771B864-3ACA-424A-A212-72A794023E9A-0>