



The Christ Hospital

INSTITUTIONAL REVIEW BOARD (TCH)

"Collaborative Institutional Training Initiative" - CITI

The Christ Hospital Institutional Review Board is seeking accreditation from the Association for the Accreditation of Human Research Protection Programs (AAHRPP). Several standards deal with the "Investigator", assuring that researchers and staff are trained in following Good Clinical Practice guidelines defined by the FDA, as well as following institutional policies and procedures. To meet the standard of educating the research staff, we have implemented the on-line training course "Collaborative Institutional Training Initiative" (CITI). This is a course commonly taken by investigators in many institutions to meet IRB regulations. We have also required our IRB members and IRB staff to complete this course. The instructions are attached for logging on to the website and taking the course.

Please note the following:

- The course will need to be completed every three years. A composite score of 80% is required by the IRB; if low scores make the composite fall below 80%, individuals may go back and re-take modules as needed. Not all the modules must be completed at the same time. You may wish to log on and take them as time allows, but total time to complete all modules is approximately 3 hours.
- Upon completion of all modules, please send a copy of the course transcript to the IRB office confirming completion. You should also print a copy of the list of completed modules, with grades, to keep for your records or to submit to other institutions if needed.
- It is the policy of The Christ Hospital IRB that investigators may not be listed as a Principal Investigator or Co-Investigator unless proof of course completion is on file in the IRB.
- If you have already taken this course, or a similar course, please provide the documentation of completion to the IRB at your earliest convenience.

We sincerely appreciate your attention to this matter. Please know that we are here to help you in any way. If you have any questions about our education policy, or need assistance with the CITI course, please don't hesitate to contact the IRB Office at 513-585-2742.

"Collaborative Institutional Training Initiative" - CITI

NEW USERS:

1. Log on to www.citiprogram.org. Click the **Log In** button. You might have to scroll to the right to see it.
 - Click **Register**.
2. Use the drop-down list to select **Greater Cincinnati Academic and Regional Health Centers** as your Participating Institution. Then click **Continue**.
3. Complete the "Personal Information" screen and click **Continue**.
4. Complete the "Create your Username and Password" screen. You may create any username and password. Then click **Continue**.
5. Complete the "Gender, Ethnicity, and Race" screen. Then click **Continue**.
6. Complete the questions about "Continuing Education Units". Then click **Continue**.
7. Complete the profile information. Then click **Continue**.

Now you have set up your profile and are ready to answer questions about the kind of research you do. Go to "Registration Questions" for instructions. After you have answered the Registration Questions there are a few more steps for you to do.

8. Click "Finalize registration", but **YOU ARE NOT FINISHED YET**.
9. CITI will send a confirmation email to the email address in your profile (step 3 above). You will need to respond to CITI's email (step 10 below).
10. Click the link in CITI's email message to confirm your email address and complete your registration.
11. Click "**Here**" in the CITI message. You will be taken to CITI's login page. Enter your username and password (set in step 4 above) to open your own Main Menu (home page).
12. Click the "Greater Cincinnati Academic and Regional Health Centers Courses" link to access your assigned curriculum(s). If you are affiliated with other institutions, their links will be shown here also.
13. Your **Main Menu** will list the courses assigned to you, based on your answers to the Registration Questions. The status of each course will be listed to the right of its title, in the Status column.

Click on the course's title to enter the course. Then click on the module's title to open it. Read the material and take the quiz, and then go on to the next module. You may re-read the material and re-take the quiz as often as you need to. To complete a course you must have a total score of 80% or higher on all modules' quizzes. When

you have completed a course its Status will change to "**Passed**". When all courses listed on your Main Menu have a Status of "**Passed**," you're finished!

Be sure to **download or print your Completion Report** for each course to document your training, and keep your Reports with your CV or résumé. There is a "**Print**" link in the Completion Report column (to the right of the Status column; you might need to scroll to the right to see it) for every course that has been completed. You may print your own Completion Reports from your Main Menu at any time. Completion Reports are NOT archived by the IRB.

If you need to change your response to any of the Registration Questions, look below your list of courses. Click on the "**Add a Course**" link to return to the Registration Questions and modify your answers. Or, if you just need to remove one or more courses, you may click "**Remove a Course**".

EXISTING USERS:

1. Begin at WWW.CITIPROGRAM.ORG. If you already have a CITI account, **DO NOT CREATE A NEW ACCOUNT**. Log In to your existing account at using your existing username and password.
 - **If you have forgotten your username or password**, you can contact CITI to have them reset it and email it to you. Click "Support." Then click "Contact Us." And email your request.
 - If you are registered with GCARHC but **your email address has changed**, contact the UC IRB office (Claudia.Norman@uc.edu or 558-5784) to reset it.
2. When you have logged in, on your **Main Menu** page there is a link to **My Profiles**, where you can change your personal profile settings.
3. There is also a link **Click here to affiliate with another institution**. Click the link and then follow the steps under "**Registration Questions**" to affiliate with GCARHC.

REGISTRATION QUESTIONS

1. Begin at WWW.CITIPROGRAM.ORG. Click the **Log In** button. You might have to scroll to the right to see it. Then enter your CITI username and password.
2. The following Registration (or affiliation) Questions are about the research studies in which you are involved. Your answers will determine the courses assigned to you. Note that most of the questions are NOT about YOUR OWN ROLE in the research projects, but about the research projects themselves. At any time you may click **Start Over** to go back to the beginning and change your answers.

If you are a student who needs to complete CITI training for a course requirement, answer the questions as if you were a researcher conducting a research study at TCH. Say "Yes" to at least these questions:

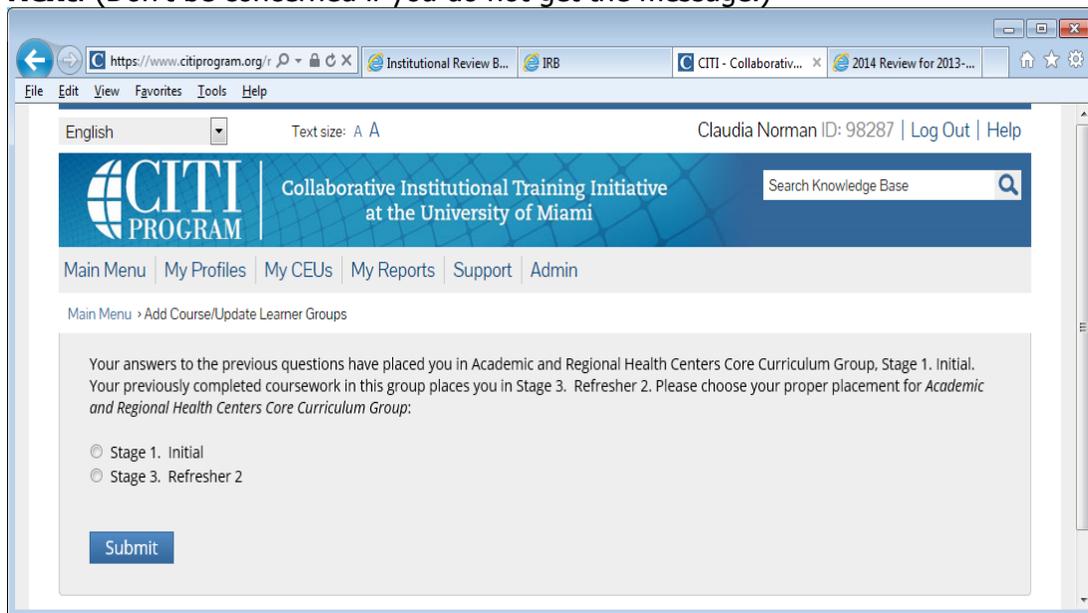
- Are you primarily employed OR involved in the conduct of research occurring at any of these institutions?

- Are you included on a protocol that will be submitted to an IRB?
- a. The first question asks if you are either employed by OR doing research at one of the Academic Medical Centers. Answer "Yes" and click **Next**.
 - b. The next question asks if your research will be submitted to an IRB. Answer "Yes" and click **Next**.
 - c. The next question asks if you are doing **health-related research**.
 - If you are NOT doing health-related research, answer "No."
 - If you are doing health-related research that is ONLY observational (no interventions or treatments), answer "No."
 - If you are doing health-related research that ONLY uses EXISTING medical records or data (all data are already in existence with no new data to be obtained), answer "No."
 - If you are doing health-related research that includes grants or contracts, answer "Yes."

Then click **Next**.

- d. The next question only applies to researchers at Children's Hospital. Most TCH researchers will answer "No." Then click **Next**.
- e. The next question is about OPTIONAL training for research coordinators and other research administrators. Select either "Yes" or "No" and click **Next**.
- f. The next question is about training specific to populations who might be vulnerable to coercion. Select any populations that are included in your research or "None of the above." Then click **Next**.
- g. Again, the next question only applies to researchers at Children's Hospital. Most TCH researchers will answer "No." Then click **Next**.
- h. The next question is about using laboratory animals in research. If you are not doing research on animals, answer "No" and click **Next**.
- i. Only researchers who have been told they need to complete Export Training need to say "Yes" to this question. Most researchers will say "No." Then click **Next**.
- j. Research funded by National Science Foundation (NSF) and/or National Institutes of Health (NIH) usually require researchers to complete Responsible Conduct of Research (RCR) training. Most other researchers do NOT need to do RCR training. If you are not sure, select "No." Then click **Next**.
- k. ONLY voting Institutional Review Board members or staff that supports the Institutional Review Board should say "Yes" to this question. Researchers who are involved in a study that has been submitted to the IRB for review should say "NO." Research staff should say "NO." Most researchers will say "NO." Then click **Next**.

1. If you have already done CITI training and have been re-answering the Registration Questions because you needed to **"Add a Course"** to revise your course list, you may receive the following message. Answer the question and click **Next**. (Don't be concerned if you do not get the message.)



After clicking "Submit" the same question might show again. Don't worry, just look in the gray ribbon at the top of the page and click "Main Menu". You should see the correct courses listed now.

3. CITI will take you to your Main Menu page (or you may click Main Menu). There will now be a list of all the courses assigned to you based on your answers to the Registration Questions.
 - The status of each course will be listed to the right of its title, in the Status column.
 - If you are a New CITI User registering for the first time, go back to **New CITI User, Step 8** to finish registering.
4. Click on the course's title to enter the course. Then click on the module's title to open it. Read the material and take the quiz, and then go on to the next module. You may re-read the material and re-take the quiz as often as you need to. To complete a course you must have a total score of 80% or higher on all modules' quizzes within that course. When you have completed a course its Status will change to **"Passed"**. When all courses listed on your Main Menu have a Status of **"Passed,"** you're finished! Please note that every course listed on your Main Menu needs to be "Passed".
 - **Completion Reports:** You may print your own Completion Reports from your Main Menu at any time. Completion Reports are NOT archived by the IRB.
 - **Adding Additional Courses:** If you need to add any courses, click **"Add a Course"** below the list of courses. That will take you back through the Registration Questions, starting at **Step 2** in the **Registration Questions** instructions above).
 - **Removing Courses:** For courses that were added in error or that are no longer needed, click **"Remove a Course"** below the list of courses. Select the course(s)

to be removed and click **Submit**. Any course that has already been successfully completed will remain in Previously Completed Coursework regardless of whether it is on your Main Menu. HOWEVER, CITI will only send refresher reminders for courses listed on your Main Menu. If you remove a course so it only is listed on Previously Completed Coursework by mistake, click "Add a Course" and re-answer the Registration Questions.

- **Viewing Previously Completed Courses:** Click "**View Previously Completed Coursework**" below the list of courses to see all courses you have completed, even if they no longer need to be listed as active courses.
 - **Updating Your Profile:** Click "**Update Institution Profile**" below the list of courses to change your language preference, departmental affiliation, address, etc. (see **Step 7** in the **New CITI User** instructions). Look at the top of your Main Menu and click **My Profiles** to change your name, password, email address, security question, etc. (see **Steps 3 and 4** in the **New CITI User** instructions).
 - **Removing Affiliation:** If you remove your affiliation with GCARHC, CITI will still retain all your course completion history but there will no longer be any link for you to open it. Also, the IRB will not be able to see your training. You would need to "Click here to affiliate with another institution" and re-register with GCARHC to see the courses again. We do NOT recommend removing your affiliation even if you leave.
5. If you have questions about the CITI affiliation process, please contact UC's HRPP office: Claudia.Norman@uc.edu or 513-558-5784.