

INSTITUTIONAL REVIEW BOARD (TCH)

“Collaborative Institutional Training Initiative” - CITI

The “Greater Cincinnati Academic and Regional Health Centers” (GCARHC) curriculum is the means by which TCH has synchronized training requirements with other area institutions. To meet the standard of educating the research staff, we have implemented the on-line training course “Collaborative Institutional Training Initiative” (CITI). CITI is the format used to ensure that researchers and staff are trained in Good Clinical Practice guidelines defined by the FDA, as well as institutional policies and procedures. These training courses are commonly taken by investigators in many institutions to meet Federal & 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 required courses.

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 Sub-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. If you have any questions about our education policy, or need assistance with the CITI course, please don't hesitate to contact the TCH IRB Office at 513-585-2742 or email [TCH IRB Office](#).

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- A. [New CITI Users](#): These instructions are for people who have never had a CITI account at all.
- B. [Existing CITI Users](#): Only for users who are **New to Greater Cincinnati Academic and Regional Health Centers**: These instructions will help you add GCARHC to your CITI account.
- C. [Registration Questions](#): These questions determine which courses are assigned to you.
 - i. [Non-BioMedical Researchers](#)
 - ii. [BioMedical Researchers](#)

Adding or removing courses: These instructions will help you add the new initial training that became effective at TCH in 2019 (HSR CORE for 2017 and Good Clinical Practice) or any other courses, or remove courses assigned incorrectly.

- D. [FAQs](#): These Frequently Asked Questions may answer your questions.

A. NEW USERS:

1. Log on to www.citiprogram.org. Click **Register**.
2. Type "Greater" and use the drop-down list to select **Greater Cincinnati Academic and Regional Health Centers** as your Participating Institution. Then click **Continue**.
3. Then click **I AGREE** and **I affirm** and Continue.
4. Complete the "Personal Information" screen and click Continue.
5. Complete the "Create your Username and Password" screen. You may create any username and password. Then click **Continue**.
6. Complete the "Gender, Ethnicity, and Race" screen. Then click **Continue**.
7. Complete the questions about "Continuing Education Units". Then click **Continue**.
8. 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.

*For researchers/investigators **NOT participating in bio-medical research** at TCH, you may complete only the HSR CORE course.*

*For researchers/investigators that **ARE participating in bio-medical research** at TCH, you must complete the HSR CORE and Good Clinical Practice (GCP) courses.*

After you have answered the Registration Questions there are a few more steps for you to do.

9. Click "Finalize registration", but **YOU ARE NOT FINISHED YET**.
10. 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).
11. Click the link in CITI's email message to confirm your email address and complete your registration.
12. 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).
13. 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.

14. Main Menu – My Courses
15. Your **Main Menu** will list the courses assigned to you, based on your answers to the Registration Questions. **The Christ Hospital** requires the modules listed in HSR Core and Good Clinical Practice to be completed for all bio-medical researchers.

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**".

B. 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 TCH IRB Office at 513-585-2742, or email at [TCH IRB Office](#).
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.

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C. 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.

Registration Questions for Non-Biomedical Research and/or to add the HSR Core Course

If you are a student or researcher who is **NOT** participating in bio-medical research at TCH, answer the following questions as advised.

- A. The first question asks if you are either employed by OR doing research at one of the Academic Medical Centers listed.
 - TCH is not listed. Answer "**No**" and click Next.
- B. The next question asks you to indicate all institutions where you are involved in the conduct of human subjects research *. (* Human Subjects Research is defined as: research that involves interaction with living human subject - OR - research involving records/information or samples/specimens that can be linked in any way to any living individual human subject.).
 - Answer "**Christ Hospital**" and click Next.
- C. The next questions is in regards to Tri-Health only.
 - Answer "**Not at this time**" and click Next.
- D. The next question asks "Are you a voting member for an Institutional Review Board (IRB) associated with UC or CCHMC?"
 - Answer "**No**" and click Next.

You should now have the HSR CORE course listed in your My Courses.

***Note:** You may also have the GCP course listed in your course list. This course is only required to be completed if you are participating in Bio-Medical research. To remove this course from your account, go to "Remove Courses" and then click Good Clinical Practice and Submit.

Registration Questions for Bio-Medical Research and/or to add the GCP Course

If you are a Researcher or Investigator who **IS** participating in bio-medical research at TCH, answer the following questions as advised.

- A. The first question asks if you are either employed by OR doing research at one of the Academic Medical Centers (TCH is not listed, do not worry about this).
 - Answer "**Yes**" and click Next

- B. The next question asks Are you currently included (or planned to be included) as part of the study team on a protocol that will be submitted to any Institutional Review Board (IRB)?
- TCH Investigators should answer “**Yes**” and click Next.
- C. The next question asks ‘Do you work as part of a research study involving’:
- Any NIH-funded human subjects research
 - Human subjects being assigned to interventions to evaluate health-related biomedical or behavioral outcomes
 - Drugs/devices/biologics/nutraceuticals
 - OR on any grants or contracts for any of the studies described above?
 - If your research is strictly limited to being observational or involving the review of existing data, please mark "No".
 - TCH Investigators should answer “**Yes**” and click Next.
- D. The next question asks ‘Are you at Cincinnati Children’s or St. Elizabeth Healthcare and working with human subjects for research using Human Gene Transfer OR genetically modified vaccines?’ (If UNSURE, mark "No".)
- TCH Investigators should generally answer “**No**” and click Next.
- E. The next question asks ‘Are you interested in optional modules (or have you been advised to take training) on the conduct/management of clinical research?’
This would be beneficial for anyone involved in the operation/execution of clinical studies.
The Supplemental Modules are required to be completed by TCH
- TCH Investigators should answer “**Yes**” and click Next.
- F. The next question asks ‘If your research involves special populations (such as: children, pregnant women/fetuses/neonates, prisoners, students, decisionally-impaired, and/or international), there is additional training available to help identify nuances of research with these populations. Would you like access to optional modules on any of these special populations?’
- TCH Investigators should answer any and all populations that apply **OR** “None of the above or not interested” and click Next.
- G. The next question asks ‘Are you at Cincinnati Children’s AND involved in laboratory-based research?’
- TCH Investigators should answer “**No**” and click Next.
- H. The next question asks ‘Do you conduct studies that utilize lab animals at Cincinnati Children’s, UC or UC Affiliates?’ (If UNSURE, select No)
- TCH Investigators should select “**No lab animal research involvement**” in most cases, and click Next.
- I. The next question asks ‘Are you involved in research at UC or UC Health and need to complete Export training?’ (Note: if UNSURE OR if you do not know what export control is, please mark "No".)

- TCH Investigators should answer “**No**” and click Next.
- J. The next question, is for research funded by National Science Foundation (NSF) and/or National Institutes of Health (NIH), these require researchers to complete Responsible Conduct of Research (RCR) training. Most other researchers do NOT need to do RCR training.
- If you **ARE** participating in research funded by the NIH or NSF, select “**Yes**” and click Next.
 - If you are **NOT** participating in research through either of these foundations, select “**No**” Then click Next.
- K. The next question is **ONLY** for **voting** Institutional Review Board members or staff. **ALL** IRB voting members should answer “**Yes**” to this question.
- *Note:** submitting research TO an IRB is not the same as being a member of an IRB
- 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.

You should now have the Good Clinical Practice and HSR courses listed in your My Courses. TCH requires **both** courses be completed to participate in the conduct of any research.

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!
For each completed course, print your Completion Report and keep it with your CV.

- **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.

If you have questions about the CITI affiliation process, please contact [TCH IRB Office](#).

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FAQs

I took the "old" CITI training. Do I need to create a new userID for this "new" training?

No. If you have an existing account, please use it. If you have forgotten your username or password, contact CITI to have them send it to you by email. See **Existing CITI Users, Step 1** above. If your email address has changed, contact the [TCH IRB office](#) to reset it.

I already took the initial GCARHC-AAFP-Advanced CITI training and am now due for a "Refresher". Do I have to take these new GCARHC courses?

Yes. Everyone will do this GCARHC CITI training when they are due for a refresher. These courses reflect the federal regulations most accurately.

How long is my CITI training valid?

The HSR and GCP courses expire 3 years from the date completed. CITI will send email reminders starting 6 months before expiration. Even if you do not receive the reminders, it is your responsibility to keep track and do the refresher courses.

What will happen to the courses I have already completed?

They will stay in your account. To see them, log on as usual. On your Main Menu, look below your course list and click the link "View Previously Completed Coursework".

How long will the GCARHC CITI training take?

It depends a great deal on the number of courses you need to take and how much you already know about human research subject protections. Some courses contain multiple modules and others contain just one. As a "rule of thumb," allow about 20-30 minutes per module.

IT IS RECOMMENDED THAT YOU DO A LITTLE AT A TIME. The system saves the modules you have passed. ALLOW PLENTY OF TIME. Do NOT wait until the last minute! IRB approval cannot be released until ALL members of your research team have completed their GCARHC CITI training.

Will I get CMEs or Contact Hours?

CME/CEU credits are available from CITI, for a fee, for completion of some courses. Details are available via the CITI website.

How can I print my Completion Certificates?

Log on to CITI. On your Main Menu screen, find the course you took, look to the right under the column called Completion Reports, and click Print. You might need to scroll to the right to see that column.

Sometimes I do social/behavioral research and sometimes biomedical research. Will this count for both?

Yes. Be sure that your answers to the registration questions reflect the diversity of research you could possibly do.

Whom do I contact with questions?

TCH IRB Office at 513-585-2742 or 513-585-2298 or email the [TCH IRB Office](#)

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