



Research Integrity & Compliance

CITI Program Education Guide

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Introduction

Trinity Health is committed to maintaining the highest ethical standards in conducting Research and the protection of human subjects. This commitment is fundamental to Trinity Health's mission, core values, and vision.

Research education and training is an on-going endeavor and responsibility. As such, Trinity Health has developed an infrastructure that supports the responsible and ethical conduct of human subjects research across the Ministries. This infrastructure provides education and training offerings through a variety of venues, including but not limited to, topical courses available in the internal learning management system; educational leadership to guide Ministries; training, materials and procedures that can be adapted to individual Ministries; and holding regular group meetings with the Ministry IRB colleagues to collaboratively share in creating and maintaining this infrastructure.

Collaborative Institutional Training Initiative (CITI Program) is one component of this structure. The CITI Program provides web-based educational courses in research, and is available to all institutional officials, investigators, research nurse coordinators, research staff, Institutional Review Board (IRB) members, IRB Staff, and IRB Chairs in Trinity Health.

This CITI Program Guide is a reference tool for local Ministry CITI administrators.

Section I: Overview


The CITI Program website: <https://www.citiprogram.org/>

The CITI Program is an online learning management system that provides the Trinity Health required courses to all individuals involved in research activities in Trinity Health and its Ministries.

The minimum score for passing each of the Trinity Health required courses is 80%. At the completion of each assigned course, the individual will receive a CITI Training Completion Record that is valid for a maximum of four (4) years, except where otherwise required by applicable laws or regulations or by Trinity Health Procedure.

Individual Ministries may require additional courses to meet local needs, which are assigned by the local CITI administrator. The minimum score for passing each of the local Ministry's courses is 80%. At the completion of each assigned course, the individual will receive a CITI Training Completion Record that is valid for a maximum of four (4) years.

See the Trinity Health Procedure, *Education and Training Requirements for Individuals Involved in Human Subjects Research*, for further details as to the education and training requirements for individuals involved in research activities in Trinity Health.

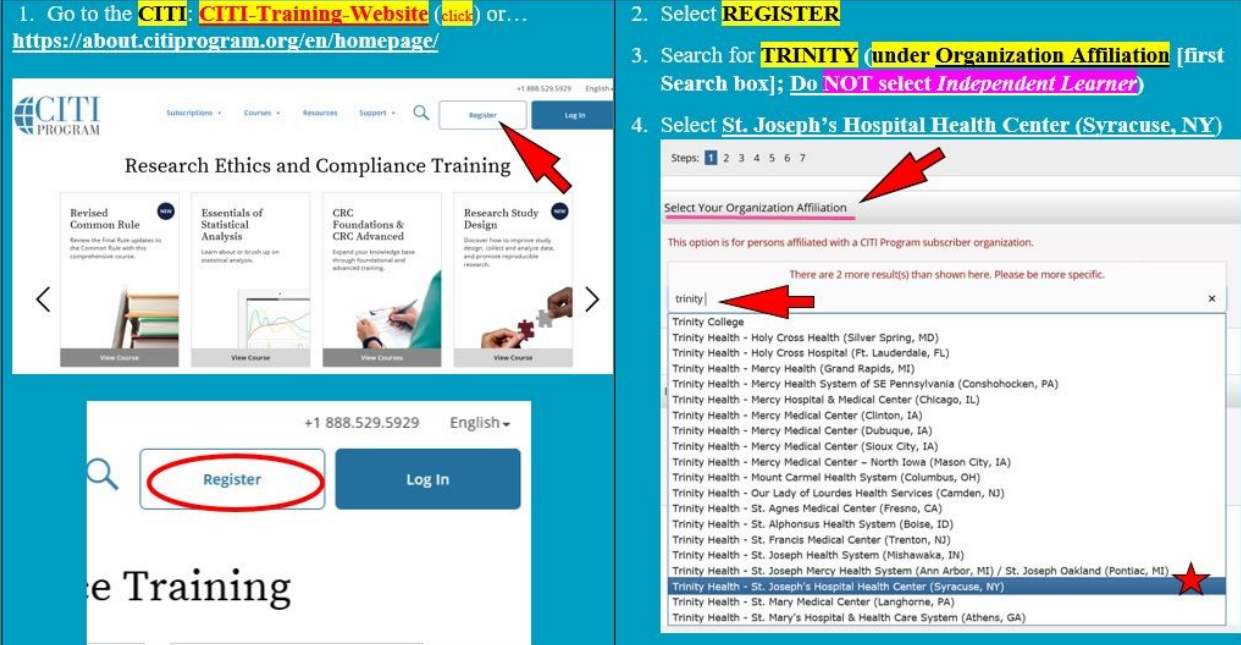


ST. JOSEPH'S HEALTH
A Member of Trinity Health

Becoming CITI Trained for the Conduct of Research at St. Joseph's Health

St. Joseph's Health Colleague Registration:

1. Go to the **CITI: CITI-Training-Website** (click) or...
<https://about.citiprogram.org/en/homepage/>
2. Select **REGISTER**
3. Search for **TRINITY** (under **Organization Affiliation** [first Search box]); **Do NOT select Independent Learner**
4. Select **St. Joseph's Hospital Health Center (Syracuse, NY)**



The image shows two screenshots of the CITI Program website. The left screenshot shows the homepage with a red arrow pointing to the 'Register' button. The right screenshot shows the 'Select Your Organization Affiliation' search results page with a red arrow pointing to the search box containing 'trinity' and another red arrow pointing to the 'St. Joseph's Hospital Health Center (Syracuse, NY)' entry in the list, which is marked with a red star.

Trinity Health Required CITI Program Courses

Effective August 2018 (FY 2019), the Trinity Health Research Integrity & Compliance Program has assigned the following required courses for individuals involved in research activities in Trinity Health and its Ministries:

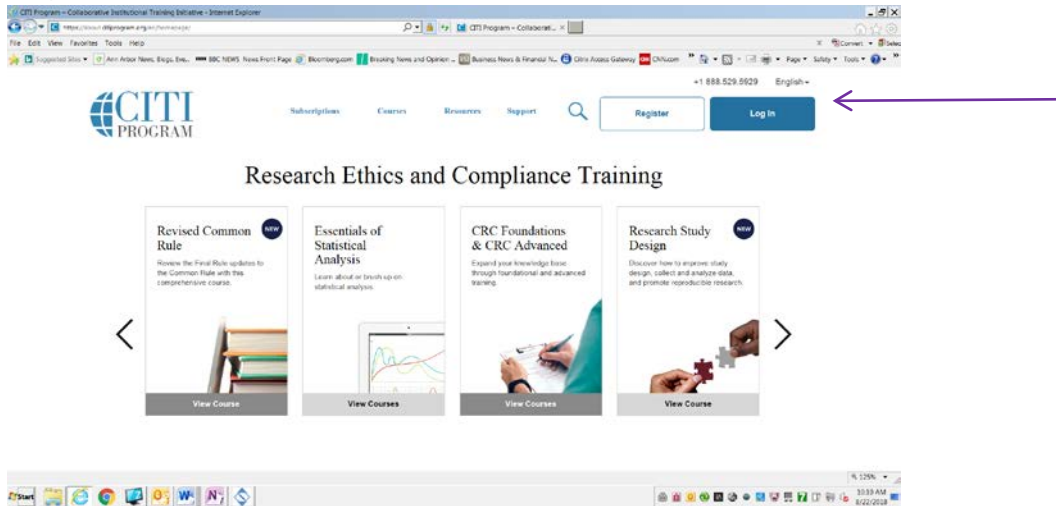
Course	Description	Details
Conflict of Interest (COI)	Provides education and training on the key elements of the U.S. Public Health Service (PHS) federal regulations on financial conflicts of interest.	All learners complete every 4 years
Responsible Conduct of Research (RCR)	Provides education and training on the core norms, principles, regulations, and rules governing the practice of research, including essential topic areas of plagiarism and research misconduct.	All learners complete every 4 years
Human Subjects Research (HSR)	Provides education and training in human subjects research, including ethical issues and current regulatory and guidance information.	All learners complete every 4 years
Good Clinical Practice (GCP)	Provides essential good clinical practice education and training for individuals involved in clinical trials of drugs, biologics, and devices (biomedical research), as well as for those individuals involved in behavioral intervention and social science research studies (social behavioral research).	All learners complete every 3 years

Section II: Course Assignment

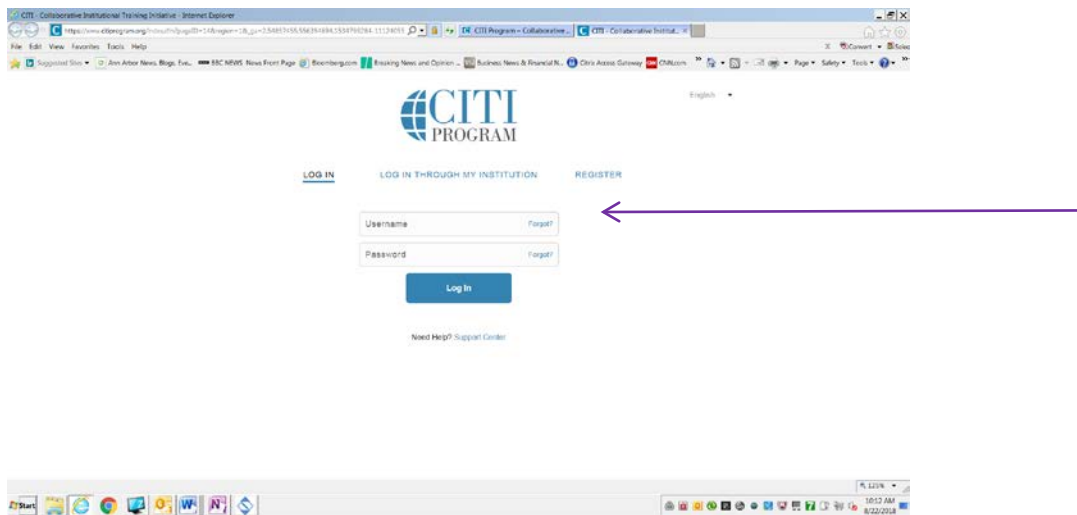
Course Assignment Basics

The learner will be assigned the Trinity Health standard courses through the **Add a Course** process.

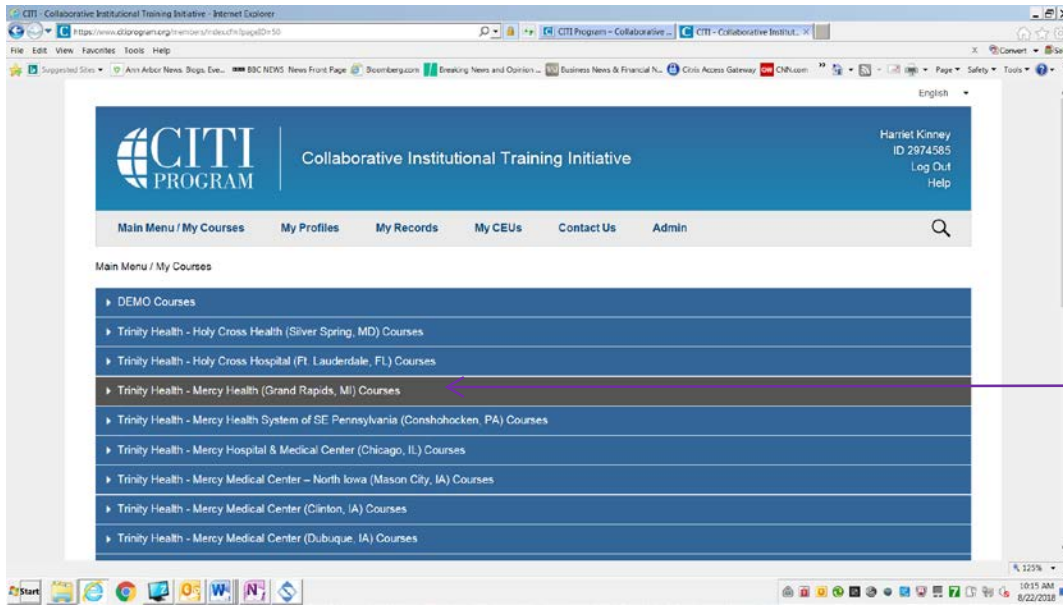
Login:



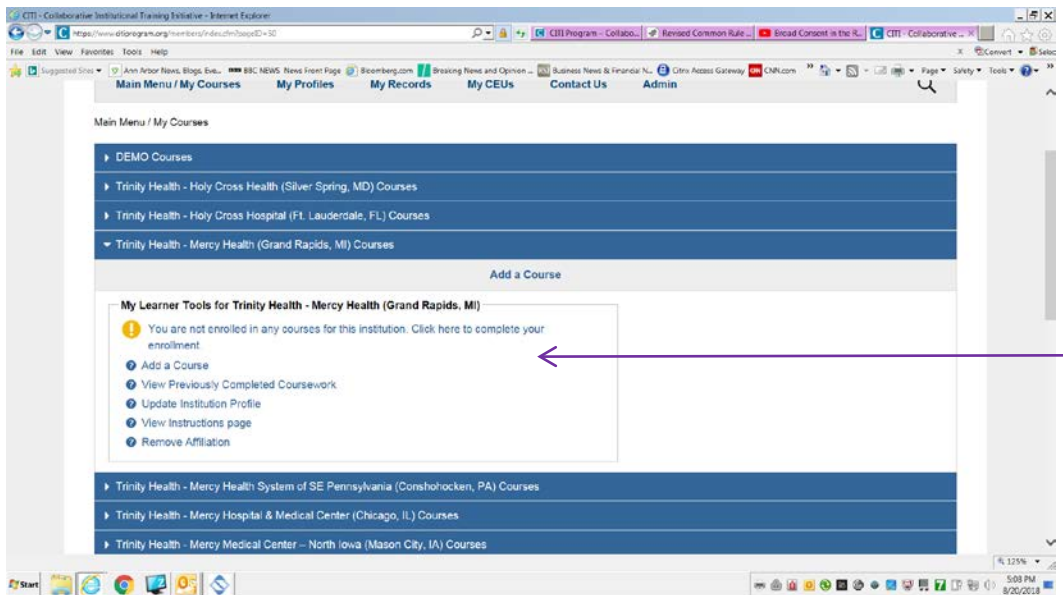
Enter User Name and Password:



On the Main Menu / My Courses, select your Ministry:



Select Add a Course:



Answer each question as it pertains to the learner. The response to the first question will drive the order of the subsequent questions.

Questions

1. Please choose your primary role in human subjects research activities:
 - a. Institutional Official
 - b. IRB Chair / IRB Member / IRB Staff
 - c. Investigator
2. Are you also an Investigator?
 - a. If YES, please choose the type of research you perform
 - i. Biomedical
 - ii. Social Behavioral
3. Are you also an IRB Member?
4. Are you also the IRB Chair?
5. Are you also the Institutional Official?

The screenshot shows a web browser window displaying the CITI Program interface. The page title is "CITI - Collaborative Institutional Training Initiative - Internet Explorer". The URL is "https://www.citiprogram.org/members/index.cfm?pageID=144&SID=19251&sdDiversity=CAACDF0807C954675A11". The page has a navigation menu with links: "Main Menu / My Courses", "My Profiles", "My Records", "My CEUs", "Contact Us", and "Admin". The main content area is titled "Home > Add a Course" and shows a dropdown menu for "Select Curriculum - Trinity Health - Mercy Health (Grand Rapids, MI) (ID: 1447)". Below this, there is a red asterisk indicating a required field. The question is: "* Please choose your primary role in human subjects research activities: Choose one answer". The options are: Institutional Official, Investigator/Research Study Coordinator/Research Staff, IRB Member/IRB Staff/IRB Chair, and *Good Clinical Practice Course*. A blue arrow points from the right side of the page to the question text. At the bottom of the form are "Next" and "Start Over" buttons. The Windows taskbar at the bottom shows the Start button, several application icons, and the system tray with the time 4:13 PM and date 10/10/2018.

After all of the questions are answered, the CITI Program will automatically assign the required Courses to the learner.

NOTE: "Good Clinical Practice Course" Is only for use by the learner who needs to complete Good Clinical Practice training. (See next section for instructions.)

St. Joseph's Health IRB requires all investigators and key personnel take the GCP [Good Clinical Practice] module either for Biomedical research or Social-Behavioral-Education Research [SBER]. Remember, this renews every three (3) years.

EXAMPLE Result:

The screenshot shows the CITI Program website interface. At the top, there is a navigation menu with options: Main Menu / My Courses, My Profiles, My Records, My CEUs, Contact Us, and Admin. Below the menu, a green checkmark icon is followed by the text: "You are now enrolled in the course(s) you selected." A dropdown menu is expanded under "DEMO Courses", showing three categories: "Trinity Health - Holy Cross Health (Silver Spring, MD) Courses", "Trinity Health - Holy Cross Hospital (Ft. Lauderdale, FL) Courses", and "Trinity Health - Mercy Health (Grand Rapids, MI) Courses". Below this, a table displays the enrollment status for three courses:

Course	Status	Completion Record	CE Credits	Survey
Conflicts of Interest (G2)	Not Started	Not Earned	Not Earned	
Human Subjects Research (G2)	Not Started	Not Earned	Not Earned	
Responsible Conduct of Research (G2)	Not Started	Not Earned	Not Earned	

Below the table, there is a section titled "My Learner Tools for Trinity Health - Mercy Health (Grand Rapids, MI)" with a list of actions: Add a Course, Remove a Course, View Previously Completed Coursework, Update Institution Profile, and View Instructions page.

For each course, the learner must complete all of the required module(s).

The screenshot shows the CITI Program website interface for a specific course. The header includes the CITI PROGRAM logo and the text "Collaborative Institutional Training Initiative". The user's name, "Harriet Kinney", and ID, "ID 2974585", are displayed along with "Log Out" and "Help" links. The navigation menu is visible at the top. The main content area shows the course title "Conflicts of Interest (G3) - Basic". Below the title, the text reads: "To pass this course you must:" followed by a list of requirements:

- Complete the required module
- Achieve an average score of at least 80% on all quizzes associated with this course's module requirements
- Supplemental modules, if provided, are optional and do not count towards passing the course or change the overall score, BUT completed CE certified modules will count toward CME credits (AMA PRA, Psychology credits, nursing credits as applicable).

Below the requirements, it states: "You have unfinished required or elective modules remaining". A blue button at the bottom of the requirements section says "Complete The Integrity Assurance Statement before beginning the course". On the right side, the text "Your Current Score" is followed by "0%". A purple arrow points from the "0%" score to the first requirement, "Complete the required module".

Some courses will also require the learner to complete an elective module:

Home > Course Responsible Conduct of Research (G4)

Responsible Conduct of Research (G4) - Basic

To pass this course you must:

- Complete all 2 required modules
- Complete 1 of 5 elective modules
- Achieve an average score of at least 80% on all quizzes associated with this course's module requirements
- Supplemental modules, if provided, are optional and do not count towards passing the course or change the overall score, BUT completed CE certified modules will count toward CME credits (AMA PRA, Psychology credits, nursing credits as applicable).

Your Current Score: **0%**

You have unfinished required or elective modules remaining

Complete The Integrity Assurance Statement before beginning the course

Required Modules

One or more modules in this gradebook will be affected by changes to the Common Rule. Affected modules will be taken offline after 21 January 2013, unless there is a change to the implementation date of the regulation. Accordingly, you may not be able to complete this course after that date. We apologize for any inconvenience.

Required Modules			
	Date Completed	Score	CE Certified
Plagiarism (RCR-Basic) (ID: 15155)	Incomplete	0/0 (0%)	Yes
Research Misconduct (RCR-Basic) (ID: 16604)	Incomplete	0/0 (0%)	Yes

Elective Modules			
	Date Completed	Score	CE Certified
Authorship (RCR-Basic) (ID: 16597)	Incomplete	0/0 (0%)	Yes
Collaborative Research (RCR-Basic) (ID: 16598)	Incomplete	0/0 (0%)	Yes
Data Management (RCR-Basic) (ID: 16600)	Incomplete	0/0 (0%)	Yes
Mentoring (RCR-Basic) (ID: 16602)	Incomplete	0/0 (0%)	Yes
Peer Review (RCR-Basic) (ID: 16603)	Incomplete	0/0 (0%)	Yes

All Courses offer supplemental modules to the learner. The learner may complete as many supplemental modules as they are interested in.

Rules (COI-Basic) (ID: 15070) Incomplete (0%) Yes

Supplemental Modules

	Date Completed	Score	CE Certified
Supplemental modules, if provided, are optional and do not count towards passing the course or change the overall score, BUT completed CE certified modules will count toward CME credits (AMA PRA, Psychology credits, nursing credits as applicable).			
Institutional Responsibilities as They Affect Investigators (COI-Basic) (ID: 15072)	Incomplete	0/0 (0%)	Yes
Conflicts of Commitment and Conscience (COI-Basic) (ID: 15073)	Incomplete	0/0 (0%)	Yes
Institutional Conflicts of Interest (COI-Basic) (ID: 16765)	Incomplete	0/0 (0%)	Yes

CE Credits Eligibility and Purchase

Please check "Action" column for either of the two following options:

"Apply Now" - If multiple purchasing options appear for a same course, carefully select the number of credits you wish to purchase. Click the course title to view on the CE Information page the maximum number of credits designated for this course and your profession.

"Complete Modules" - Indicates the total number of CE certified modules you need to complete to earn CE credits. Please complete the needed additional CE certified modules to equal that number. **Be aware that test score of each and all completed modules must at least be 70%.**

The learner may purchase Continuing Education (CE) credits prior to starting the course.

Trinity Health system office does not reimburse the learner for CITI Program CE credits. If the learner is interested in being reimbursed for the purchase of CITI Program CE credits, it is the learner's responsibility to negotiate the reimbursement with their direct supervisor or department leader.

Introduction to RCR (RCR-Basic) (ID: 17009) Incomplete 0/0 (0%) --

Reproducibility of Research Results (ID: 17756) Incomplete 0/0 (0%) --

CE Credits Eligibility and Purchase

Please check "Action" column for either of the two following options:

"Apply Now" - If multiple purchasing options appear for a same course, carefully select the number of credits you wish to purchase. Click the course title to view on the CE Information page the maximum number of credits designated for this course and your profession.

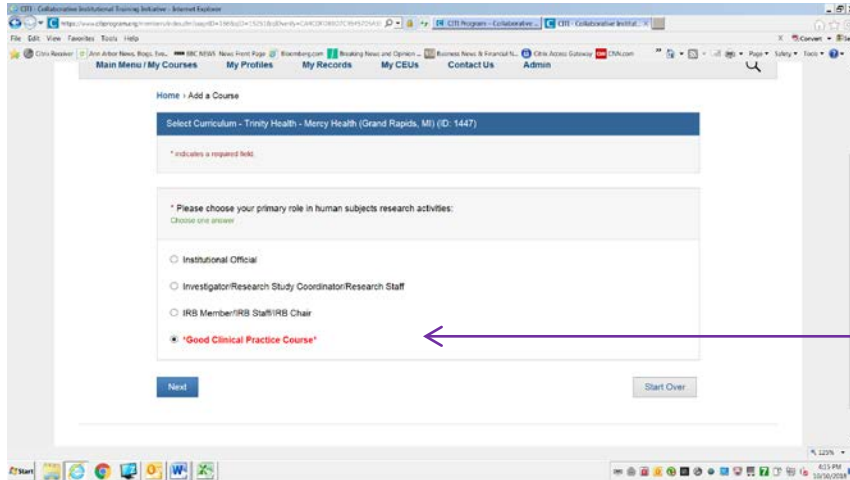
"Complete Modules" - Indicates the total number of CE certified modules you need to complete to earn CE credits. Please complete the needed additional CE certified modules to equal that number. **Be aware that test score of each and all completed modules must at least be 70%.**

CE Credit Status	Course	Category	Cost	Action
Eligible for 4 credits	Responsible Conduct of Research (RCR) Basic Course	AMA PRA Category 1 Credits™	\$60.00	Complete 8 Modules

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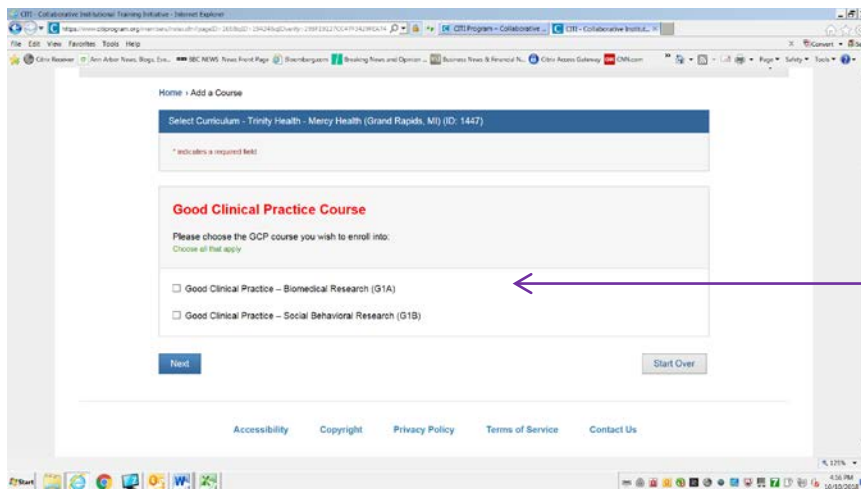
Good Clinical Practice Course

The option, "Good Clinical Practice Course", is for learners who need to complete Good Clinical Practice training.



The GCP course may be selected by the learner or assigned by the local CITI IRB Administrator to learners who are involved in the conduct, oversight, or management of Clinical Trials (e.g., drug, biologic, device trials), no matter the source of the funding. The learner is required to complete GCP education and training every three (3) years.¹

The GCP course has 2 options: biomedical research and social behavioral research. Select the course based on the type (biomedical; social behavioral) of research the learner is involved in.



¹ Research Integrity & Compliance Procedure: *Education and Training Requirements for Individuals Involved in Human Subjects Research*

Section III: Learner Groups

When the learner completes the questions in the **Add A Course** process in CITI, s/he will be assigned to a Group.

Group	Description
1A	Biomedical investigators, Study Coordinators, and Research Staff
1B	Social Behavioral investigators, Study Coordinators, and Research Staff
2	IRB Chair, IRB Members, and IRB Staff
3	Institutional Official
4	When the learner is a member of Group 1A and Group 2
5	When the learner is a member of Group 1B and Group 2
6	When the learner is a member of Group 1A and Group 3
7	When the learner is a member of Group 1B and Group 3
8	When the learner is a member of Group 1A, Group 2, and Group 3
9	When the learner is a member of Group 1B, Group 2, and Group 3
10	When the learner is a member of Group 2 and Group 3

The Group assignment reflects the learner's tasks, responsibilities, and duties in research activities. For example, a learner who is a biomedical investigator and is also an IRB member will be assigned Group 4.

Each Group has all four Courses assigned. The number of modules per Course is different depending upon the Group assignment of the learner.

Group	No. of Required Modules Assigned Per Course			
	COI	RCR	GCP	HSR
1A	2	2	13	9
1B	2	2	7	6
2	2	2	13	15
2 (IRB Chair)	2	2	13	3
3	2	2	N/A	4
4	2	2	13	15
5	2	2	20	18
6	2	2	13	10
7	2	2	20	7
8	2	2	13	15
9	2	2	20	18
10	2	2	13	15

For a complete list of the required, elective, and supplemental modules, refer to the appendices. If the learner needs more courses or modules than assigned, contact the Trinity Health CITI Administrator.

Section IV: Refresher Education & Training

The CITI Program COI, RCR, and HSR courses are valid for four (4) years; the Good Clinical Practice (GCP) course is valid for three (3) years. At the successful completion of each course, the learner will receive a Training Completion Record that is valid for the appropriate time period. Prior to the expiration of a current Training Completion Record, the learner is to complete refresher education and training. Upon completion of the refresher education and training, the learner will receive a new, valid, Training Completion Record.

It is the responsibility of the local CITI Program Administrator to run the "**Complete Reports That Will Expire**" Report at least every ninety (90) days, and send out email reminders to the individuals who are due for refresher CITI Program education and training. **NOTE:** With September 1, 2018 revisions to the required courses, the automatic reminder from CITI will not be triggered and the local CITI Administrator is responsible for sending out expiration reminders.

Directions for Informing Current Learners Whose Training Completion Record is Due for Renewal

- Log into the CITI program @ www.citiprogram.org
- Click on main menu/my courses
- Click "Admin" for the Administrators Menu
- Click on your Ministry's name
- Scroll down to Choose "Completion Reports that will soon Expire"
- Scroll down to "Show reports that Expire within 30, 60 or 90 days". Choose one of the time ranges.
- Choose all course groups that you would like to run reports
- Scroll down to the bottom of the page and click "Submit"

The CITI Program Administrator will work from this Report to send out reminders for individuals whose Training Completion Record is due for renewal. It may be best to first determine who on the report has active studies and needs to complete the refresher coursework. If individuals do not have active studies, there may be no reason for them to complete the new training.

The CITI Program Administrator may update each learner's account, then send the individual an email reminder to complete the required refresher education and training; or, the Administrator may require that the individual update their CITI account to include the new refresher education and training coursework.

Tips:

1. If an individual is only due for the HSR training and are not yet due for the COI or RCR training, it may be best to have the individual complete all three courses at the same time to keep them on track to be due for all three courses at the same time in the future.
2. The GCP course may be added to a learner's account by either the learner or the local CITI Program Administrator. This may be done by accessing the learner's CITI account, clicking on "**Add a Course**", selecting the "**Good Clinical Practice Course**" radio button, and then clicking on the appropriate GCP Course (Biomedical or Social Behavioral) radio button.
3. It is the responsibility of the local CITI Program Administrator to run the "**Complete Reports That Will Expire**" Report at least every ninety (90) days (and can be set up every 30, 60, or 90 days), and send out email reminders to the individuals who are due for refresher CITI Program education and training. To set up CITI to run a report automatically: