

Collaborative Institutional Training Initiative (CITI) Module Requirements for Human Subject Protection (HSP), Conflicts of Interest (COI) and Responsible Conduct of Research (RCR)

Abbreviated Background and Instructions for Research Personnel

As part of our institutional goal of maintaining training within the research community and promoting an organizational culture that encourages integrity and compliance at Hartford Hospital, the Human Research Protections Program (HRPP) has adopted the web-based modules within the Collaborative Institutional Training Initiative (CITI) for certification in Human Subject Protection (HSP) and Laboratory Animal Welfare Training. These web-based modules are available at www.citiprogram.org.

All personnel (employees, medical staff, students, and volunteers) involved with the conduct, administration, or review of human subjects research must complete a training course in **Human Subjects Protection**, every 3 years.

All personnel performing research that involves the use of animals are required to complete the applicable CITI training modules in **Laboratory Animal Welfare**, every 3 years.

All personnel performing research are required to complete the **CITI Conflicts of Interest (COI)** training, every 4 years.

Investigators and research staff conducting federally-funded research (i.e. NIH supported), are required to take the **Responsible Conduct in Research (RCR) Course**. This course only needs to be completed once.

The **Good Clinical Practice (GCP) Course** is **OPTIONAL for everyone**. This course consists of 12 modules focused on Good Clinical Practice and ICH guidelines for investigators conducting FDA-regulated clinical drug/device trials. The CITI basic course should be completed before attempting this more advanced course. This course only needs to be completed once.

All Hartford Hospital clinical research personnel who interact with study participants or who have access to study participant information shall initially complete the "Basic Course". Individuals will enroll in a Learner Group appropriate to their specific role in Human Subjects/Laboratory Animal Research. ***The "Basic Course" for each Learner Group consists of the Modules that have been pre-defined for that Group by the HRPP.***

There are 6 Learner Groups:

Group 1: Biomedical Research Investigators and Study Personnel -Most MD's and research staff need to complete the Group 1 module

Group 2: Social & Behavioral Research Investigators and Study Personnel

Group 3: Students conducting no more that minimal risk research -This is for undergraduate students

Group 4: IRB members

Group 5: Human Research Protections Program Staff

Group 6: Research with Data or Laboratory Specimens ONLY (no direct contact with human subjects)

The minimum passing aggregate score for the quizzes is 80%. The Hartford Hospital HRPP CITI institutional administrator receives automatic electronic mail notifications containing completion reports for each user.

Refresher Training: The CITI Program will e-mail users an alert 90 days prior to the expiration date.

Instructions:

1. Go to the Collaborative Institutional Training Initiative (CITI) website at <http://www.citiprogram.org>.
2. Beside New Users, click on “Register Here” link.
 - **What if I already completed CITI somewhere else?** If you already have a CITI username and password and have completed modules while at another institution, log in, click on “Affiliate with another institution” on the Main Menu, and follow the instructions below. There will be several HHC specific modules you’ll need to do to complete the transfer.
3. Select “Hartford Hospital” in the “Organization Affiliation” search box.
4. Scroll down and complete the rest of the page with your personal information and click on Submit. Items with an asterisk (*) are required fields.
5. Complete the next page with your personal “Member Information” and click on Submit.
6. At the “Select Curriculum” screen, choose one answer that will determine the type of training you need (**Human Subjects Course Only**, Laboratory Animal Welfare Course Only, or Human Subjects AND Lab Animal Welfare Courses. After making your selection, click on “Next Question”.
7. At the next screen, choose the appropriate answer that describes whether you need the Basic Course for initial training or the Refresher Course. After making your selection, click on “Next Question”.

[CHOOSE “NO, I have NOT completed the Basic Course in the Protection of Human Research Subjects in the past. This is the first time using the CITI Program at this institution. I need to complete the Basic Course”]

At the next screen you will need to choose a Learner Group (1-6) appropriate for your role in Research. After making your selection, click on “Next Question”.

[CHOOSE “Group 1 – Biomedical Researchers”]

8. The next screen will present the user with 2 additional Courses. Depending on your research activities, determine if you are required to complete the “Responsible Conduct in Research (RCR)”. If you conduct federally-funded research (i.e. NIH supported), you are required to take the RCR Course. Make a selection based on this determination.

After making your selection, click on “Next Question”.

9. On the next page, click “No” to continue, unless you plan to affiliate with another institution.
10. Click on the Main Menu link to begin the courses.
11. The “My Courses” column lists the courses that you have enrolled in. Click on the “Enter – Re-enter” link beneath “Status” (to the right of course name).
12. Complete “The Integrity Assurance Statement” and click on Submit. This will enable the link to each of the modules in the course.
13. Click on Belmont Report and CITI Course Introduction. Review the module and click on Take the quiz for Belmont Report and CITI Course Introduction in order to complete the module.
14. Complete the 3-question quiz and click on Submit.
15. Once you have successfully completed the Belmont Report quiz (under “Required Modules”, there should be a completion date and a score), you can continue to complete other required modules/courses or come back and finish them at a later date.
16. Once you complete all required modules and courses, an email will automatically be generated and sent to the Hartford Hospital HRPP administrator.
17. After you have completed Group 1 “Basic Biomedical” please log back into CITI.
18. Click on “Hartford Hospital Courses and then click “Add a course or update learner groups.”

[Choose “Conflicts of Interest”]

After making your selection, click on “Next”.

19. Click on “Conflicts of Interest” to begin the modules. You may need to click “Complete the integrity assurance statement before beginning the course” in order to start the modules.
20. Once you complete all required (COI) modules and courses, an email will automatically be generated and sent to the Hartford Hospital HRPP administrator.
21. Optional Modules will be available to you on the Main Menu once you have completed all required modules. The page within Optional Modules lists all courses you can take. Click on the course name you would like to complete to launch the course.

Printing documentation of completion of CITI Modules

If you wish to print documentation of completed modules for your records:

1. From the Main Menu, scroll down and click on Previous Coursework Completed.
2. Print this page.