



Connecticut Children's– Human Research Protection Program

Human Subject Protections Training

All individuals involved in human subject research at Connecticut Children's are required complete human subject protection training. This requirement applies to all persons involved in the conduct of human subject research, including students, residents, fellows and those who work with only human tissue or identifiable private data regarding living individuals. This requirement is satisfied by successfully completing the *Collaborative Institutional Training Initiative (CITI) Course in the Protection of Human Research Subjects* found at www.citiprogram.org

The Connecticut Children's Institutional Review Board (IRB) and the Human Research Protection Program identified four groups of individuals requiring training. They are:

- **Group 1 – Biomedical Research**
- **Group 2 – Social/Behavioral Research**
- **Group 3 - Data and Specimens Only** (*For researchers who do not interact with subjects. Interaction includes, but is not limited to: obtaining consent, conducting interviews, conducting focus group discussions, administering surveys, and administering study medication.*)
- **Group 4 - IRB members** (*This course is only for appointed Board members*)

Most modules have a short quiz. The minimum "passing" aggregate score for the quizzes is 80%. A running tally is compiled in the Grade Book. If you want to improve a score on a quiz, you may repeat the quiz. You may work at your own pace, over the course of several days if you would like, as you may sign on and off using your individual user name and password. Each of the Group 1 through Group 4 human subject protections courses should take no longer than 4 to 6 hours. Certification will be valid for three years from the date of completion. Upon your completion of the course, e-mail notification will be sent from CITI to you and the Connecticut Children's IRB staff. You may print a copy of the notification for your records.

Research Personnel who have completed CITI training through another Institution are required to affiliate with Connecticut Children's Medical Center and register for the appropriate group (see groups 1-3 above) via the CITI website. Any equivalent modules that have been previously completed will transfer over and show as complete. Any CCMC required courses that have not been previously completed will be auto populated and are required in order to fulfill training requirements.

Good Clinical Practice (GCP) Training

The GCP training module is optional. Researchers involved in sponsored research may be required to submit documentation of Good Clinical Practice training to the sponsor.

Conflict of Interest (COI) Training

Connecticut Children's key study personnel, including employees and registered volunteers/students are required to complete COI training. Key study personnel who are not affiliated with Connecticut Children's are also required to complete COI training, including residents, fellows, or researchers from

Hartford Hospital, University of Connecticut Health Center, and the University of Connecticut, Storrs. Refresher COI training is required every four years.

There are five modules.

- CITI Conflict of Interest Course – Introduction (mandatory)
- Financial Conflicts of Interest: Overview, Investigator Responsibilities, and COI Rules (mandatory)
- Institutional Responsibilities as They Affect Investigators (mandatory)
- Conflicts of Interest Institution-Specific Policies (mandatory)
- Conflicts of Commitment, Conscience, and Institutional Conflicts of Interest (optional)

Most modules have a short quiz at the end. The minimum "passing" aggregate score for the quizzes is 80%. A running tally is compiled in the Grade Book. If you want to improve a score on a quiz, you may repeat the quiz. The mandatory modules should take no longer than 2 hours. Certification will be valid for four years from the date of completion. Upon your completion of the course, e-mail notification will be sent to you and the Connecticut Children's IRB staff. You may print a copy for your records.

Instructions for CITI Training for New Users:

- Go to www.citiprogram.org
- Click on the "Register" box for new users.
- On the Registration page, enter "Connecticut Children's Medical Center" in the "Organization Affiliation" box. Fill out the rest of the registration.
- Information page, fill out required information.
- Select the type of training that you would like to take. You may choose all of the following three that apply:
 - Human Subjects Research: Please note, you do not need to select multiple Groups; please select the Group that is relevant to your individual training as described on page 1.
 - Good Clinical Practice
 - Conflict of Interest
- Click "Complete Registration."
- Under "Main Menu," you will see your list of Connecticut Children's Courses.
- Enter the course by clicking on the title. You will have to Complete The Integrity Assurance Statement before beginning the course.

Instructions for Registered Users Completing Additional Modules

If you are registered on the CITI website, please follow the following instructions to complete additional modules.

- Go to www.citiprogram.org
- Log into your CITI account and follow the instructions in one of the following 3 bullets.
- If you were previously affiliated only with Connecticut Children's, click on "**Add a course or update learner groups**" and follow the instructions above for new users, beginning with *Select the type of training that you would like to take.*
- If you are affiliated with more than one institution, including Connecticut Children's,
 - Click on Connecticut Children's Medical Center
 - Click on "**Add a course or update learner groups**"
 - Follow the instructions above for new users, beginning with *Select the type of training that you would like to take.*
- If you are not affiliated with Connecticut Children's, click on "Click here to affiliate with another institution" and follow the instructions above for new users, beginning with entering "Connecticut Children's Medical Center" in the Organization Affiliation box.

Placement will be Research-Emergency Department

