



Collaborative Institutional Training Initiative (CITI) Human Subjects Protection Training

What is CITI Training?

Founded by Dr. Karen Hansen at the Fred Hutchinson Cancer Research Institute and Dr. Paul Braunschweiger at the University of Miami, CITI is the approved human subjects protection course at Allina Health. It provides research ethics courses that consist of web-based educational modules which may contain a short quiz at the end to assess the learner's understanding of the content covered.

Who must complete the CITI modules?

Allina Health requires that all study personnel who interact or intervene with subjects, or who have access to subjects' identifiable information for the purposes of research (HSR responsibilities), complete the required CITI courses. If any study personnel are listed on Application Part 1 but will not interact or intervene with subjects, or have access to subjects' identifiable information for the purposes of research, then they will only need to complete the required Conflict of Interest (COI) course. For studies subject to IBC review, the requirement extends to lab and pharmacy personnel with any direct responsibilities for the agent under review.

When do the modules have to be completed?

All study personnel must complete the required modules **before** applying for IRB/IBC review of a new study or continuing review of an existing study.

Which courses do researchers need to take?

Required Courses

- 1. Basic/Refresher Course:** All researchers with HSR responsibilities are required to complete a basic course in human subject protection. Choose the course most appropriate for the type of research being conducted and your study role. **The completion report expires, and must be refreshed, every three years.**
 - Biomedical Research
 - Social & Behavioral Research
 - Data or Specimens Only Research
- 2. Health Information Privacy and Security (HIPS):** The HIPS course provides educational materials suitable for a health care organization's workforce to meet the training requirements of HIPAA and other US statutory/regulatory authorities. All researchers with HSR responsibilities are required to complete the HIPS course once. However, when new federal or institutional compliance regulations are implemented, researchers may need to obtain an updated certificate prior to engagement in any research activities.
- 3. Conflict of Interest (COI) Initial/Refresher Course:** All researchers are required to complete the CITI COI training course. **The completion report expires, and must be repeated, every four years.** Earlier re-training may be required if circumstances warrant (e.g., there is a significant change in policy requirements).
- 4. Biosafety/Biosecurity Basic Course:** Completion of the CITI Biosafety/Biosecurity course is required prior to submission of studies for Institutional Biosafety Committee (IBC) review. Training is required for the Principal Investigator and personnel with responsibility for the



article(s) that require Institutional Biosafety Committee oversight (i.e., research involving recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins). **The completion report expires, and must be refreshed, every three years.**

5. **Good Clinical Practice (GCP) Course:** The GCP course is required for all research personnel listed on the IRB application for NIH-funded clinical trials and can be accepted in lieu of the Basic Biomedical Course for FDA-regulated Clinical Trials. Researchers should complete one of the following tracks that is most applicable to the type of research being conducted: GCP for Clinical Investigations of Devices, GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus), or GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus).

Optional Courses

1. **OSHA Bloodborne Pathogens Standard Course:** This course is made available as a courtesy for study personnel who handle or have contact with human blood, tissues, body fluids or other potentially infectious materials.
2. **Shipping Regulated Biological Materials:** This course is made available as a courtesy for study personnel who package and ship diagnostic or clinical human and animal specimens, human and animal pathogens, and related regulated biohazards.

How do I access the courses?

The CITI Courses can be accessed by following the steps below.

1. Go to www.citiprogram.org.
2. Click Register located under "Create an Account"
3. Enter **Allina Health** in "Select Your Organization Affiliation"
4. Enter your Name, Email Address, User Name, Password, Security Question and Answer, and remaining questions and click submit.
5. Within the Main Menu, Click on the link for "Add a course" within "Allina Health Courses" to access the required and optional course options.
6. Select the required courses applicable to your research and study responsibilities: Question 1 for initial training, Question 2 for retraining, Question 3 for GCP, Question 4 for Health Information Privacy and Security, Question 5 for Conflicts of Interest, Question 6 for Biosafety). You can take more than one of the required courses if you are conducting multiple types of research (e.g., biomedical and social-behavioral).
7. Select any optional courses you wish to complete (Questions 3 if you are not conducting a NIH-funded clinical trial and components of question 6).
8. Click "Submit"
9. On the Main Menu screen, click the name of the course you would like to begin. You do not need to complete the required modules in one session. You can log off at any time and your work will be saved.

What do I do with the Completion Reports?

Print or download the completion report for your records.



If you have created an IRBNet account, you can link your completion reports (that are affiliated with Allina Health) to your IRBNet account by completing the following steps:

1. Log in to IRBNet and click the "User Profile" link in the top right corner of the screen.
2. In the External Accounts section, click "Add an External Account".
3. In the pop-up box, enter your associated CITI Member ID from your CITI account. This number can be found at the top of your CITI homepage upon login.
4. To verify your ownership of the CITI account, you will receive a verification link to the email address associated with your CITI account.
5. Once you receive the email, click the verification link. Your coursework will automatically populate in IRBNet over the next 24 hours.

To upload completion reports not affiliated with Allina Health to IRBNet:

1. Log in to IRBNet and click the "User Profile" link in the top right corner of the screen.
2. In the Training & Credentials section (at the bottom of the page), click "Add a New Training & Credentials Record".
3. Select the appropriate document type from the drop-down menu.
4. In the "Effective Date" section, write the date the course was completed.
5. Attach the completion report in the "File" section.
6. Click "Attach".
7. Once you verify the document has been attached to your User Profile, click "submit".
8. Choose "Allina Health IRB Office" from the "Select a Board" section and click "Continue".
9. Click "Submit". The IRB Office will be notified as soon as your document is submitted.

What is involved in meeting the training requirement?

To successfully complete a required module, review the content materials and take a short quiz, when applicable. You must achieve the minimum score, aggregated across all quizzes, to successfully complete a training course and obtain IRB approval. If you do not achieve the passing score, you may review the materials and retake the quizzes until you pass.

What if I have completed the CITI Course at another institution?

Your CITI basic course certificate may meet the Allina Health requirements, but you will be required to take Allina's HIPS course. To verify whether your basic course meets Allina's requirements, follow these steps:

1. Log in to CITI.
2. Select the link "View Previously Coursework Completed" under the heading of your previous institution (near the bottom of the page).
3. On the next screen, click the link "See coursework completed for X".
4. Click the link "Share" under the column Completion Report.
5. Copy and paste the link provided on the page.
6. Send the link to IRB@allina.com.
7. The IRB Office will review the modules and determine whether the course meets Allina's requirements.

If your previous CITI certificates from another institution do not meet all of Allina's CITI requirements, you will need to affiliate with Allina Health on the CITI website to complete the required courses. The



CITI website allows you to affiliate with multiple institutions. Affiliating with a new institution will not affect or delete your previous completion reports with a different institution.

Can I earn CMEs for CITI courses?

Yes, CME/CEU credits are available through the University of Miami for completion of these courses. Please consult the CME/CEU link on the Main Menu for more information; then follow the "[click here](#)" link embedded in the paragraph on the next page. (You must be a registered user to access this information.)