Collaborative Institutional Training Initiative (CITI) Human Subjects Protection Training

Federal regulations and Allina Health require research personnel and IRB members to complete training in human subject protection. For researchers, this requirement applies to all human subject research, including research classified as exempt or expedited. The IRB office must receive documentation of training before research studies will receive approval. Human subject protection training must be renewed every three years.

What are the CITI modules?

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 subject protection course at Allina Health. It provides research ethics courses that consist of web-based educational modules that take approximately 15-30 minutes each to complete.

Who must complete the CITI modules?

Individuals engaged in the types of research activities listed below must complete the CITI Basic Course **before** initiating, supervising, reviewing, or participating in any research-related activities.

- Biomedical Research
- Social & Behavioral Research
- Data and Specimens Only Research

IRB Members are required to complete the CITI IRB Members course.

When do the modules have to be completed?

Principal Investigators, co-investigators, and study coordinators must complete all of the required modules **before** applying for IRB approval of a new study or continuing review of an existing study. IRB administrative staff will have access to the completion records to verify training completion dates and the modules completed. Completion of a refresher course is required every three years.

Which courses do I need to take?

Two Required Courses

1. **Basic/Refresher Courses**: These courses provide the information essential for human subject research: Biomedical Research; Social & Behavioral Research and Data and Specimen Only Research (i.e., chart review studies). Most of the modules contain a short quiz at the end to assess the learner's understanding of the content covered.

   Optional modules are also available (upon completion of all required course modules). Investigators and coordinators may be required to complete one or more optional modules if they are relevant to their research topics.

2. **Health Information Privacy and Security (HIPS)**: Because of the ongoing need to protect the privacy and confidentiality of research subjects, Allina Health's IRBs have chosen to require this

course of all research personnel. The Health Information Privacy and Security (HIPS) series was developed for CITI in conjunction with University of Miami Ethics Programs to provide educational materials suitable for a health care organization's workforce, to meet the training requirements of HIPAA, and other US statutory/regulatory authorities.

<u>One Optional Course: Good Clinical Practice Guidelines</u>

Some of the topics discussed in this course are listed below.

- Overview of New Drug Development
- Conducting Investigator-Initiated Studies According to FDA Regulations and Good Clinical Practices
- Investigator Obligations in FDA-Regulated Clinical Research
- Managing Investigational Agents According to GCP Requirements
- Conducting Clinical Trials of Medical Devices
- Informed Consent: An Ongoing Process
- Detection and Evaluation of Adverse Events
- Reporting Serious Adverse Events
- Monitoring of Clinical Trials by Industry Sponsors
- Audits and Inspections in Clinical Trials

How do I access the courses?

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

1. Go to www.citiprogram.org.
2. Click: **New Users <u>Register Here</u>**.
3. Select **Allina Health** from the list of Participating Institutions. (Leave the other fields blank.)
4. Enter a Username and Password.
5. Enter your Name and Email Address.
6. Click: Submit.
7. Complete the CITI Registration page.
8. In response to the question, "Which course do you plan to take?" Select either "Biomedical Research – Basic/Refresher", "Social & Behavioral Research – Basic/Refresher" or "Data or Specimens Only Research – Basic/Refresher"
9. In response to Question 1, select your Learner Group.
   - If you are involved in more than one type of research, choose the option that reflects the majority of the research you conduct.
   - If you serve on the IRB, select "IRB Member."
10. In response to Question 2, you may check the box for "Good Clinical Practice (GCP)" or leave it blank.
11. In response to Question 3, check the box under "Health Information Privacy and Security (HIPS)" that reflects your status.
12. Then click "Continue."
13. On the Learner's Menu screen, click the link under "Status" that reads "Not Started - <u>Enter</u>."
14. Complete the required modules. Note that you do not need to complete the program in one sitting. You can sign off at any point and pick up where you left off the next time you sign in.
15. Print or download a Completion Report for your records. A copy of your record will automatically be sent to the institutional administrator in the Allina IRB office, so you do not need to submit a copy to the IRB.

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 a minimum score of 75% correct, aggregated across all quizzes, to successfully complete the training and obtain IRB approval. If you do not achieve the passing score, you may review the materials and retake the quizzes until you pass. The final record will reflect results from the last quizzes taken.

Certificates for the Basic/Refresher Courses remain in effect for three years from the date of issue. The HIPS course must be completed one time. However, whenever new federal or institutional compliance regulations are implemented, researchers may need to obtain an updated certificate prior to engagement in any research activities.

What if I've completed the CITI Course at another institution?

Your CITI certificate is valid at Allina. Simply follow these steps:

1. Log in to CITI.
2. Select the link "Previous 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 on the far right "Print Completion Report."
5. When the report appears, click "File" in the upper left and select "Send."
6. Send either the page or the link to IRB@allina.com.

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.)