



Ascension WI IRB Guidance

CITI Program Training User Guide

Ascension Wisconsin requires a basic level of human subject protection training for all researchers and research personnel listed on an application. The Collaborative IRB Training Initiative (CITI) is the only IRB approved human subject protection training requirement for all researchers and research staff at Ascension Wisconsin.

The CITI courses are designed to help users understand human subjects' protection issues through a web based program and to promote ideals for scientific and scholarly integrity and to minimize institutional risks. CITI training must be re-certified or refreshed every 3 years. The IRB recommends that researchers and research staff also maintain their own records of CITI course completion.

For research that is subject to HIPAA, Ascension WI requires all personnel handling PHI to obtain HIPAA training. CITI is also used for financial and non-financial Conflict of Interest training.

CITI Site Instructions

- Learner instructions for Ascension Health can be accessed here: <https://www.citiprogram.org/citidocuments/AH/citiinstructions.htm>
- CITI instructions and support can be accessed here: <https://support.citiprogram.org/s/>

Completing CITI Training

1) Log into CITI

CITI is an online program; to log in, go to: <http://www.citiprogram.org>



If you DO NOT have a CITI user account:


- a. Click the "Register" button.
- b. Search for the organization *Ascension Health* and agree to the terms.
- c. Enter your Personal Information (name & email).
- d. Select a User Name, password, security questions and additional information.


If you DO have a user account, but are not affiliated with Ascension:

- a. Log into your account.
- b. Select to "affiliate" with another institution.



- c. Select Ascension Health and complete the Ascension specific questions.

To find your organization, enter its name in the box below, then pick from the list of choices provided. 

 I AGREE to the [Terms of Service](#) for accessing CITI Program materials.
 I affirm that I am an affiliate of Ascension Health. 

Continue

2) Select the CITI Courses you need to complete.

- a. Select "View Courses" then "Add a Course".
- b. Select your learner group based on your role in research at Ascension to choose your basic Human Subject Training Modules.

Select all that apply. The descriptions in CITI will outline the categories to help you determine which group(s) you should select.

If any courses are duplicated in learner groups, you will only need to complete it once.

Similarly, any duplicate courses completed at another institution will not need to be repeated if they were completed within the previous three years.

Choose the learner group(s) below based on your role and the type of human subjects activities you will conduct. You will be enrolled in the Basic Course for that group.

This question is required. Choose all that apply.

Investigators
Select this learner group if: You are a researcher who will serve as Principal Investigator, Sub-Investigator or Co- Investigator on human subject research protocols.

Research Coordinators
Select this learner group if: You are a researcher who will provide research coordination support, such as a clinical research coordinator, research nurse or regulatory specialist, on human subject research protocols.

Other Research Team Members
Select this learner group if: You are a researcher who will be involved in research or part of a study team, other than an investigator or coordinator, such as a data manager or research associate on human subject research protocols.

Humanitarian Use Devices (HUDs)
Select this course group if: You are a physician user of Humanitarian Use Devices (HUDs).

IRB Members
Select this course group if: You are a member of an IRB, ethics or other research oversight board.

Signatory Institutional Official
Select this course group if: You are the Signatory Institutional Official (IO or SO) on the institutions Federalwide Assurance (FWA)

Research Admin. Staff /IRB staff
Select this course group if: You are staff who provide administrative support for research. Examples include grants, contracts, billing compliance or the IRB/HRPP.

I don't want to take a basic course
Use this option only if instructed by local ministry guidance.

I would like to enroll into the Refresher course

Start Over **Next**

- c. Select any additional courses to take, based on the kind of research you will be involved with.

Again, review the descriptions in CITI to determine if you should take any additional courses.

While these are available for anyone to take- some courses are only required in very specific cases.

Do you plan to take any of the following courses:

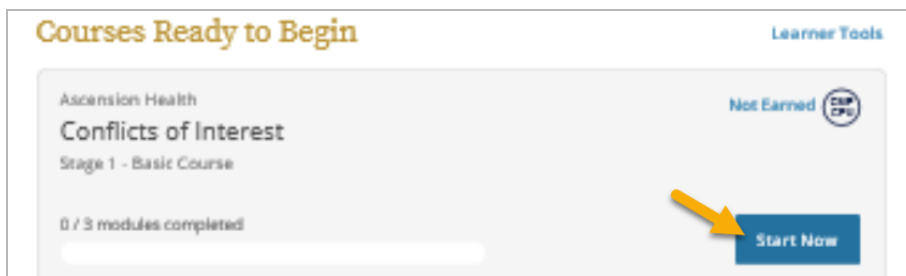
This question is required. Choose all that apply.

- Good Clinical Practice (GCP)**
Select this learner group if: You are a researcher who needs to complete GCP training that satisfies requirements for ICH GCP Investigator Site Personnel Training required by TransCelerate BioPharma or National Institutes of Health (NIH) funded clinical trials. See ministry specific guidance for other requirements.
- Responsible Conduct of Research (RCR)**
Select this course if: You are a researcher who needs to complete RCR training that satisfies the requirements of the National Institutes of Health (NIH), National Science Foundation (NSF), and U.S. Department of Agriculture (USDA). See ministry specific guidance for other requirements.
- Financial Conflict of Interest for Researchers (COI)**
Select this course if: You are a researcher who needs to complete financial conflict of interest training that satisfies the requirements of the Public Health Service (PHS) regulations. See ministry specific guidance for other requirements.
- Information Privacy & Security (IPS)**
Select this course if: You want to learn about the principles of data protection, focusing on the healthcare-related privacy and information security requirements of the Health Insurance Portability and Accountability Act (HIPAA) and the educational records and data-related requirements of the Family Educational Rights and Privacy Act (FERPA). See ministry specific guidance for other requirements.
- Not at this time.

[Start Over](#) [Next](#)

3) Complete the selected courses

- a. All selected courses will be listed, click "Start Now" to begin each course.



- b. Read provided information and agree to continue.
- c. A dashboard at the top of each course page will provide instructions and an overview of progress.
- d. **When you complete each module, there will be a brief quiz. You must complete the quiz with a score of at least 80% to advance to the next module.**
- e. You will see a list of both required and supplemental modules to complete.

The required modules near the top are required by all researchers.

The supplemental modules are available for you if you would like to complete them. The IRB may require additional supplemental modules to be completed based on the type of research, such as targeted vulnerable populations, or previous non-compliance, etc.

f. Click "Start" to begin each module for the course.

The screenshot displays a user interface for a course. At the top, it is titled "Required Modules" and includes the instruction "Complete all 3 required modules." Below this is a table with three rows of modules. The first row, "Financial Conflicts of Interest: Overview, Investigator Responsibilities, and COI Rules (COI-Basic) (ID 15070)", has a blue "Start" button highlighted with a yellow arrow. The second and third rows, "Institutional Responsibilities as They Affect Investigators (COI-Basic) (ID 15072)" and "Conflicts of Commitment and Conscience (COI-Basic) (ID 15073)", have white "Start" buttons. Below the required modules is a section titled "Supplemental Modules" with an information icon. It contains one row: "Institutional Conflicts of Interest (COI-Basic) (ID 16765)", which has a blue "Start" button. Each module row includes columns for "Modules", "Completed", and "Score", and a "CME/CEU" icon.

Modules	Completed	Score	
Financial Conflicts of Interest: Overview, Investigator Responsibilities, and COI Rules (COI-Basic) (ID 15070)	Incomplete	-	Start
Institutional Responsibilities as They Affect Investigators (COI-Basic) (ID 15072)	Incomplete	-	Start
Conflicts of Commitment and Conscience (COI-Basic) (ID 15073)	Incomplete	-	Start

Modules	Completed	Score	
Institutional Conflicts of Interest (COI-Basic) (ID 16765)	Incomplete	-	Start

g. Once complete, you will be given the option to save and/or share your completion report. You can also access the completion reports from the "Courses" tab.

You should also save a copy of the completion report and/or certificate for the study file, showing both the date the course was completed and the expiration date, as PIs should maintain a training record for themselves and study members in their own research study files.

The IRB will be notified of your completion automatically, however, based on the account set up, they may ask for additional information to confirm.

f. Optional purchase of CE credits can be made by scrolling down to the bottom of the "Courses" tab.