

Ascension WI IRB Guidance

Completing CITI Training

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 medical/social 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.

Using CITI

CITI Site Instructions

There are learner instructions on the CITI site. You can access those instructions at:

<https://www.citiprogram.org/citidocuments/AH/citiinstructions.htm>

CITI Log In Instructions

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



Research Ethics and Compliance Training

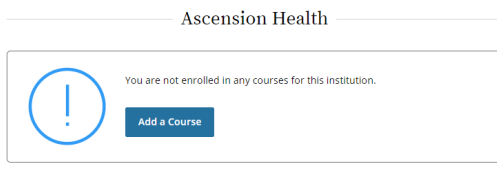


- 1) If you do not have a CITI user account, click the “Register” button.
 - a. Search for you organization- *Ascension Health*
 - i. Agree to the terms and Continue to Step 2
 - b. Enter your Personal Information (name & email)
 - c. Select a User Name, Password and security questions, Continue to step 4
 - d. Enter the additional information to complete your account.

- 2) If you do have a user account, but are not affiliated with Ascension, you can log into your account and select to “affiliate” with another institution
 - a. Select Ascension Health and complete the Ascension specific questions.



- 3) Select Curriculum – Ascension Health and choose the appropriate category – Investigators, Research Coordinators, etc.
 - 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.
 Note, 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.

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.



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

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.

[You should complete ICH-GCP if you are working on any study that is FDA regulated, or where the Sponsor requires you to follow ICH-GCP.](#)

[You should complete the fCOI courses if you will work on any study that complies with the PHS fCOI regulations. Note- this includes NIH, including the National Cancer Institute.](#)

[Click here for a list of funding organizations require adherence to PHS fCOI regulations.](#)

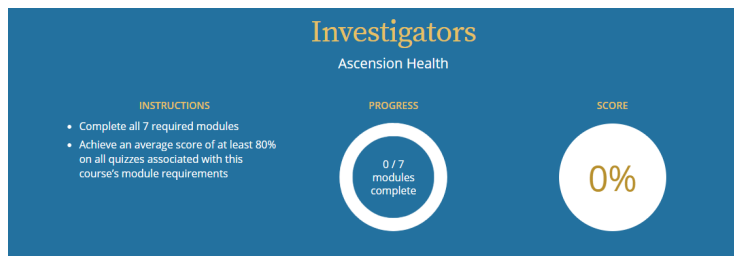
[Start Over](#) [Next](#)

4) 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. When you complete each module, there will be brief quiz. You must complete the quiz with a score of at least 80% to advance to the next module.










- d. 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 be completed based on the type of research, such as targeted vulnerable populations, or previous non-compliance, etc.


Click "Start" to begin each course in the module.

Required Modules

Complete all 7 required modules.

Modules	Completed	Score	
Basic Institutional Review Board (IRB) Regulations and Review Process (ID 2)	Incomplete	-	<input type="button" value="Start"/> 
Informed Consent (ID 3)	Incomplete	-	<input type="button" value="Start"/> 
Research and HIPAA Privacy Protections (ID 14)	Incomplete	-	<input type="button" value="Start"/> 
History and Ethics of Human Subjects Research (ID 498)	Incomplete	-	<input type="button" value="Start"/> 
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID 14777)	Incomplete	-	<input type="button" value="Start"/> 
Populations in Research Requiring Additional Considerations and/or Protections (ID 16680)	Incomplete	-	<input type="button" value="Start"/> 
Conflicts of Interest in Human Subjects Research (ID 17464)	Incomplete	-	<input type="button" value="Start"/> 


Supplemental Modules


Modules	Completed	Score	
Social and Behavioral Research (SBR) for Biomedical Researchers (ID 4)	Incomplete	-	<input type="button" value="Start"/> 

e. Once complete, you will be given the option to save and/or share your completion report.

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

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.

 Congratulations! You have completed the "Investigators - Basic Course" course.

 [Access your Completion Records](#)
View, Print, or Share via link your Completion Certificate or Completion Report for this course.

You can also access the completion reports from the "Courses" tab.

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