

CSDE 502: Responsible Conduct of Research
CITI Online Certification in Human Subjects Protection
Assignment Due: Friday, April 26, 2024 by 5pm via email

Assignment Instructions:

Complete the Online Certification for Human Subjects Protection (HSP)

- The specific [CITI](#) course for basic training in HSP is called: “Research with human subjects.” The area of study is Social/Behavioral.
 - FYI - All UW students may complete any of the three courses gratis.
- Complete all the modules for the certification and the selected supplemental modules indicated below.
- When you have completed the course, save a copy of your Completion Certificate and Report for your records and for CSDE’s records.
- Email Dr. Godwin (jlg0003@uw.edu) the PDF of your certification.
 - Filename convention: Last Name_CITI_HumSubj_yyyymmdd.pdf
OR LastName_CITI_HumSubjRefresh_yyyymmdd.pdf

Why You Are Required to Complete a Course in Human Subjects Protection

Researchers, including research study staff and students, working with human subjects or data and samples from humans must sometimes complete training in human subjects protections in order to meet the requirements of the organizations they are affiliated with or of funding organizations. Investigators and all key personnel involved in the design or conduct of NIH-funded research using human subjects must comply with the NIH’s Human Subjects Education Policy and undergo education in the protection of human subjects in research. Pre-doctoral trainees must also receive human subjects education.

For information on human subjects research, please see the [Human Subjects Education FAQs](#), and see [Training & Resources-Education Requirement](#) for specific information on the NIH’s Human Subjects Education Policy.

What is CITI?

NIH no longer offers a course on the protection of human research participants (PHRP). Institutions seeking to fulfill the Human Subjects Education Policy requirement need to use another training program or develop a program to meet the requirement. The UW has partnered with the [Collaborative Institutional Training Initiative \(CITI\)](#) to provide free online training for those who are affiliated with UW or collaborating with someone who is affiliated with UW in Human Subjects Protections.

CITI also provides classes in:

1. Good Clinical Practice
2. Responsible Conduct of Research
3. Stem Cell Research Oversight.

NIH requires all trainees meet the NIH requirement for education in research with human subjects. This training educates researchers about the ethical principles for working with human research subjects and the regulatory requirements for conducting research. The National Science Foundation requires pre-doctoral graduate students, post-doctoral researchers and research trainees to complete training in the Responsible Conduct of Research which contains human subjects protection components.

Refresher options are available for Human Subjects Protections (HSP) and for Good Clinical Practice. If you have already completed the modules in the table below, please provide me with the Completion Report AND the Completion Certificate for your original course and take the Human Subjects Learners (Refresher) course. Submit these along with the Completion Report and Completion Certificate for the 7 modules in the Refresher. If you took most but not all of the required modules in the table below, complete the additional modules in the original course before doing the Refresher.

Steps to Complete the CITI Human Subjects Protections (HSP) Requirements

The following steps are taken to complete the CITI modules required for CSDE 502.

1. Set up CITI account if you do not already have one (see CITI_Registration_Instructions document on Canvas)
2. Register for the course
 - a. From the Main Menu, select “Courses” then “View Courses” by University of Washington
 - b. Scroll to the bottom of the page and select “Add a Course” under Learner Tools
 - c. Scroll to the bottom of the page and choose the top box, “I am registering to take a CITI course for the first time”
 - d. Scroll to the bottom of the page and choose:
 - “Research with human subjects” or “Human Subjects Learners” for basic human subjects protections training **OR**
 - “Research with human subjects (Refresher)” or “Human Subjects Learners (Refresher)” if you have previously taken the basic human subjects protections course and need to take refresher training
3. Click the Title of the Course to begin or continue the course.
4. Complete all of the course modules listed in the table below: CSDE 502 requires completion of all the required modules and completion of selected Supplemental models.

Required for CSDE 502	CITI Required Modules
✓	History and Ethical Principles – SBE (ID 490)
✓	Defining Research with Human Subjects – SBE (ID 491)
✓	Basic Institutional Review Board (IRB) Regulations and Review Processes (ID 2)
✓	Informed Consent – SBE (ID 504)
✓	Privacy and Confidentiality – SBE (ID 505)
✓	Records-Based Research (ID 5)
✓	Populations in Research Requiring Additional Considerations and/or Protections (ID 16680)
	CITI Supplemental Modules
Optional	Overview of the Clinical Trial Agreement (CTA) (ID 17356)

Optional	Understanding the Terms of the Clinical Trial Agreement (CTA) (ID 17357)
Optional	Role of the Researcher and Site in Managing the Clinical Trial Agreement (CTA) (ID 17358)
Optional	Clinical Trial Agreement (CTA) Negotiation for Researchers and Sites (ID 17359)
✓	Assessing Risk – SBE (ID 503)
✓	Genetic Research in Human Populations (ID 6)
✓	Research with Children – SBE (ID 507)
✓	Research in Public Elementary and Secondary Schools – SBE (ID 508)
✓	International Research – SBE (ID 509)
✓	Internet-Based Research – SBE (ID 510)
Optional	FDA-Regulated Research (ID 12)
✓	Research and HIPAA Privacy Protections (ID 14)
✓	Vulnerable Subjects – Research Involving Workers/Employees (ID 483)