

IRB Human Subjects Protection CITI Training Requirements

Initial certification requirements for all Wright State **Biomedical** investigators:

- IRB Biomedical Research Investigators Basic Course
- IRB Vulnerable Populations - Biomedical Course (if Targeting Vulnerable Populations Only)
- Good Clinical Practice and ICH Course (if Clinical Trial Only)
- Conflict of Interest (if Annual Disclosure Required Only)

Initial certification requirements for all Wright State **Social/Behavioral/Educational** investigators:

- IRB Social/Behavioral/Educational Investigators Basic Course
- IRB Vulnerable Populations - SBE Course (if Targeting Vulnerable Populations Only)
- GCP – Social and Behavioral Research Best Practices for Clinical Research (if Clinical Trials only)
- Conflict of Interest (if Annual Disclosure Required Only)

Initial certification requirements for all Wright State **HUD Clinicians**:

- HUD Clinicians Course

Initial certification requirements for all investigators handling **HIPAA-protected PHI**:

- Health Privacy (HIPAA) Basics

Note: If you conduct both biomedical and SBE research you only need to complete the biomedical requirements.

Re-Certification Requirements - Wright State Investigators:

- Biomedical or Social/Behavioral/Educational Refresher Course - **Every four years**
- IRB Vulnerable Populations Course - **Re-certification not required**
- Biomedical or SBE Good Clinical Practice (GCP) Refresher Course - **Every three years**
- HUD Clinician - **Re-certification not required**
- HIPAA Basics for Healthcare Professionals or Researchers - **Re-certification not required**
- Conflict of Interest Refresher - **Every four years**

Note: VA Medical Center (VAMC) or Dayton Children's Hospital (DCH) researchers, Wright State University will accept the completion of VAMC/DCH human subject training requirements in lieu of the above for projects taking place at those respective sites. You must upload a copy of CITI completion report in the electronic submission system.

The biomedical courses have a sequence of the basic course, then 3 refresher courses. The Social/Behavioral/Educational courses have a sequence of the basic course, then 2 refresher courses. Once these sequences are complete, additional training is not required. You do not need to start the sequence over again.

Instructions for Enrolling in the CITI program

CITI training does not have to be completed in one sitting. You may start the modules, complete some of them, and come back later. CITI will highlight the next appropriate module for you. All investigators must successfully pass (80%) required courses.

To register at CITI, follow the steps below:

1. Open your internet browser and go to: citiprogram.org and click Register.



2. If you are an employee or student at Wright State University, click on **Log in through your institution**. In the text field, begin typing Wright State University. Select the 'Wright State University SSO' option and complete the registration process. Use your w# and password as your log in information.



If you are not a WSU employee or student, click on '**Register**'. In the Organization Affiliation field start typing Wright State, then select the 'Wright State University' option. Continue with the registration process. We ask that you use your work email address during registration. This address should be the same one you use to login to Cayuse Human Ethics electronic submission system.



3. Enter your full name (this will appear on the completion report so ensure it is correct).
4. Provide at least one email address (WSU email for employees or students; work email for external users). This email **MUST** match the email used in Cayuse. This email address will be used to reset passwords if needed and to notify you when certification is close to expiring.
5. Click the Submit button.

6. On the CITI Course Enrollment Questions page, choose 'Human Subjects Research (HSR), then click Next.



7. Select the option that is most appropriate for your area of research

- a) AS APPLICABLE: Depending on your research you may be required to take the Conflicts of Interest (COI) course. This course is required for all federally supported projects (NIH, DoD, etc.), projects subject to FDA regulations, projects indicating a conflict of interest exists, and/or if a compliance committee has determined a disclosure is needed. Check with the IRB Office if you are unsure whether this course will be required for you.
 - i) Choosing this option will automatically register you for the following required course:
 - (1) Conflict of Interest (if Annual Disclosure Required Only)

Question 2

Conflicts of Interest (COI)

Is the project funded by a federal agency (NIH, NSF, DoD, etc.) or does it involve drugs or devices regulated by the FDA or has a compliance committee requested that you complete the Conflicts of Interest course?

This question is required. Choose one answer.

Yes
 No

- b) Question 3. This is the primary course selection screen. You will choose the types of courses you need to take.
 - i) BASIC COURSE: The Biomedical course is for individuals who work primarily with drug/device studies and/or medical records review. The Social Behavioral Educational (SBE) course is for individuals who do research primarily via surveys and interviews.
 - (1) Choose the most applicable option to register for the appropriate course:
 - (a) Biomedical Research Investigators OR
 - (b) Social/Behavioral Investigator (SBE)
 - ii) AS APPLICABLE: HUD Clinician. If you are a clinician being added to a HUD treatment protocol, select this option instead.

Do not select IRB Committee Member, IRB Chair, or Institutional Official.

Human Subjects Research

Choose a course that is appropriate to your research role and activities. You will be enrolled in the Basic Course.

Choose all that apply

Biomedical Research Investigator: Researchers and research staff (including faculty, staff, and students) who are engaged, primarily or exclusively, in research in the Biomedical Sciences.

Social/Behavioral Research Investigator: Researchers and research staff (including faculty and staff) who are engaged, primarily or exclusively, in research in the Social and/or Behavioral Sciences.

IRB Committee Member

HUD Clinician

IRB Chair

Institutional Official

- c) AS APPLICABLE: Depending on your research you may be required to take the Vulnerable Populations course. This course is required of all investigators whose research focuses on a vulnerable population such as children, pregnant women, prisoners, decisionally impaired, etc. Check with the IRB Office if you are unsure whether this course will be required for you.
 - (1) Choose the most applicable option to register for the appropriate course:
 - (a) IRB Vulnerable Populations - Biomedical Course OR
 - (b) IRB Vulnerable Populations - SBE Course

IRB Vulnerable Populations

Will vulnerable populations (e.g., children, pregnant women, inmates, decisionally impaired, etc.) be the focus of your research?
Choose one answer

Yes

No

- d) AS APPLICABLE: Depending on your research you may be required to take the Health Privacy (HIPAA) course. This course is required of all investigators working with HIPAA protected PHI.
 - i) Choosing this option will register you for the following required course:
 - (1) Health Privacy (HIPAA) Course

Question 4

Health Privacy HIPAA

Will you have access to Protected Health Information (PHI) (e.g., medical records, chart reviews, limited data sets, etc.)?

Choose one answer.

Yes

No

- e) AS APPLICABLE: Indicate in the follow-up question if you will be participating as a researcher in a clinical trial and need to take the federally mandated Good Clinical Practice (GCP) course.
 - i) Choosing this option will register you for one of the following required courses:
 - (1) Good Clinical Practice and ICH (biomedical researchers) OR
 - (2) Good Clinical Practice for SBE Researchers

Question 5

Good Clinical Practice

Will you be involved in a clinical trial?

Choose one answer.

Yes

No

Click Next when you have finished making your selections.

8. The My Courses page will list the courses you have selected. Click Start Now or Continue Course to Begin/Continue the course.
9. Complete the required modules and associated quizzes.
10. When all the modules within a course are complete, you will have the opportunity to download the completion report. You are advised to save this report and keep it for your records. CITI course completion data is sent to Cayuse overnight.

Instructions for Affiliating with Wright State if you have an Existing CITI Account:

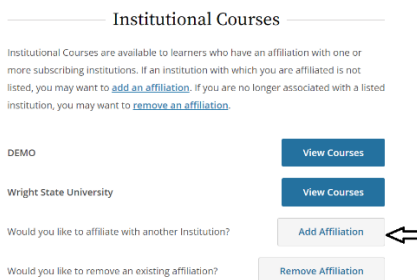
It is possible for you to register at more than one institution. This might be very useful if you are:

- Affiliated with another institution such as the local VA that requires similar training.
- Collaborating with an investigator at another CITI participating institution.
- Were employed or a student at another institution utilizing the CITI program.

The advantage is that if the affiliated organizations require the same modules in the course, you will only need to complete the modules not yet taken.

Open your internet browser and go to: <http://www.citiprogram.org>.

1. Enter your username and password and click Submit.
2. The My Courses page has an 'Add Institutional Affiliation' option.
3. Select the institution/organization to affiliate with. To do this, type the institution name in the text box. Choose the correct institution from the options and check the box agreeing to the CITI terms of service and the box that affirms you are affiliated with the institution. Then click Continue.
4. Complete the registration process as listed above.



Institutional Courses

Institutional Courses are available to learners who have an affiliation with one or more subscribing institutions. If an institution with which you are affiliated is not listed, you may want to [add an affiliation](#). If you are no longer associated with a listed institution, you may want to [remove an affiliation](#).

DEMO	<input type="button" value="View Courses"/>
Wright State University	<input type="button" value="View Courses"/>
Would you like to affiliate with another Institution?	<input type="button" value="Add Affiliation"/> ←
Would you like to remove an existing affiliation?	<input type="button" value="Remove Affiliation"/>

Note: Investigators must not let certification expire while conducting human subject research and should initiate the re-certification process at least one month prior to their current expiration date. Failure to maintain certification may result in a loss of research privileges.