

Why did you receive the requirement for Good Clinical Practice (GCP) training?

Good Clinical Practice is required when your name is listed in IRES IRB on a research study that meets the definition of a clinical trial: *A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.* For more detailed definitions of terms, please see [‘Notice of Revised NIH Definition of ‘Clinical Trial’](#).

How is a clinical trial indicated in IRES IRB?

Basic Information page of the IRES IRB application asks about prospective assignment of subjects and the existence of health-related or behavioral outcomes. If the answer to both questions is YES, the study is considered a clinical trial. A Good Clinical Practice requirement will be assigned in Training Management System the day after an individual is listed on that study.

6. * Does the study prospectively assign research subjects to one or more interventions? 

Yes No [Clear](#)

6a. * Does the study have a health-related biomedical or behavioral outcome? 

Yes No [Clear](#)

How long is Good Clinical Practice training valid for?

The training is valid for 3 years, after which it has to be retaken. Alternatively, refresher courses are available through CITI. Yale HRPP and YCCI offer GCP courses and refresher live courses a few times a year. Communication about the sessions is sent out to the entire research community.

Contact

You can email irb.training@yale.edu with any questions about the GCP and Human Subject Protection training requirements.

If you completed CITI GCP training through your affiliation with another institution, you can email the completion certificate. It will be entered into your TMS record.

Instructions for Good Clinical Practice courses through CITI

1) [Log to CITI](#) through Training Management System.

The screenshot shows the Yale University Training and Certification portal. The user is logged in as 'Human Subjects Research' and is viewing the 'CITI GCP Courses (Alternates Available)' page. The page contains a description of the GCP series, an objective, and a list of courses. A red arrow points to the link '> Click here to access this course.' which is highlighted in blue. Below the link is contact information for Human Subjects Research.

Yale University
Training and Certification
Search for a Course: Enter Keywords [Search]
Narrow Search: Select Course Owner [v]

Home | Courses by Owner: Human Subjects Research > Good Clinical Practice > CITI GCP Courses

CITI GCP Courses (Alternates Available)

The GCP series includes three distinct basic courses tailored to the different types of clinical research, along with three corresponding refresher courses that are intended to provide learners with a highlighted review of what is covered in the basic modules. The available GCP courses include: • GCP for Clinical Trials with Investigational Drugs and Medical Devices (ICH/FDA Focus) • GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus) • GCP for Clinical Investigations of Devices • GCP FDA Refresher • GCP ICH Refresher Once logged in, click on "Main Menu" and choose Yale University Training Opportunities Courses. Next, click on "Add a Course". CITI will notify the HRSP when you have successfully completed the training. HRSP will update your record in TRS.

Objective: Audience

Approval Required: None
Delivery Type: Web Delivered
Fee: None

> Click [here](#) to access this course.

Human Subjects Research
25 Science Park
150 Munson Street
New Haven CT 06511
(203) 737-4434 (Phone)
eh.training@yale.edu
<http://www.yale.edu/trpp/>

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2) Once you are logged in, click on the **Main Menu** tab and then **Add a Course**.

The screenshot shows the CITI PROGRAM Collaborative Institutional Training Initiative user interface. The user is logged in as 'Monika Lau ID: 1808055'. The 'Main Menu' tab is highlighted in red. Under 'My Learner Tools for Yale University Training Opportunities', the 'Add a Course' option is selected and highlighted in red. The page also displays a table of courses and their completion status.

English | Text size: A A | Monika Lau ID: 1808055 | Log Out | Help

CITI PROGRAM Collaborative Institutional Training Initiative | Search Support Center

Main Menu | My Profiles | My CEUs | My Reports | Support | Admin

Main Menu

- DEMO Courses
- Yale University Training Opportunities Courses

Course	Status	Completion Record	Survey
Biomedical Research - Basic/Refresher	Incomplete	Not Earned	
Biomedical Sciences	Not Started	Not Earned	
GCP - Social and Behavioral Research Best Practices for Clinical Research	Not Started	Not Earned	
GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus)	Incomplete	Not Earned	
Good Clinical Practice Course (US FDA focus)	Incomplete	Not Earned	
Hot Topics	Not Passed	Not Earned	
Humanities	Not Started	Not Earned	
SBE Refresher 1 - History and Ethical Principles	Not Started	Not Earned	

My Learner Tools for Yale University Training Opportunities

- Add a Course
- Remove a Course
- View Previously Completed Coursework
- Update Institution Profile
- View Instructions page
- Remove Affiliation

Affiliate With Another Institution

Affiliate as an Independent Learner

3) From the list of the available courses, choose the one that fits your needs.

Note: if you need to complete initial Good Clinical Practice training, choose any of the highlighted courses below. *Human Subjects Research* will satisfy only the Human Subject Protection training requirement. *Responsible Conduct of Research* does NOT satisfy the Human Subjects Protection training nor Good Clinical Practice.

CITI PROGRAM Collaborative Institutional Training Initiative Search Support Center

Main Menu | My Profiles | My CEUs | My Reports | Support | Admin

Main Menu > Add a Course

Select Curriculum - Yale University Training Opportunities (1541)

* indicates a required field.

* To enable the software to present the appropriate course work for your needs, you will be asked a series of questions. Please read the questions carefully and provide the most appropriate answer.

Do you conduct research in any of the following settings?

Responsible Conduct of Research (RCR) and Good Clinical Practice GCP does not satisfy the requirement for Human Subject Research training.
Choose all that apply

- Yes, I need/want to take courses on Human Subjects Research.
- Yes, I need/want to take the course on Responsible Conduct of Research (RCR).
- Yes, I need/want to take the course on Good Clinical Practice (GCP).
- Yes, I need/want to take the Refresher course on Good Clinical Practice (GCP).
- Yes, I need/want to take the course on GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus).
- Yes, I need/want to take the Refresher course on GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus).
- Yes, I need/want to take the course on GCP – Social and Behavioral Research Best Practices for Clinical Research.

Next Start Over

4) Once you add the course, it will appear in the main screen under Yale University Training Opportunities Courses list. Click on the name of the course to open the modules.

Yale University Training Opportunities Courses			
Course	Status	Completion Record	Survey
Biomedical Research - Basic/Refresher	Incomplete	Not Earned	
Biomedical Sciences	Not Started	Not Earned	
GCP – Social and Behavioral Research Best Practices for Clinical Research	Not Started	Not Earned	
GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus)	Incomplete	Not Earned	
Good Clinical Practice Course (US FDA focus)	Incomplete	Not Earned	
Hot Topics	Not Passed	Not Earned	
Humanities	Not Started	Not Earned	
SBE Refresher 1 – History and Ethical Principles	Not Started	Not Earned	

- 5) Before beginning the modules, you need to complete the Integrity Assurance Statement. After submitting your assurance statement, the first module in the course will become available.

The screenshot shows the CITI PROGRAM interface for the 'Good Clinical Practice Course (US FDA focus) - Refresher Course'. At the top, there is a navigation menu with links for 'Main Menu', 'My Profiles', 'My CEUs', 'My Reports', 'Support', and 'Admin'. Below the navigation, the course title is displayed. The main content area includes a section titled 'To pass this course you must:' with two bullet points: 'Complete all 15 required modules' and 'Achieve an average score of at least 95% on all quizzes associated with this course's module requirements'. To the right, it shows 'Your Current Score' as '0%'. Below this, a message states 'You have unfinished required or elective modules remaining' with a green arrow pointing to a button that says 'Complete The Integrity Assurance Statement before beginning the course'. At the bottom, there is a table titled 'Required Modules' with columns for 'Date Completed' and 'Score'.

Required Modules	Date Completed	Score
GCP for Clinical Trials with Investigational Drugs and Medical Devices (ID: 1289)	Incomplete	0/0 (0%)
Overview of New Drug Development (ID: 1606)	Incomplete	0/0 (0%)
Overview of ICH GCP (ID: 1607)	Incomplete	0/0 (0%)
ICH - Comparison Between ICH GCP E6 and U.S. FDA Regulations (ID: 1609)	Incomplete	0/0 (0%)
Conducting Investigator-Initiated Studies According to FDA Regulations and GCP (ID: 1610)	Incomplete	0/0 (0%)
Investigator Obligations in FDA-Regulated Clinical Research (ID: 1611)	Incomplete	0/0 (0%)
Managing Investigational Agents According to GCP Requirements (ID: 1612)	Incomplete	0/0 (0%)
Overview of U.S. FDA Regulations for Medical Devices (ID: 1613)	Incomplete	0/0 (0%)

- 6) You must complete all modules within the course. CITI will notify the HRPP Office the day after you complete the training and your records in TMS will be updated.