



How to Enroll in Principal Investigator and Study Team Member Recertification

STEP BY STEP GUIDE

Step 1 – Enrolling in Courses

- ▶ To enroll in the Principal Investigator or Study Team Member Recertification, first log in to myLearning
- ▶ Search “Principal Investigator Human Subjects Research Recertification” or “Study Team Member Human Subjects Research Recertification” and select the correct course when it appears. The course you take depends on if you are a PI on any research study.
- ▶ Click on “Add to Dev Plan” at the bottom of the screen.
- ▶ You must select “Add to Dev Plan” no matter which training course is needed.

JOHNS HOPKINS UNIVERSITY & MEDICINE

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Jonathon Harris

Study Team Member Human Subjects Recertification

Welcome to Human Subjects Research recertification for study team members who are not PIs of their own studies. This re-certification is required every 3 years in order to be compliant with Johns Hopkins Medical Center IRB policies. If you are a study team member participating on School of Medicine IRB research studies, you are required to complete this training.

Recertification has been updated to include Good Clinical Practice (GCP) compliance training.

At the time of completion of this training, you will have met the requirements of Human Subjects Research recertification as well as Good Clinical Practice (a compliance training requirement established by NIH for all NIH Awardees involved in NIH-funded Clinical Trials).

Please note that all training components must be completed in order to obtain a final certificate.

Study Team Member Human Subjects Recertification includes four mandatory online courses:

- Refresher Course: An Overview of Research with Vulnerable Subjects
- Refresher Course: Genetics Research
- Refresher Course: Records Based Research
- Good Clinical Practice (CITI) (13 modules)

If the course links below are not active, you need to complete your enrollment in the Study Team Member Human Subjects Recertification (see instructions below):

HOW TO ENROLL IN AND COMPLETE STUDY TEAM MEMBER RECERTIFICATION-

- Scroll to the bottom and click 'Add to Dev Plan'
- Go to My Plan and select the 'Self-Enrollments' tab
- Click on Study Team Member Human Subjects Recertification (course links will now be active)
- To access training to complete the individual coursework, please right click each course to open in another tab. You will be directed to the CITI website.
- Select the Johns Hopkins Medical Institution affiliation on the CITI website. **DO NOT** complete courses under the Johns Hopkins University affiliation.
- Click View Courses to begin completing coursework.
- Look for corresponding course titles on the CITI website under the Active Courses sub-header.
- **DO NOT** complete the following titles on the CITI website to obtain recertification credit: Human Subjects Research, Biomedical Research, Responsible Conduct of Research, Pregnant Women & Fetuses, and Researchers. They **DO NOT** count towards recertification training credit.
- Please allow up to 24 hours for CITI to communicate a completed status to myLearning training courses.

SPECIAL NOTE:

In order for coursework to process on the myLearning side, the online courses have to be activated. To activate courses, right-click on all courses listed as **Not Started**. Courses can be opened in a new window or a new tab. After all courses have been activated in myLearning, the course status will reflect **Incomplete**. CITI will communicate any courses completed on their website to myLearning overnight.

If you have any questions, please email JHM eIRB Help Desk at jhmeIRB@jhmi.edu

Course Title	Certificate	Status	Date Started	Completion Date
Required Courses - Complete All				
Refresher Course: An Overview of Research with Vulnerable Subjects (CITI) *R			Not Started	
Refresher Course: Genetics Research (CITI) *R			Not Started	
Refresher Course: Records Based Research (CITI) *R			Not Started	
Required Courses GCP - Complete All				
Refresher Course GCP: Audits and Inspections in Clinical Trials (CITI) *R			Not Started	
Refresher Course GCP: Conducting Clinical Trials of Medical Devices (CITI) *R			Not Started	
Refresher Course GCP: Conducting Investigator-Initiated Studies According to FDA Regulations and Good Clinical Practices (CITI) *R			Not Started	
Refresher Course GCP: Detection and Evaluation of Adverse Events (CITI) *R			Not Started	
Refresher Course GCP: GCP Introduction (CITI) *R			Not Started	
Refresher Course GCP: Informed Consent—An Ongoing Process (CITI) *R			Not Started	
Refresher Course GCP: International Conference on Harmonization - ICH for Investigators (CITI) *R			Not Started	
Refresher Course GCP: International Conference on Harmonization (ICH): GCP Requirements (CITI) *R			Not Started	
Refresher Course GCP: Investigator Obligations in FDA-Regulated Clinical Research (CITI) *R			Not Started	
Refresher Course GCP: Managing Investigational Agents According to GCP Requirements (CITI) *R			Not Started	
Refresher Course GCP: Monitoring of Clinical Trials by Industry Sponsors (CITI) *R			Not Started	
Refresher Course GCP: Overview of New Drug Development (CITI) *R			Not Started	
Refresher Course GCP: Reporting Serious Adverse Events (CITI) *R			Not Started	

NOTE: All course titles displaying a *R must be completed.

Reviews and Ratings

Add to Dev Plan

Reminder

- If you are a Principal Investigator on any study, register for “Principal Investigator Human Subject Recertification.” An In-Person/Virtual activity is also required.
- Visit our [Recertification Training Page](#) for more information and approved in-person/virtual activities.

Step 2 – Adding Courses to Your Plan

- ▶ You can view the added courses by going to the “My Plan” screen in myLearning and from there select the 'Self-Enrollments' tab
- ▶ Click on the course under ‘Course Name’

My Plan for Jessica Jones

Auto-Enrollments 1 Self-Enrollments 5 Outside Learning Activities Pending Course Evaluations

Your learning plan tracks internal and external training.

- **Auto-Enrollments:** Courses in which you have been enrolled by your department or program.
- **Self-Enrollments:** Courses that you enrolled in yourself as well as Optional courses you were enrolled in by others (management).
- **Outside Learning:** Courses, conferences, classes, etc. in which you participated or which you completed that were outside of myLearning.
- **Pending Course Evaluations:** Evaluations for courses you have completed. Please share your feedback.

You can:

- Add courses by searching the [Catalog](#).
- Remove self-enrollments that have a red 'X' in the **Remove** column.
- Add an outside learning activity.
- Complete pending course evaluations.

Auto-Enrollments

Course Name	Status	Date Started	Completion Deadline	Provider
Study Team Member Human Subjects Recertification	Not Started		11/17/2022	JHM IRB Training

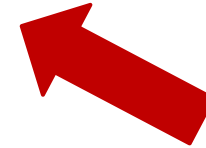
Step 3 – Accessing Courses

To access course:

- ▶ Turn off Pop-up blockers
- ▶ Click on any of the 16 modules to open course in CITI.

If you have any questions, please email JHM eIRB Help Desk at jhmelRB@jhm.edu

Course Title	Certificate Status	Date Started	Completion Date
Required Courses - Complete All			
Refresher Course: An Overview of Research with Vulnerable Subjects (CITI) *R	Not Started		
Refresher Course: Genetics Research (CITI) *R	Not Started		
Refresher Course: Records Based Research (CITI) *R	Not Started		
Required Courses GCP - Complete All			
Refresher Course GCP: Audits and Inspections in Clinical Trials (CITI) *R	Not Started		
Refresher Course GCP: Conducting Clinical Trials of Medical Devices (CITI) *R	Not Started		
Refresher Course GCP: Conducting Investigator-Initiated Studies According to FDA Regulations and Good Clinical Practices (CITI) *R	Not Started		
Refresher Course GCP: Detection and Evaluation of Adverse Events (CITI) *R	Not Started		
Refresher Course GCP: GCP Introduction (CITI) *R	Not Started		
Refresher Course GCP: Informed Consent—An Ongoing Process (CITI) *R	Not Started		
Refresher Course GCP: International Conference on Harmonization - ICH for Investigators (CITI) *R	Not Started		
Refresher Course GCP: International Conference on Harmonization (ICH): GCP Requirements (CITI) *R	Not Started		
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Refresher Course GCP: Monitoring of Clinical Trials by Industry Sponsors (CITI) *R	Not Started		
Refresher Course GCP: Overview of New Drug Development (CITI) *R	Not Started		
Refresher Course GCP: Reporting Serious Adverse Events (CITI) *R	Not Started		



NOTE: All course titles displaying a *R must be completed.

Reviews and Ratings

Enroll Others

Click on any of the modules to open the course in CITI

Step 4 – Adding Courses in CITI


- ▶ Once you click on one of the 16 modules (3 single modules and 13 modules comprising ICH GCP) in myLearning, you will be directed to <https://about.citiprogram.org/>
- ▶ SOM affiliates should select “Johns Hopkins Medical Institutions” as their institution from the drop down list
- ▶ Select “My Courses” at the top of the page and add a course

The screenshot shows the CITI PROGRAM user interface. At the top, the navigation menu includes "My Courses", "Records", "My CE/CMEs", "Support", and "Admin". The "My Courses" tab is highlighted with a red circle. Below the navigation, a welcome message for "Jonathon Harris" is displayed, along with statistics: "15 Courses Completed" and "8 Years of Membership". A dropdown menu for "Show Courses for:" is open, showing "Johns Hopkins Medical Institutions - TEST" selected and circled in red. Below this, a message states "You are not enrolled in any courses for this institution." with an "Add a Course" button. A "Learner Tools for Johns Hopkins Medical Institutions - TEST" section lists options: "Add a Course", "View Previously Completed Coursework", "Update Institution Profile", and "Remove Affiliation".

Step 5- Confirming Your Course in CITI

- ▶ PI's and Study Team Members should select the fourth option if they need to recertify their HSR training.
- ▶ Select "Next" to view the individual courses.
- ▶ SOM affiliates are required to recertify every 3 years.

English ▾

CITI PROGRAM My Courses My Records My CE/CMEs Support Admin  Jonathon Harris ID 3454910 ▾

Select Curriculum


Johns Hopkins Medical Institutions - TEST


Question 1

Which training do you need to complete (select only one option)?

This question is required. Choose one answer.

- I need Initial IRB Compliance training only (This selection will add Basic Human Subjects Research and Health Privacy Issues for Research. Conflict of Interest has been automatically added in MyLearning)
- I need Initial IRB Compliance training and Good Clinical Practice (GCP) training (This selection will add Basic Human Subjects Research and Health Privacy Issues for Research. Conflict of Interest has been automatically added in MyLearning)
- I only need Good Clinical Practices training
- I need to complete Recertification Training (This course includes Good Clinical Practices training and is required for both PI and Study Team recertification)



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Step 6- PI and Study Team Member Recertification

- ▶ Courses will appear under “Courses Ready to Begin”. Select “Start Now” to begin.

Course titles that need to be completed:

- ▶ 101 Refresher Course - An Overview of Research with Vulnerable Subjects
 - ▶ 101 Refresher Course - Genetics Research
 - ▶ 101 Refresher Course - Records Based
 - ▶ The Good Clinical Practice and ICH course is also required and consists of 13 individual modules
- ▶ Once courses are completed, they will appear under “Completed Courses”. Certificates will be available approximately after 24 hours in myLearning.

The screenshot displays the Johns Hopkins Medical Institutions - TEST myLearning interface. The page is titled "Johns Hopkins Medical Institutions - TEST" and features a navigation bar with "Active Courses" and "Learner Tools". Below the navigation bar, a message states "You have no active courses for this Institution." The main content area is divided into two sections: "Courses Ready to Begin" and "Completed Courses". The "Courses Ready to Begin" section is highlighted with a red box and contains four course cards, each with a "Start Now" button. A red arrow points to the "Courses Ready to Begin" section header. The "Completed Courses" section is also highlighted with a red box and contains a "Completed Courses" header. The "Start Now" buttons for the four courses in the "Courses Ready to Begin" section are circled in red.

Johns Hopkins Medical Institutions - TEST

Active Courses [Learner Tools](#)

You have no active courses for this Institution.

Courses Ready to Begin [Learner Tools](#)

Johns Hopkins Medical Institutions - TEST
101 Refresher Course - An Overview of Research with Vulnerable Subjects
Stage 1
0 / 1 modules completed [Start Now](#)

Johns Hopkins Medical Institutions - TEST
101 Refresher Course - Genetics Research
Stage 1
0 / 1 modules completed [Start Now](#)

Johns Hopkins Medical Institutions - TEST
101 Refresher Course - Records Based
Stage 1
0 / 1 modules completed [Start Now](#)

Johns Hopkins Medical Institutions - TEST
Good Clinical Practice and ICH
Stage 1 - Basic Course
0 / 13 modules completed [Start Now](#)

Completed Courses [Learner Tools](#)

available in [Records](#).

For questions, contact the JHM IRB Help
Desk at jhmeirb@jhmi.edu