



JHM IRB CITI Training Update

STEP BY STEP GUIDE

Update

- ▶ On January 10, 2022 improvements are being implemented to the enrollment process for required human subject compliance training.
- ▶ The CITI (Collaborative Institutional Training Initiative) site will now feature a new JHU SOM IRB training page designed to help JHU SOM affiliates select the courses they need to complete to maintain compliance with requirements.
- ▶ Included here is a step by step guide to help you navigate completion of the following training:
 - ▶ Initial IRB Compliance Training (Human Subjects Research-Biomedical Research Training [previously Basic Human Subjects Research]), Conflict of Interest and Researchers [previously Health Privacy Issues for Researchers]
 - ▶ Initial IRB Compliance Training with Good Clinical Practice Training
 - ▶ Only Good Clinical Practice Training
 - ▶ Recertification requirements for Principal Investigators and Study Team Members

What Changed?

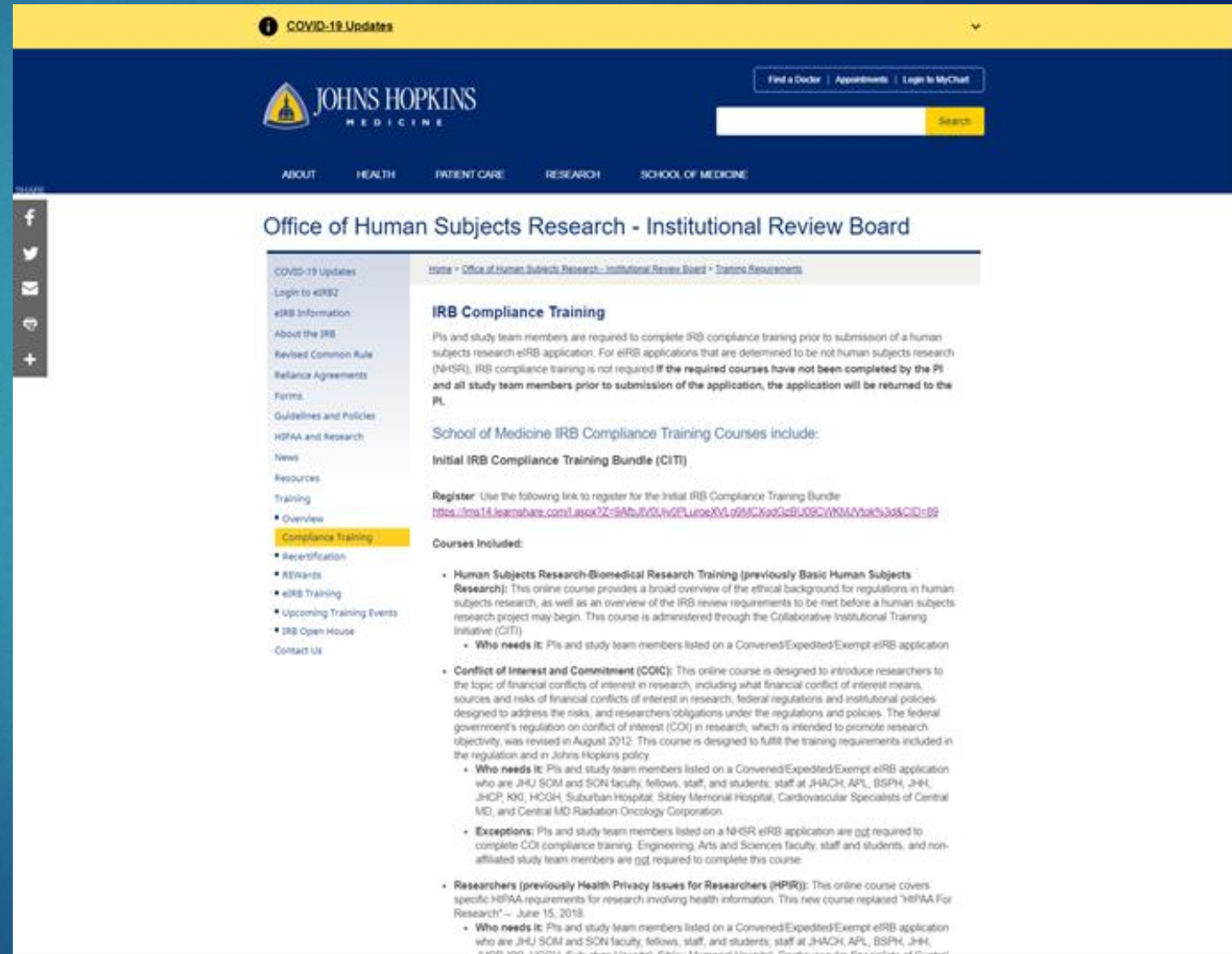
- ▶ Prior to 01/10/2022, to enroll in required compliance training you have to enroll in each course in myLearning and were then directed to take the courses in CITI.
- ▶ As of 01/10/2022, you will now be able to select one course bundle in MyLearning for initial IRB compliance training. You will then be directed to the CITI program to confirm the desired course and it will populate in your CITI profile.

Advantages

- ▶ The update will eliminate the repetitive steps of right clicking on each course in myLearning to add it to your CITI profile then completing the courses in CITI.
- ▶ To help lessen the confusion of which courses to take, course names in CITI will now correspond to the course names in myLearning.

Update to IRB Website

- ▶ Go to https://www.hopkinsmedicine.org/institutional_review_board/training_requirements/ to review SOM's IRB compliance training guidelines and links to each bundle. Once you have determined the course needed, click on the course link and you will be directed to myLearning.
- ▶ PIs and study team members can easily access the right courses in myLearning by clicking these links



The screenshot displays the Johns Hopkins Medicine website's Institutional Review Board (IRB) page. At the top, there is a yellow banner for "COVID-19 Updates" and a navigation bar with the Johns Hopkins Medicine logo and links for "Find a Doctor", "Appointments", and "Login to MyChart". Below the navigation bar, the page title is "Office of Human Subjects Research - Institutional Review Board". A left sidebar contains a menu with items like "COVID-19 Updates", "Login to eIRB", "eIRB Information", "About the IRB", "Revised Common Rule", "Reliance Agreements", "Forms", "Guidelines and Policies", "HPPAA and Research", "News", "Resources", "Training", "Overview", "Compliance Training" (highlighted in yellow), "Recertification", "IRB Awards", "eIRB Training", "Upcoming Training Events", "IRB Open House", and "CONTACT US". The main content area is titled "IRB Compliance Training" and includes the following text: "PIs and study team members are required to complete IRB compliance training prior to submission of a human subjects research eIRB application. For eIRB applications that are determined to be not human subjects research (N-HSR), IRB compliance training is not required if the required courses have not been completed by the PI and all study team members prior to submission of the application, the application will be returned to the PI." It lists "School of Medicine IRB Compliance Training Courses include:" and "Initial IRB Compliance Training Bundle (CITI)". A "Register" section provides a link to register for the Initial IRB Compliance Training Bundle: <https://mo14.learnshare.com/LaseXZzr9NfyjV0Lvg0LuroeXVr05Gx9q3C8J05CjW0AA9at53d3CID:88>. The "Courses Included:" section lists three courses: "Human Subjects Research@Biomedical Research Training (previously Basic Human Subjects Research)", "Conflict of Interest and Commitment (COIC)", and "Researchers (previously Health Privacy Issues for Researchers (HPIRI))".



How to Enroll in Initial IRB Compliance Training

Step 1 – Enrolling in Courses

- ▶ To enroll in the initial IRB compliance training, first log in to myLearning.
- ▶ Search “Initial IRB Compliance Training Bundle” select it when it appears.
- ▶ Click on “Add to Dev Plan” at the bottom of the screen.
- ▶ You must select “Add to Dev Plan” to ensure the course is added to your plan.

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HOME QUICK LINKS REPORTS ADMINS HELP Jonathon Harris

Initial IRB Compliance Training Bundle (CITI) New SSO

Welcome to Human Subjects Research Initial IRB Compliance Training Bundle. If you are a study team member participating on School of Medicine IRB research studies, you are required to complete this training. Completion of these courses are required in order to be compliant with Johns Hopkins Medicine IRB policies.

Initial IRB Compliance Training Bundle includes three mandatory online courses:

- Basic Human Subjects Research (CITI)
- Health Privacy Issues for Researchers (CITI)
- Conflict of Interest and Commitment

HOW TO ENROLL IN AND COMPLETE Initial IRB Compliance Training Bundle:

- Scroll to the bottom and click '**Add to Dev Plan**'
- Go to **My Plan** and select the '**Self-Enrollments**' tab
- Click on **Initial IRB Compliance Training Bundle** (course links will now be active)
- To access training to complete the individual coursework:
 - Turn off Pop-up blockers
 - Click each course to open in a new browser window. You will be directed to the CITI website.
- Answer the question based on if you need Initial training or if you also need GCP training.
- Click **View Courses** to begin completing coursework.
- Look for corresponding course titles on the CITI website under the **Active Courses** sub-header.
- Please **allow up to 24 hours for CITI to communicate a completed status to myLearning** training courses.

| Course Title | Certificate | Status | Date Started | Completion Date |
|---|-------------|-------------|--------------|-----------------|
| Human Subjects Research – Biomedical Research (CITI) New SSO *R | | Not Started | | |
| Researchers (CITI) New SSO *R | | Not Started | | |
| Conflict of Interest and Commitment *R | | Not Started | | |

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

Reviews and Ratings

Average: ☆☆☆☆☆

Add to Dev Plan

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
- ▶ Select 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.

Self-Enrollments

Courses will appear here

| Course Name | Status | Date Started | Completion Deadline | Remove | Provider |
|---|-------------|--------------|---------------------|--------|------------------|
| Initial IRB Compliance Training Bundle (CITI) New SSO | Not Started | | | X | JHM IRB Training |

Step 3 – Accessing Courses

To access the specific courses within the bundle:

- ▶ Turn off Pop-up blockers
- ▶ Click on Human Subjects Research – Biomedical Research (Previously Basic Human Subjects Research) or Researchers (Previously Health Privacy Issues for Researchers) to open the course in CITI.
 - ▶ Human Subjects Research-Biomedical Research course and the Researchers course will take you to the CITI page
- ▶ Conflict of Interest and Commitment course will be completed in myLearning
- ▶ You must complete Human Subjects Research-Biomedical Research course and the Researchers course in CITI and complete Conflict of Interest and Commitment in myLearning to get the full credit for the bundle

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HOME QUICK LINKS REPORTS ADMINS HELP Jonathon Harris

Initial IRB Compliance Training Bundle (CITI) New SSO

Welcome to Human Subjects Research Initial IRB Compliance Training Bundle. If you are a study team member participating on School of Medicine IRB research studies, you are required to complete this training. Completion of these courses are required in order to be compliant with Johns Hopkins Medicine IRB policies.

Initial IRB Compliance Training Bundle includes three mandatory online courses:

- Basic Human Subjects Research (CITI)
- Health Privacy Issues for Researchers (CITI)
- Conflict of Interest and Commitment

HOW TO ENROLL IN AND COMPLETE Initial IRB Compliance Training Bundle:

- Scroll to the bottom and click 'Add to Dev Plan'
- Go to **My Plan** and select the 'Self-Enrollments' tab
- Click on **Initial IRB Compliance Training Bundle** (course links will now be active)
- To access training to complete the individual coursework:
 - Turn off Pop-up blockers
 - Click each course to open in a new browser window. You will be directed to the CITI website.
- Answer the question based on if you need Initial training or if you also need GCP training.
- Click **View Courses** to begin completing coursework.
- Look for corresponding course titles on the CITI website under the **Active Courses** sub-header.
- Please **allow up to 24 hours for CITI to communicate a completed status to myLearning** training courses.

| Course Title | Certificate | Status | Date Started | Completion Date |
|---|-------------|-------------|--------------|-----------------|
| Human Subjects Research – Biomedical Research (CITI) New SSO *R | | Not Started | | |
| Researchers (CITI) New SSO *R | | Not Started | | |
| Conflict of Interest and Commitment *R | | Not Started | | |

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

Reviews and Ratings

Average: ☆☆☆☆

My Rating: ☆☆☆☆

Enroll Others

Clicking on a course name will take you to the CITI website.

Step 4: Adding Courses in CITI

- ▶ Once you click on Human Subjects Research-Biomedical Research course or the Researchers course 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 click add a course

The screenshot displays the CITI PROGRAM website interface. At the top, the navigation bar includes the CITI PROGRAM logo, a search icon, and user information for Jonathon Harris (ID 3454910). The main navigation menu contains links for My Courses, My Records, My CE/CMEs, Support, and Admin. A red arrow points to the 'My Courses' link. Below the navigation, a welcome message for Jonathon is displayed, along with statistics for Courses Completed (15) and Years of Membership (8). The main content area shows a dropdown menu for 'Show Courses for:' with 'Johns Hopkins Medical Institutions - TEST' selected. A red box highlights this dropdown. Below it, a message states 'You are not enrolled in any courses for this institution.' with an 'Add a Course' button. A red arrow points to this button. Below the message, a section titled 'Learner Tools for Johns Hopkins Medical Institutions - TEST' lists several options: Add a Course, View Previously Completed Coursework, Update Institution Profile, and Remove Affiliation. The footer contains support and legal information, including contact details and links for Accessibility, Copyright, Privacy and Cookie Policy, Statement of Security Practices, and Terms of Service.

Step 5- Confirming Your Course Selection in CITI

- ▶ If you only need Initial IRB Compliance Training, select the first option. This option does not include Good Clinical Practice (GCP) training.
- ▶ Select “Next” to view the individual courses

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)

Start Over Next

SUPPORT 888.529.5929 LEGAL [Accessibility](#)

CITI PROGRAM

Step 6- Completing Initial IRB Compliance Training

- ▶ Select “Start Now” to begin a course.
 - Course titles that need to be completed-
 - ▶ Human Subject Research-Biomedical Research
 - ▶ Researchers
- ▶ Reminder: Conflict of Interest and Commitment (COIC) is not taken in CITI. COIC is taken in myLearning and will be automatically included on the “My Plan” page in myLearning when you add the bundle to your development plan.
- ▶ Once courses are complete, they will appear under “Completed Courses”. Certificates will be available in myLearning approximately 24 hours after course completion.
- ▶ Reminder: The certificate for the three course bundle will not be available until all courses have been completed in CITI and myLearning

✓ You are now enrolled in the course(s) you selected.

Show Courses for: Johns Hopkins Medical Institutions - TEST [Institution List](#)

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
Researchers
Stage 1 - Basic Course
0 / 1 modules completed [Start Now](#)

Completed Courses [Learner Tools](#)

Johns Hopkins Medical Institutions - TEST
Human Subject Research - Biomedical Research
Stage 1 - Basic Course
[Post-Course Survey](#)
Passed 21-Sep-2021 [Review Course](#) [View - Print - Share Record](#)

Learner Tools for Johns Hopkins Medical Institutions - TEST

- [Add a Course](#)
- [Remove a Course](#)
- [View Previously Completed Coursework](#)
- [Update Institution Profile](#)
- [Remove Affiliation](#)

SUPPORT 888.526.9029 LEGAL Accessibility



How to Enroll in Initial Compliance and GCP Training

Step 5- Confirming Your Course Selection in CITI

- ▶ Complete steps 1-4 to enroll in and complete Initial IRB Compliance Training
- ▶ Select the second option if you need Initial IRB Compliance Training and Good Clinical Practice (GCP) training.
- ▶ Select “Next” to view the individual courses.

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 Practice training.
- I need to complete Recertification Training (This course includes Good Clinical Practices training and is required for both PI and Study Team recertification)

Start Over Next

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Step 6-Initial Compliance and GCP Training

- ▶ Select “Start Now” to begin a course.
 - Course titles that need to be completed-
 - ▶ Human Subject Research-Biomedical Research
 - ▶ Researchers
 - ▶ Good Clinical Practice & ICH
- ▶ Reminder: Conflict of Interest and Commitment (COIC) is not taken in CITI. COIC is taken in myLearning and will be automatically included on the “My Plan” page in myLearning when you add the bundle to your development plan.
- ▶ Once courses are completed, they will appear under “Completed Courses”. Certificates will be available in myLearning approximately 24 hours after course completion.
- ▶ Reminder: The certificate will not be available until all courses have been completed in CITI and myLearning

The screenshot displays the user interface for Johns Hopkins Medical Institutions - TEST. It is divided into three main sections: Active Courses, Courses Ready to Begin, and Completed Courses. A red arrow points to the 'Courses Ready to Begin' section. In this section, two courses are listed: 'Good Clinical Practice and ICH' and 'Researchers'. Both courses show '0 / 13 modules completed' and '0 / 1 modules completed' respectively. Each course has a 'Start Now' button circled in red. The 'Completed Courses' section is also circled in red and shows a course titled 'Human Subject Research - Biomedical Research' which has been 'Passed 21-Sep-2021'. Below this, there are buttons for 'Review Course' and 'View - Print - Share Record'. At the bottom, there is a 'Learner Tools' section with links for 'Add a Course', 'Remove a Course', 'View Previously Completed Coursework', 'Update Institution Profile', and 'Remove Affiliation'. The footer includes 'SUPPORT', 'LEGAL', and the hashtag '#CITI'.

How to Enroll in Only GCP Training

Step 1 – Enrolling in Courses

- ▶ To enroll in the Good Clinical Practice (GCP) Training, first log in to myLearning
- ▶ Search “Good Clinical Practice” and select it when it appears.
- ▶ Click on “Add to Dev Plan” at the bottom of the screen.

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HOME QUICK LINKS REPORTS ADMINS HELP

Jonathon Harris

Good Clinical Practice (CITI)

The Good Clinical Practice (GCP) course is suitable for research teams involved in clinical trials of drugs, biologics, and devices. To earn a certificate of completion, you are required to complete all 13 modules listed below.

| Course Title | Certificate Status | Date Started | Completion Date |
|--|--------------------|--------------|-----------------|
| Refresher Course GCP: GCP Introduction (CITI) *R | Complete | 12/30/2021 | 12/30/2021 |
| Refresher Course GCP: Audits and Inspections in Clinical Trials (CITI) *R | Complete | 12/30/2021 | 12/30/2021 |
| 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: Informed Consent—An Ongoing Process (CITI) *R | Complete | 12/30/2021 | 12/30/2021 |
| Refresher Course GCP: International Conference on Harmonization - ICH for Investigators (CITI) *R | Complete | 11/23/2021 | 12/30/2021 |
| 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

Average: ★★★★★ (234)

Add to Dev Plan

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 name under ‘Course Name’

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HOME QUICK LINKS REPORTS ADMINS HELP

Jonathon Harris

My Plan for Jonathon Harris

Auto-Enrollments 3 Self-Enrollments 22 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.

Self-Enrollments

| Course Name | Status | Date Started | Completion Deadline | Remove | Provider |
|-------------------------------|-------------|--------------|---------------------|--------|------------------|
| Good Clinical Practice (CITI) | Not Started | | | | JHM IRB Training |


Courses will appear here.

Step 3 – Accessing Courses

To access course:

- ▶ Turn off Pop-up blockers
- ▶ Click on any of the 13 modules to open course in CITI.

Good Clinical Practice (CITI)



| | |
|---------------|------------------|
| Delivery Type | Certificates |
| Duration | |
| Provider | JHM IRB Training |

The Good Clinical Practice (GCP) course is suitable for research teams involved in clinical trials of drugs, certificate of completion, you are required to complete all 13 modules listed below.

Course Title

Modules

- Refresher Course GCP: GCP Introduction (CITI) *R
- Refresher Course GCP: Audits and Inspections in Clinical Trials (CITI) *R
- Refresher Course GCP: Conducting Clinical Trials of Medical Devices (CITI) *R
- Refresher Course GCP: Conducting Investigator-Initiated Studies According to FDA Regulations and Good Clinical Practices (CITI) *R
- Refresher Course GCP: Detection and Evaluation of Adverse Events (CITI) *R
- Refresher Course GCP: Informed Consent—An Ongoing Process (CITI) *R
- Refresher Course GCP: International Conference on Harmonization - ICH for Investigators (CITI) *R
- Refresher Course GCP: International Conference on Harmonization (ICH): GCP Requirements (CITI) *R
- Refresher Course GCP: Investigator Obligations in FDA-Regulated Clinical Research (CITI) *R
- Refresher Course GCP: Managing Investigational Agents According to GCP Requirements (CITI) *R
- Refresher Course GCP: Monitoring of Clinical Trials by Industry Sponsors (CITI) *R
- Refresher Course GCP: Overview of New Drug Development (CITI) *R
- Refresher Course GCP: Reporting Serious Adverse Events (CITI) *R

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

Reviews and Ratings

Average: ★★★★★ (234)
My Rating: ☆☆☆☆☆

[Enroll Others](#)

Click on any of the 13 modules to open course in CITI

Step 4 – Adding Courses in CITI

- ▶ Once you click on one of the 13 modules 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" link is circled in red. Below the navigation, the user is greeted with "Welcome, Jonathon" and "Add Institutional Affiliation Register as Independent Learner". On the right, there are two circular statistics: "15 Courses Completed" and "8 Years of Membership". The main content area features a "Show Courses for:" dropdown menu with "Johns Hopkins Medical Institutions - TEST" selected, and an "Institution List" button. Below this, the selected institution name "Johns Hopkins Medical Institutions - TEST" is also circled in red. A message box with an exclamation mark icon states "You are not enrolled in any courses for this institution." and includes an "Add a Course" button. Below the message, there is a section titled "Learner Tools for Johns Hopkins Medical Institutions - TEST" with a list of links: "Add a Course", "View Previously Completed Coursework", "Update Institution Profile", and "Remove Affiliation". At the bottom of the page, there are links for "SUPPORT" (888.529.5929, 9:30 a.m. - 7:30 p.m. ET, Monday - Friday, Contact Us) and "LEGAL" (Accessibility, Cookies, Privacy and Cookie Policy, Statement of Security Practices, Terms of Service). The CITI PROGRAM logo is in the bottom right corner.

Step 5 – Confirming Your Course in CITI

- ▶ Select the third option if **ONLY** Good Clinical Practice (GCP) Training is needed.
- ▶ Select “Next” to view the individual course.

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)

[Start Over](#) [Next](#) ←

SUPPORT 888.529.5929 LEGAL [Accessibility](#)

CITI PROGRAM

Step 6 - GCP Training Only

- ▶ Course will be located under “Courses Ready to Begin”. Select “Start Now” to begin.

Course titles that need to be completed-

- ▶ Good Clinical Practice and ICH
- ▶ The Good Clinical Practice and ICH course consists of 13 individual modules.
- ▶ Once modules are completed, they will appear under “Completed Courses”.
- ▶ Certificates will be available in myLearning approximately after 24 hours after course completion.

Welcome, Jonathon
Add Institutional Affiliation
Register as Independent Learner

15 Courses Completed
8 Years of Membership

✔ You are now enrolled in the course(s) you selected.

Show Courses for: Johns Hopkins Medical Institutions - TEST [Institution List](#)

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

Completed Courses [Learner Tools](#)
You have not recently completed any courses for this institution. Full records of past completions are available in [Records](#).

Learner Tools for Johns Hopkins Medical Institutions - TEST

- [Add a Course](#)
- [Remove a Course](#)
- [View Previously Completed Coursework](#)
- [Update Institution Profile](#)
- [Remove Affiliation](#)



How to Enroll in Principal Investigator and Study Team Member Recertification

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.

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HOME QUICK LINKS REPORTS ADMINIS HELP

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

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 | | |
| 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

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 displays 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 circled in red. Below the navigation, a welcome message for 'Jonathon' is shown, along with statistics for 'Courses Completed' (15) and 'Years of Membership' (8). The main content area features a 'Show Courses for:' dropdown menu with 'Johns Hopkins Medical Institutions - TEST' selected, also 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'. The footer contains support and legal information, including contact details and links to 'Accessibility', 'Cookies', 'Privacy and Cookie Policy', 'Statement of Security Practices', and 'Terms of Service'.

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)



SUPPORT 888.529.5929 LEGAL [Accessibility](#) 

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 myLearning interface for Johns Hopkins Medical Institutions - TEST. The page is divided into two main sections: "Active Courses" and "Courses Ready to Begin".

- Active Courses:** This section is currently empty, with the message "You have no active courses for this Institution." and a "Learner Tools" link.
- Courses Ready to Begin:** This section contains four course cards, each with a "Start Now" button. A red arrow points to this section from the left. A red oval highlights the "Start Now" buttons for all four courses.
 - 101 Refresher Course - An Overview of Research with Vulnerable Subjects (Stage 1, 0 / 1 modules completed)
 - 101 Refresher Course - Genetics Research (Stage 1, 0 / 1 modules completed)
 - 101 Refresher Course - Records Based (Stage 1, 0 / 1 modules completed)
 - Good Clinical Practice and ICH (Stage 1 - Basic Course, 0 / 13 modules completed)
- Completed Courses:** This section is currently empty, with a "Learner Tools" link. A red oval highlights this section.

At the bottom of the page, there is a link to "Records" with the text "available in Records."

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