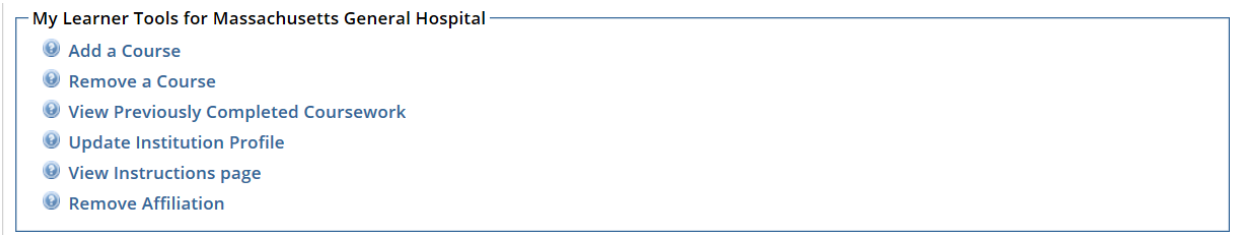
CITI GCP Course Instructions

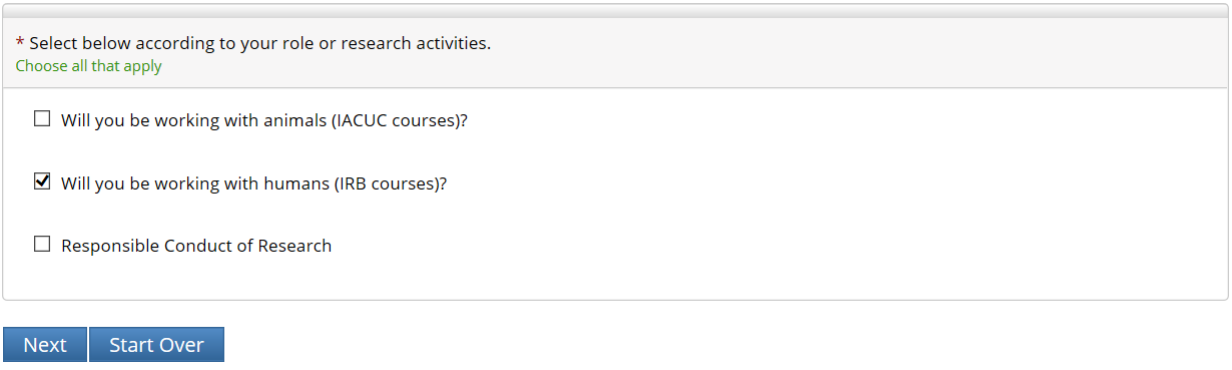
1. Go to https://citiprogram.org
2. Log in to your CITI account using your CITI Username and Password

3. Click on the applicable institution (Brigham and Women's Hospital or Massachusetts General Hospital)
4. Click **Add a Course**
5. Click **Next**

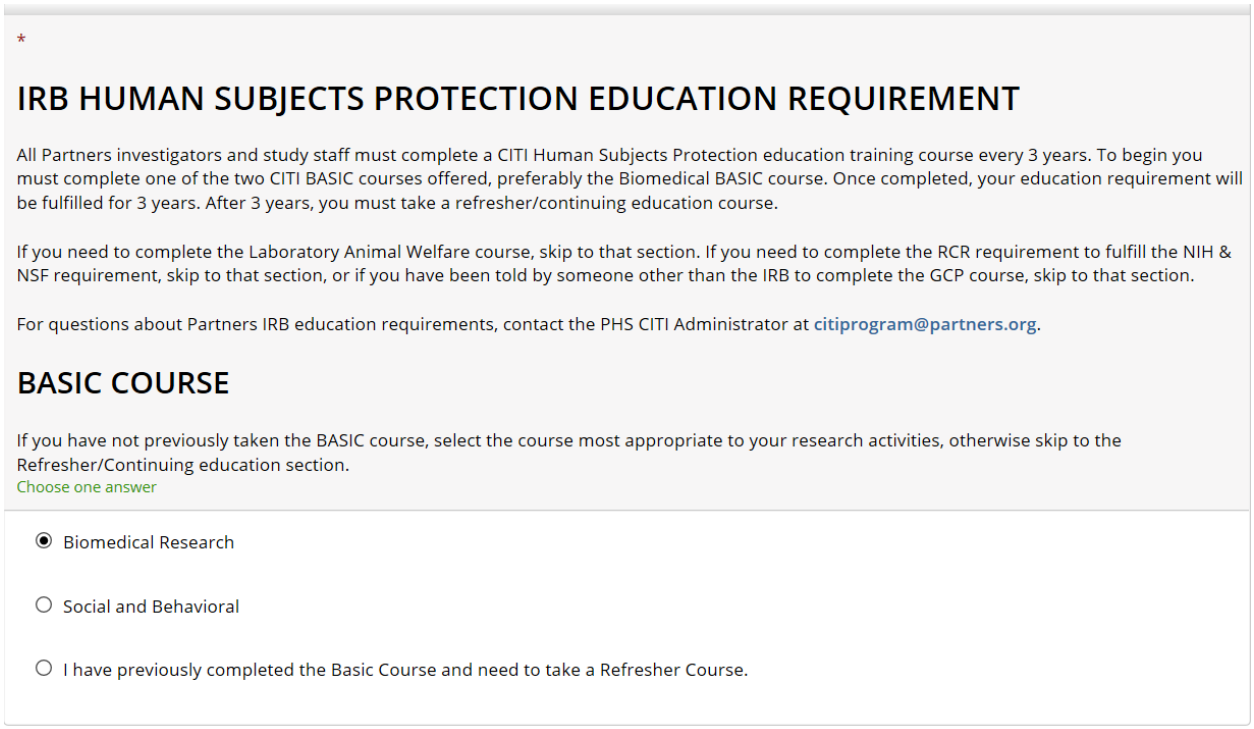


MASSACHUSETTS GENERAL HOSPITAL SCREEN SHOTS (BWH learners go to #12 for BWH SCREEN SHOTS)

6. Check the box next to **Will you be working with humans (IRB courses)?**
7. Click **Next**



8. Select **Biomedical Research**
9. Click **Next**



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IRB HUMAN SUBJECTS PROTECTION EDUCATION REQUIREMENT

All Partners investigators and study staff must complete a CITI Human Subjects Protection education training course every 3 years. To begin you must complete one of the two CITI BASIC courses offered, preferably the Biomedical BASIC course. Once completed, your education requirement will be fulfilled for 3 years. After 3 years, you must take a refresher/continuing education course.

If you need to complete the Laboratory Animal Welfare course, skip to that section. If you need to complete the RCR requirement to fulfill the NIH & NSF requirement, skip to that section, or if you have been told by someone other than the IRB to complete the GCP course, skip to that section.

For questions about Partners IRB education requirements, contact the PHS CITI Administrator at citiprogram@partners.org.

BASIC COURSE

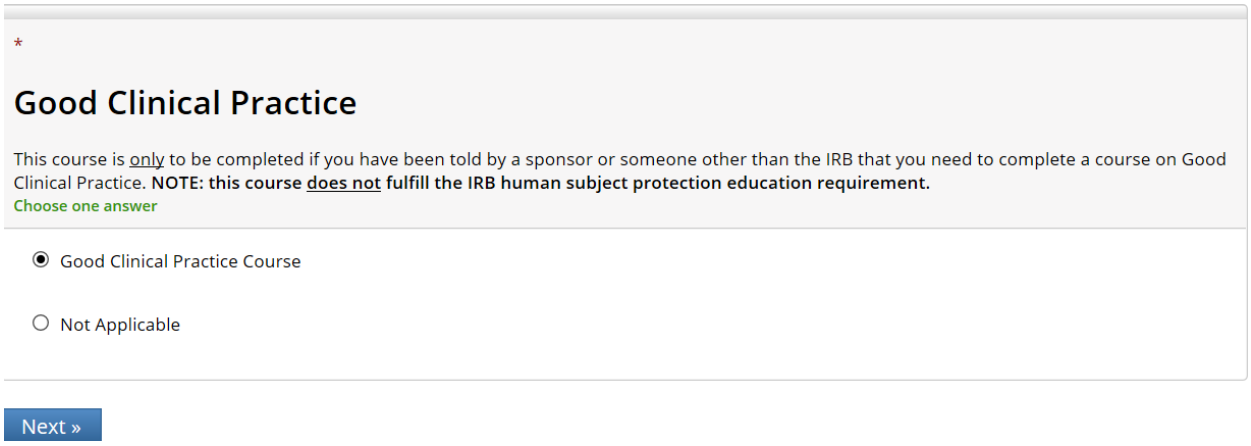
If you have not previously taken the BASIC course, select the course most appropriate to your research activities, otherwise skip to the Refresher/Continuing education section.

Choose one answer

- (•) Biomedical Research
- ( ) Social and Behavioral
- ( ) I have previously completed the Basic Course and need to take a Refresher Course.

Next »

10. Select **Good Clinical Practice Course**
11. Click **Next**



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Good Clinical Practice

This course is only to be completed if you have been told by a sponsor or someone other than the IRB that you need to complete a course on Good Clinical Practice. **NOTE: this course does not fulfill the IRB human subject protection education requirement.**

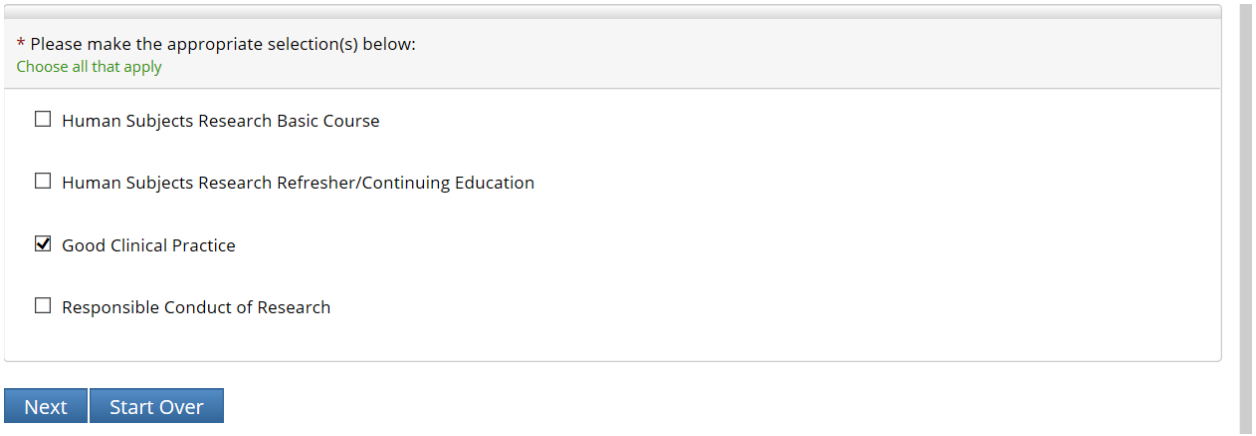
Choose one answer

- (•) Good Clinical Practice Course
- ( ) Not Applicable

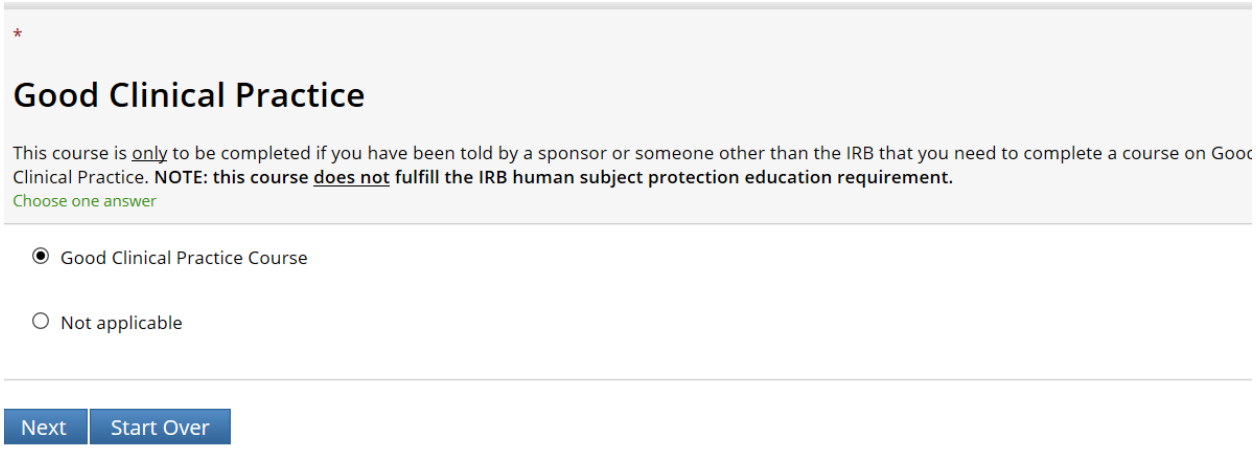
Next »

BRIGHAM AND WOMEN'S HOSPITAL SCREENS

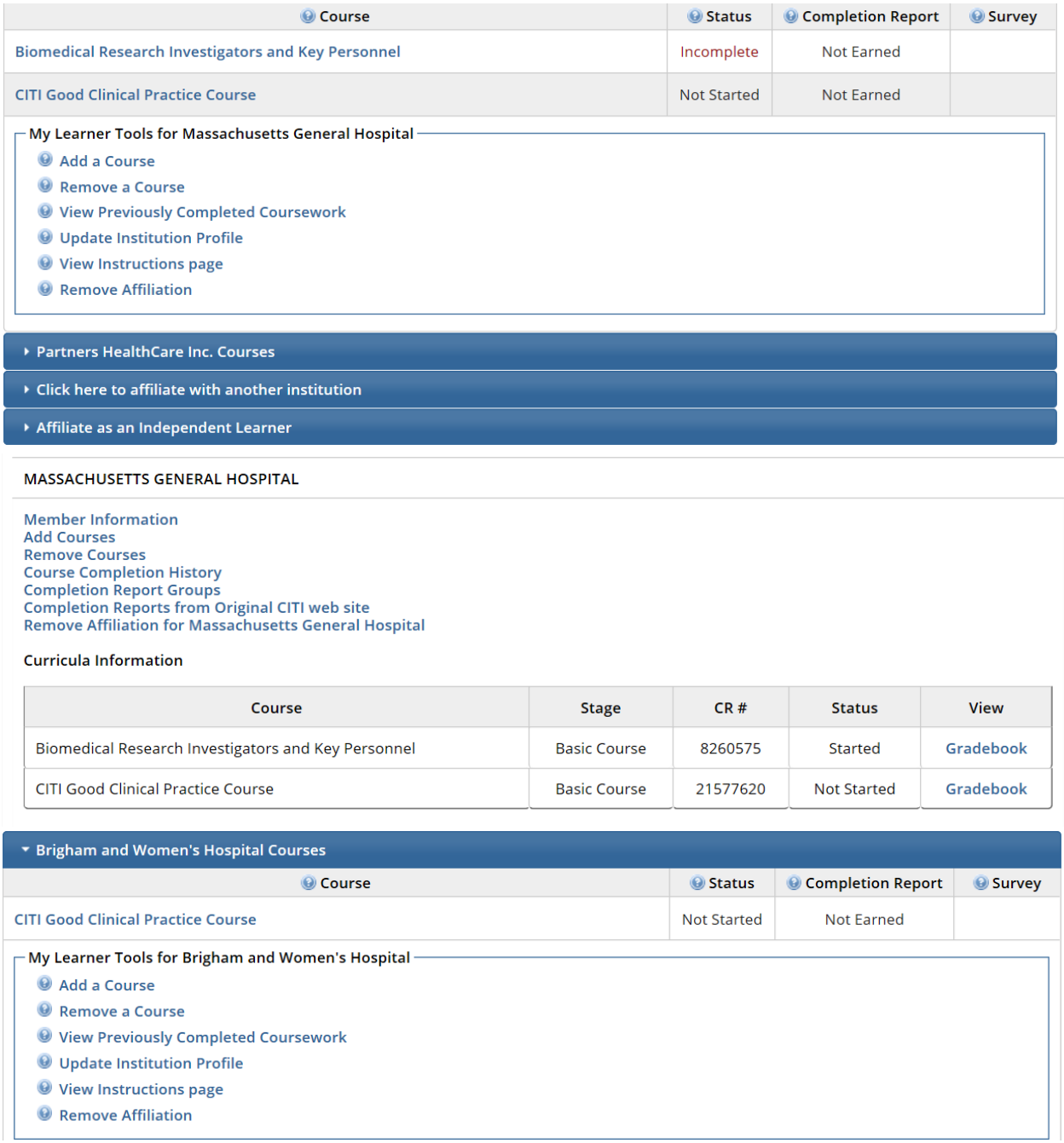
12. Check the box **Good Clinical Practice**
13. Click **Next**



14. Select **Good Clinical Practice Course**
15. Click **Next**



16. Click on **CITI Good Clinical Practice Course** to begin the course



Course	Status	Completion Report	Survey
Biomedical Research Investigators and Key Personnel	Incomplete	Not Earned	
CITI Good Clinical Practice Course	Not Started	Not Earned	

My Learner Tools for Massachusetts General Hospital

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

▸ Partners HealthCare Inc. Courses

▸ Click here to affiliate with another institution

▸ Affiliate as an Independent Learner

MASSACHUSETTS GENERAL HOSPITAL

Member Information
Add Courses
Remove Courses
Course Completion History
Completion Report Groups
Completion Reports from Original CITI web site
Remove Affiliation for Massachusetts General Hospital

Curricula Information

Course	Stage	CR #	Status	View
Biomedical Research Investigators and Key Personnel	Basic Course	8260575	Started	Gradebook
CITI Good Clinical Practice Course	Basic Course	21577620	Not Started	Gradebook

▾ Brigham and Women's Hospital Courses

Course	Status	Completion Report	Survey
CITI Good Clinical Practice Course	Not Started	Not Earned	

My Learner Tools for Brigham and Women's Hospital

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

17. Click on Complete **The Integrity Assurance Statement before beginning the course**
18. Read and check the box I agree...
19. Click on each required module and complete them sequentially.

Complete The Integrity Assurance Statement before beginning the course

Required Modules

	Date Completed	Score
The CITI Good Clinical Practice Course for Clinical Trials Involving Drugs and Devices (ID: 1350)	Incomplete	0/0 (0%)
Overview of New Drug Development (ID: 1351)	Incomplete	0/0 (0%)
Overview of ICH GCP (ID: 1352)	Incomplete	0/0 (0%)
ICH - Comparison Between ICH GCP E6 and U.S. FDA Regulations (ID: 1354)	Incomplete	0/0 (0%)
Conducting Investigator-Initiated Studies According to FDA Regulations and GCP (ID: 1355)	Incomplete	0/0 (0%)
Investigator Obligations in FDA-Regulated Research (ID: 1356)	Incomplete	0/0 (0%)
Managing Investigational Agents According to GCP Requirements (ID: 1357)	Incomplete	0/0 (0%)
Overview of U.S. FDA Regulations for Medical Devices (ID: 1358)	Incomplete	0/0 (0%)
Informed Consent in Clinical Trials of Drugs, Biologics, and Devices (ID: 1359)	Incomplete	0/0 (0%)
Detecting and Evaluating Adverse Events (ID: 1360)	Incomplete	0/0 (0%)
Reporting Serious Adverse Events (ID: 1361)	Incomplete	0/0 (0%)
Monitoring of Clinical Trials by Industry Sponsors (ID: 1362)	Incomplete	0/0 (0%)
Audits and Inspections of Clinical Trials (ID: 1363)	Incomplete	0/0 (0%)
Completing the CITI GCP Course (ID: 1364)	Incomplete	0/0 (0%)

20. The Partners Human Research Office generates reports of course completions every business day for the prior business day and, when applicable, weekend/holiday and uploads the information to the Insight users' training tab in Insight.
21. Contact the **IRB Help Line 857-282-1900** or Rosalyn Gray 857-282-1903 if you have any questions.