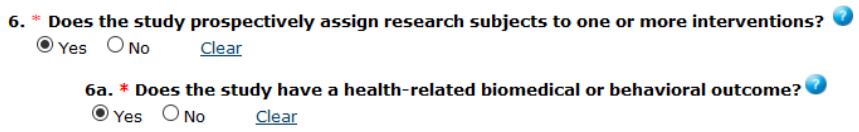
Why did you receive the requirement for Good Clinical Practice (GCP) training?

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.



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.

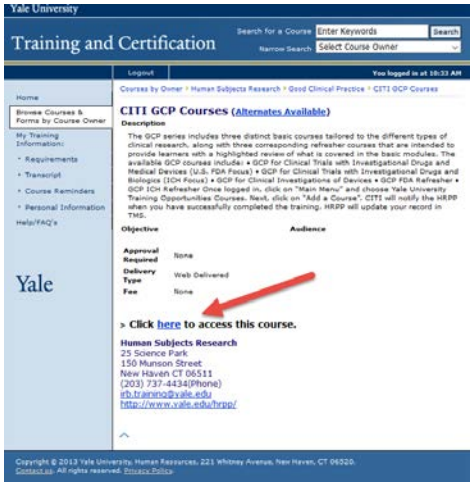
Contact

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

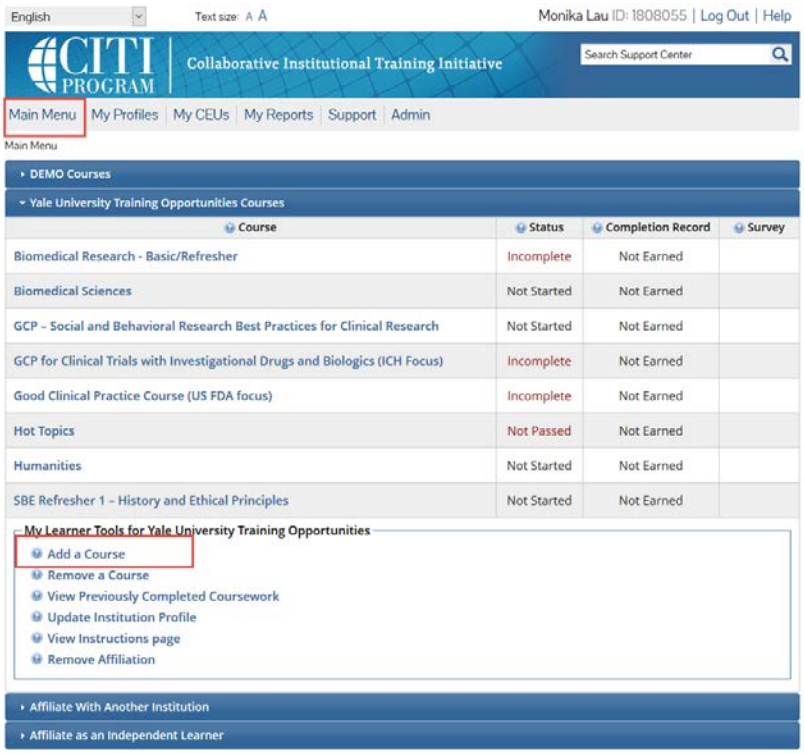
If you completed CITI GCP training through your affiliation with another institution, you can email the completion certificate. It will be entered into your TMS record.

Instructions for Good Clinical Practice courses through CITI

1) Log to CITI through Training Management System.

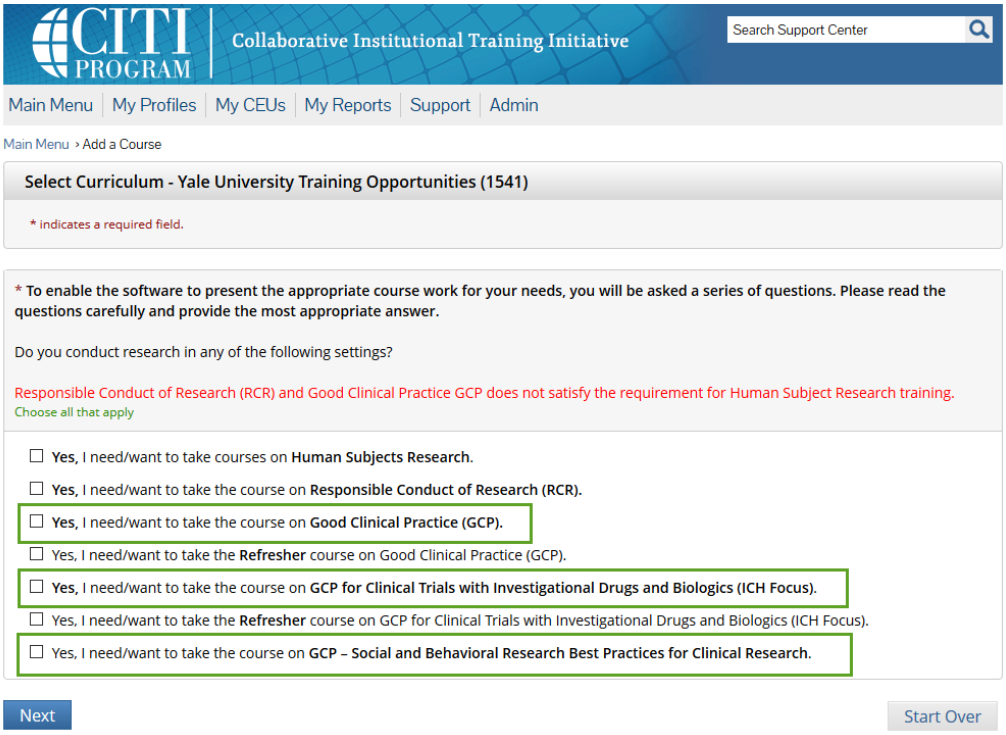


2) Once you are logged in, click on the **Main Menu** tab and then **Add a Course**.

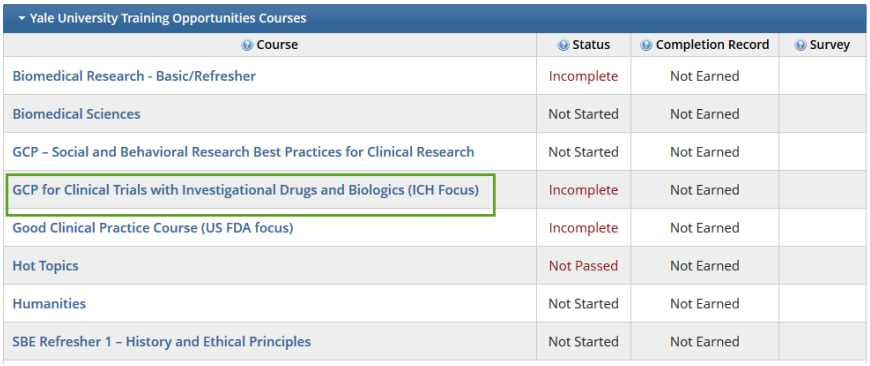


3) From the list of the available courses, choose the one that fits your needs.

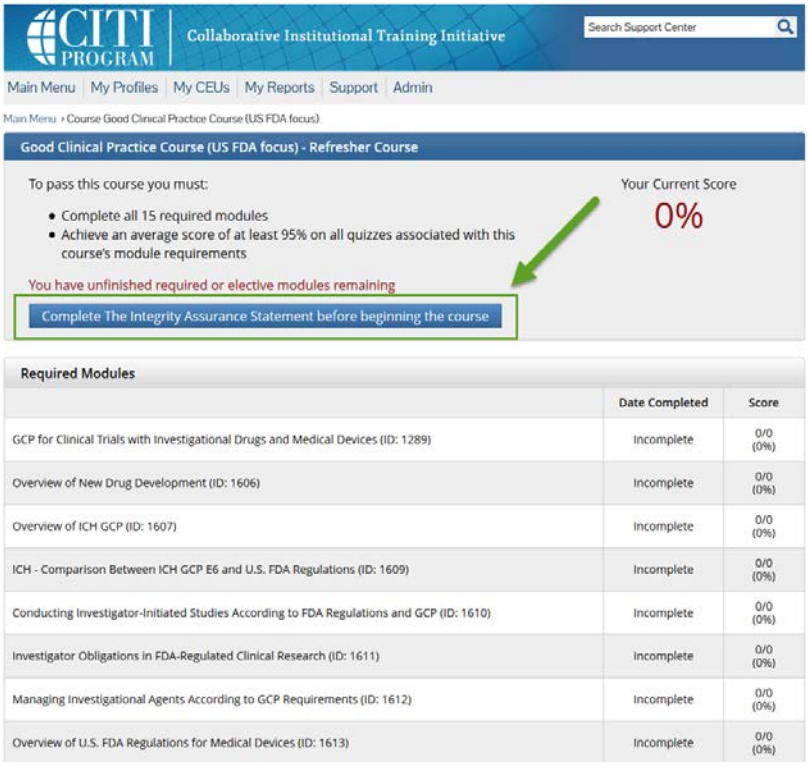
Note: if you need to complete initial Good Clinical Practice training, choose any of the highlighted courses below. *Human Subjects Research* will satisfy only the Human Subject Protection training requirement. *Responsible Conduct of Research* does NOT satisfy the Human Subjects Protection training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



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.



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.



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.