# CITI Program Training Instructions

**Version April 22, 2020:**

**Summary of Training**

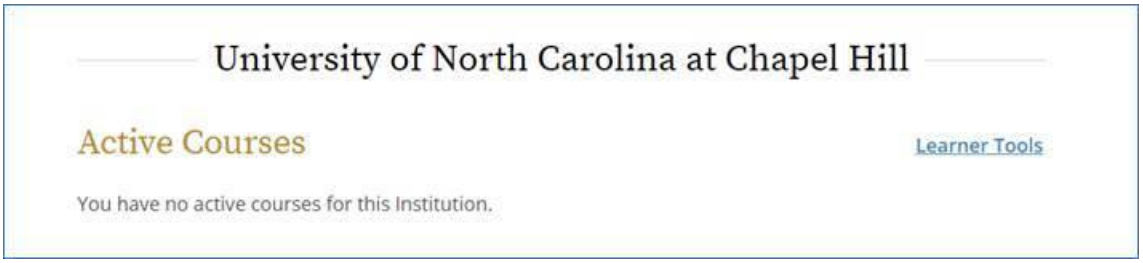


## Human Subjects Protection Training (HSP) – First Time Core Training

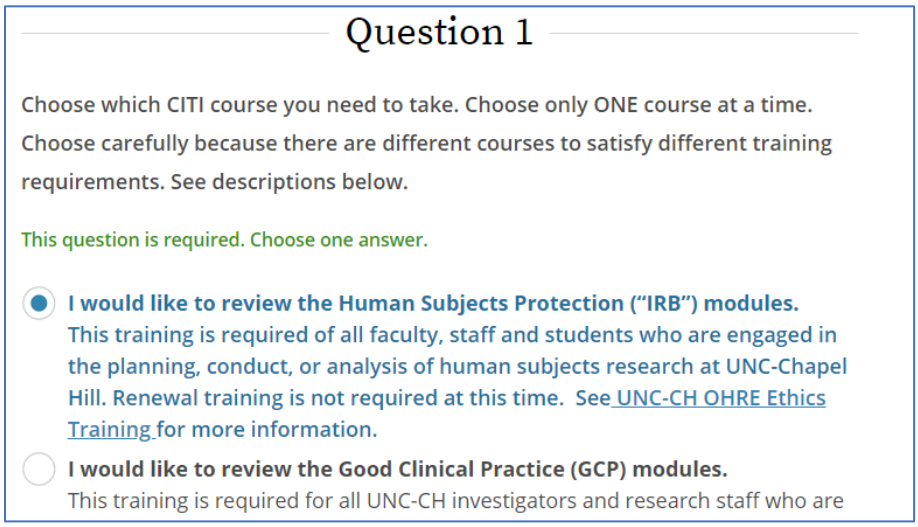
This training is required of all faculty, staff and students who are engaged in the planning, conduct, or analysis of human subject research at UNC Chapel Hill. The Human Subjects Protection modules are grouped by categories of research. You only need to complete one group of modules. You should choose the group that best fits the type of research you usually conduct. If in doubt, ask your IRB. Human Subjects Protection training must be renewed every three years, per UNC Chapel Hill policy. To complete the HSP refresher course, please follow these instructions.

- Group 1: Biomedical Research: Medical, physiological or pharmacological studies that typically involve direct contact with subjects. Includes, but is not limited to, research with drugs, devices or other interventions.
- Group 2: Social and Behavioral Research: Studies on sociological, psychological, anthropological or educational phenomena that typically involve direct contact with subjects. Does not include drug or device studies.
- Group 3: Data and Specimens ONLY: No direct contact with human subjects. Research limited to use of records, data (including secondary data sets), or biological samples.

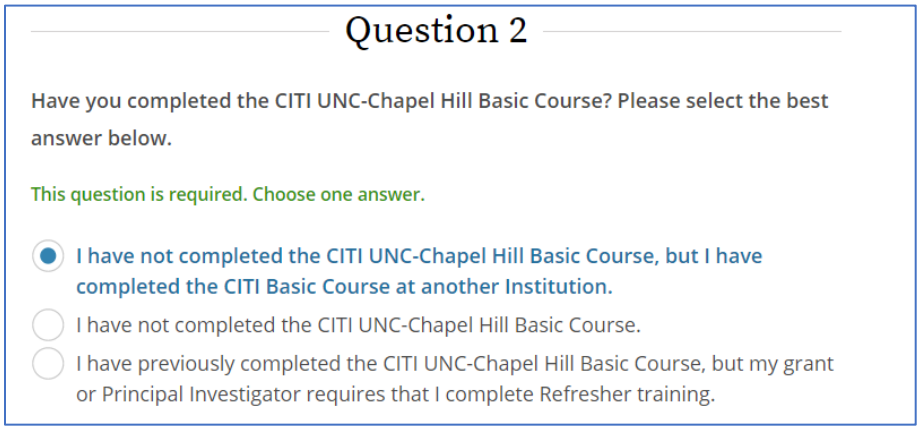
Under Learner Tools for UNC Chapel Hill, click Add a Course.




At Question 1, select "I would like to review the Human Subjects Protection ("IRB") modules.":

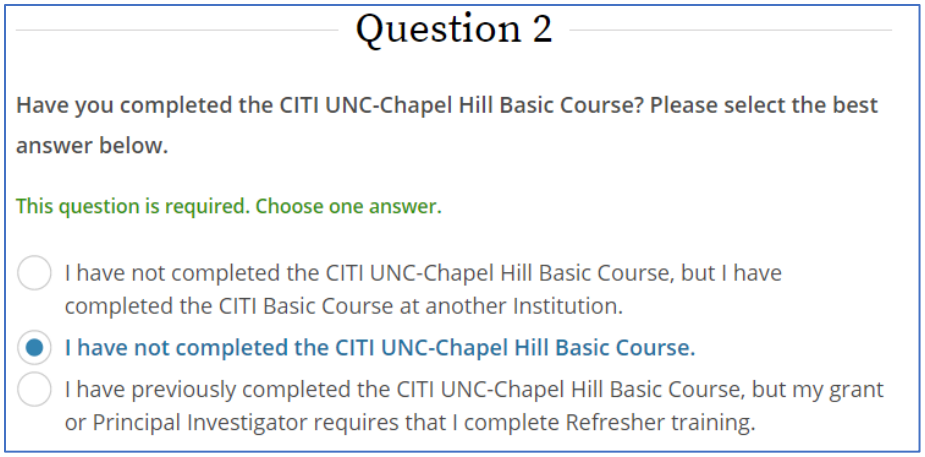



At Question 2, please confirm if you have already completed the course at another institution.

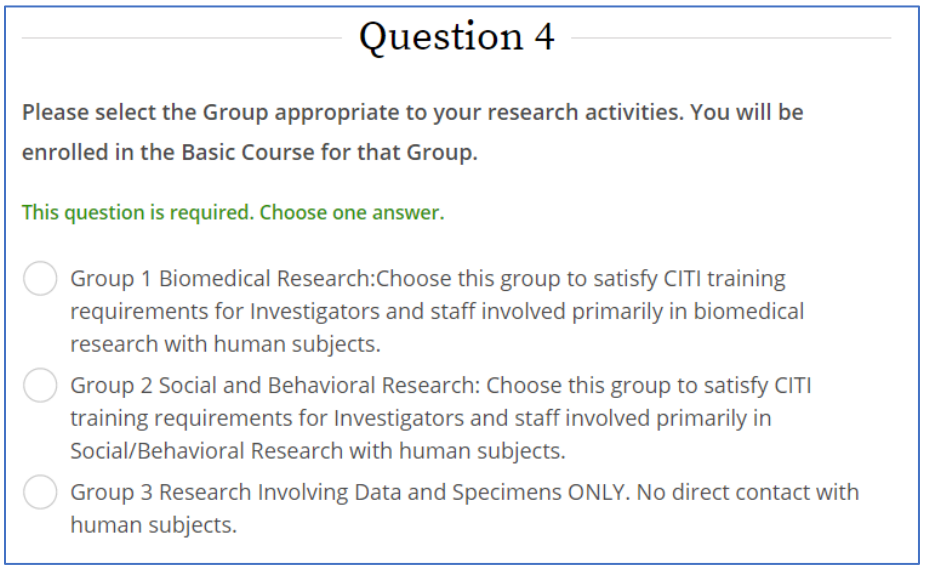



If you have, CITI will allow you to select the other Institution to see if any of the modules overlap. If they do, you will only be required to complete those that UNC Chapel Hill requires that have not yet been fulfilled.

If you have not yet completed a CITI Basic Course at another Institution, please select the second option:




At Question 4, make your selection regarding which Human Subjects Protection Training you wish to complete:




You should now be enrolled in the course(s) you selected. Complete all requirements, and your training will sync to the UNC Research Training Database in 24 hours.

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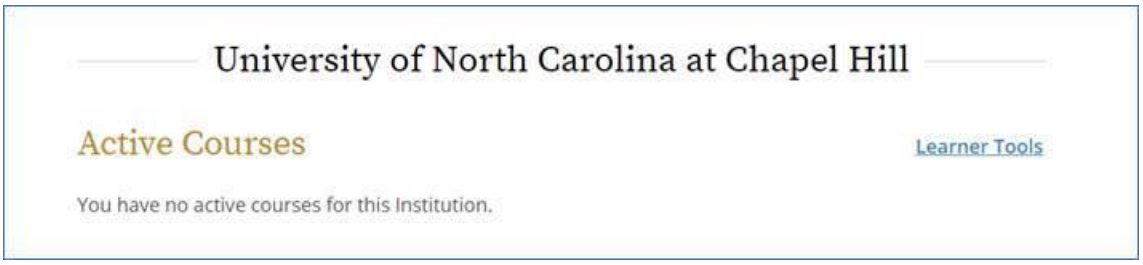
## Good Clinical Practice (GCP) – First Time Core Training

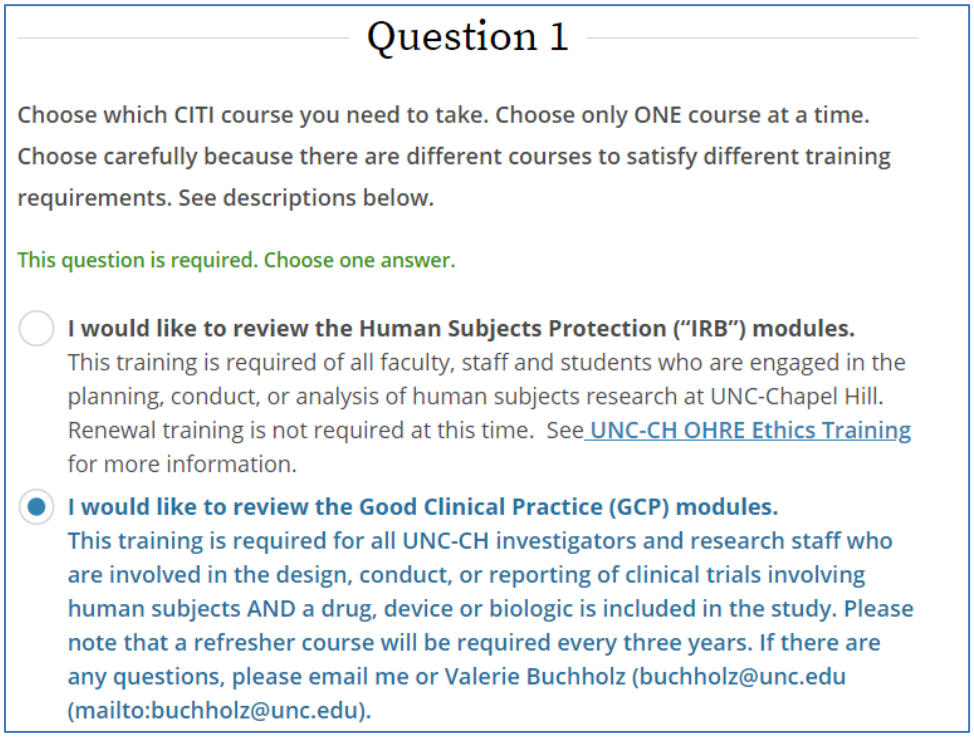
Good Clinical Practice training is required for all UNC Chapel Hill investigators and research staff who are involved in the design, conduct, or reporting of clinical trials involving human subjects AND a drug, device or biologic is included in the study. A refresher course will be required every three years. If you have already completed this requirement and wish to do a refresher course, please click here.

Under Learner Tools for UNC Chapel Hill, click Add a Course.

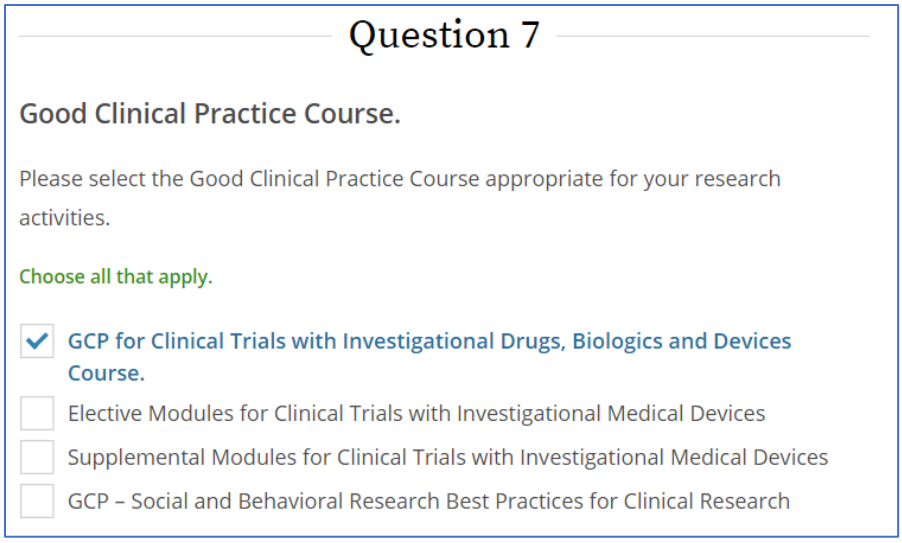




At Question 1, If you are taking GCP training for the first time, choose: I would like to review the Good Clinical Practice (GCP) modules.




At Question 7, please select the appropriate course for your research activities. 'GCP for Clinical Trials with Investigational Drugs, Biologics and Devices Course.' Is strongly recommended as it will fulfill the UNC Chapel Hill GCP training requirement:




You should now be enrolled in the course(s) you selected. Complete all requirements, and your training will sync to the UNC Research Training Database in 24 hours.

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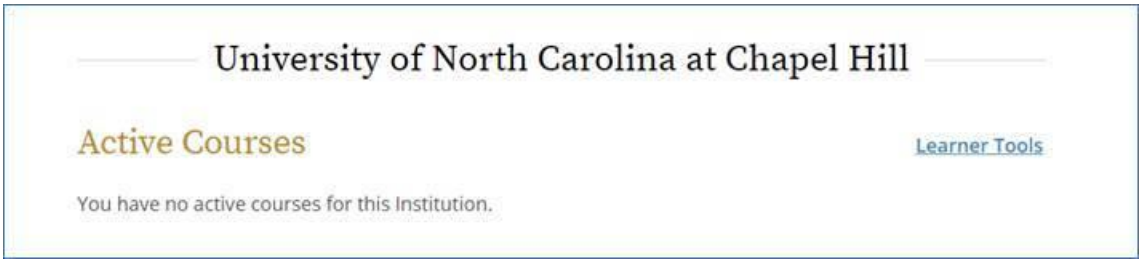
## Human Subjects Protection (HSP) – Refresher Course

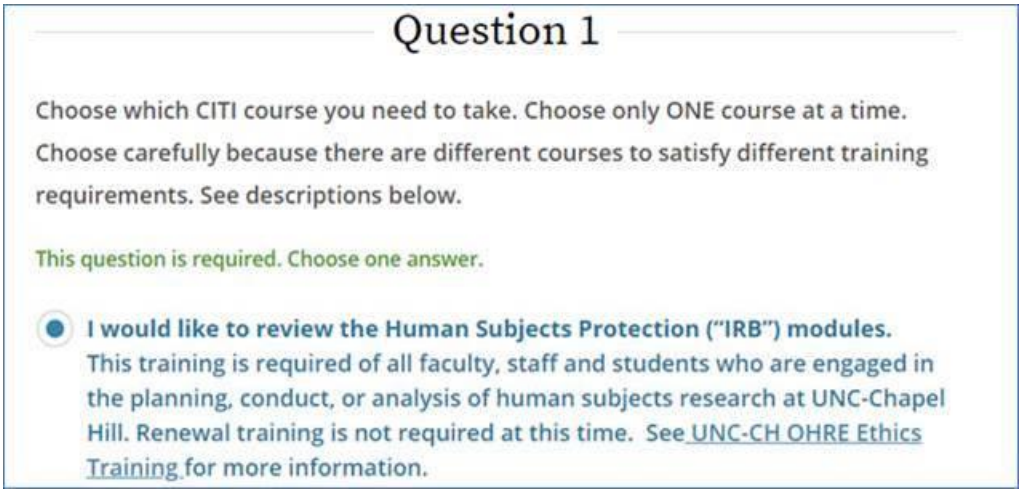
Human Subjects Protection training must be renewed every three years, per UNC Chapel Hill policy. To complete the HSP refresher course, please follow these instructions:

Under Learner Tools for UNC Chapel Hill, click Add a Course.

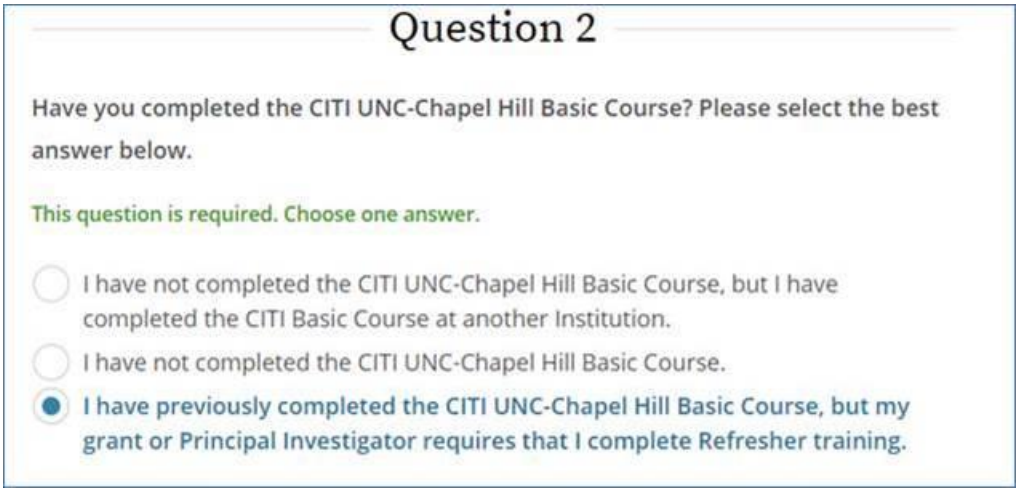




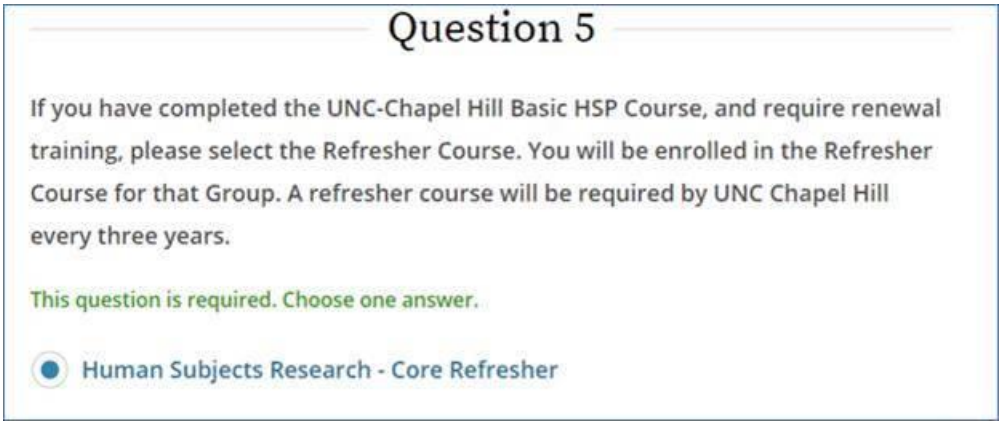
At Question 1, renew your Human Subjects Protection Training, choose: I would like to review the Human Subjects Protection ("IRB") modules.




Under Question 2, select: I have previously completed the CITI UNC-Chapel Hill Basic Course, but my grant or Principal Investigator requires that I complete Refresher training.




Under Question 5, select the Human Subjects Research - Core Refresher.



You should now be enrolled in the course(s) you selected. Complete all requirements, and your training will sync to the UNC Research Training Database in 24 hours.

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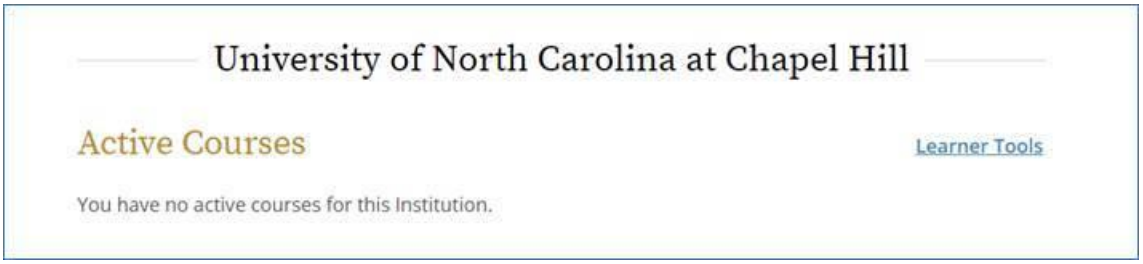
## Good Clinical Practice (GCP) – Refresher Course

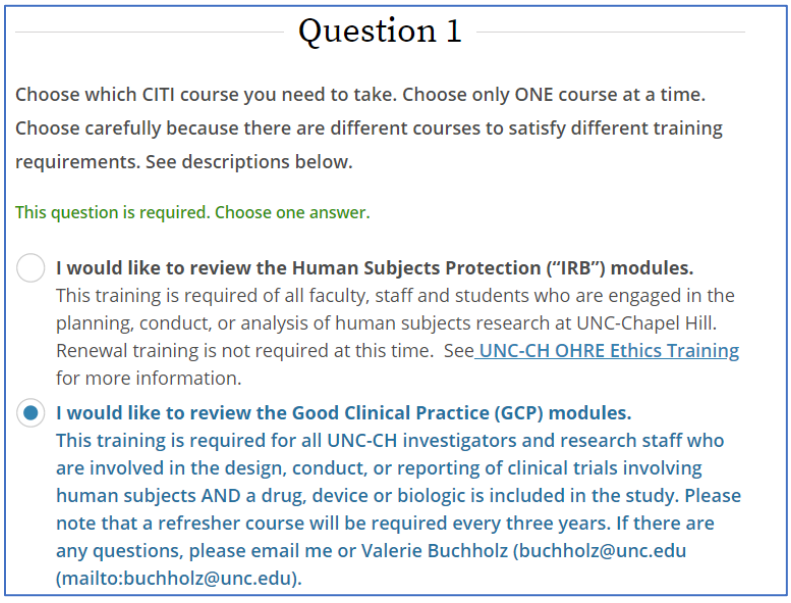
Good Clinical Practice training must be renewed every three years, per UNC Chapel Hill policy. To complete the GCP refresher course, please follow these instructions:

Under Learner Tools for UNC Chapel Hill, click "Add a Course".

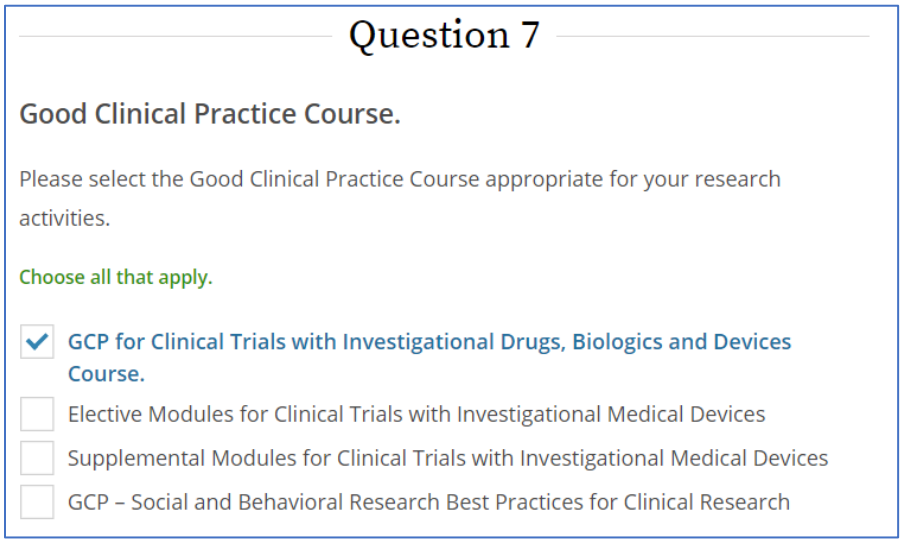




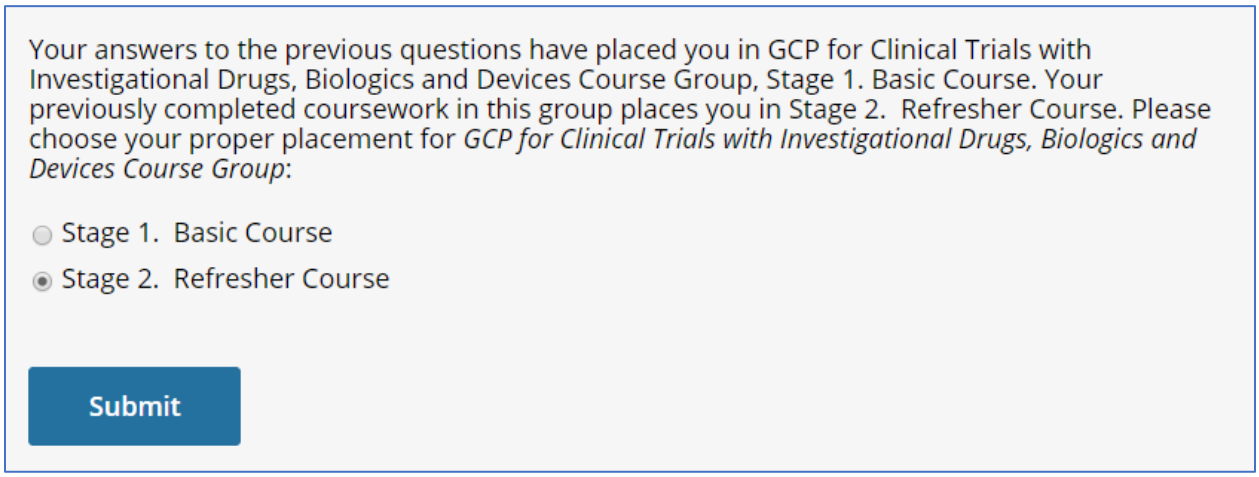
To renew your Good Clinical Practice Training, at Question 1, choose: I would like to review the Good Clinical Practice (GCP) modules.



At Question 7, please select 'GCP for Clinical Trials with Investigational Drugs, Biologics and Devices Course':




If you have previously completed the Basic Course and wish to complete the refresher, choose 'Stage 2. Refresher Course' to access the modules.




You should now be enrolled in the course(s) you selected. Complete all requirements, and your training will sync to the UNC Research Training Database in 24 hours.

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## Other Training

Additional training modules are available in the CITI Program from UNC Chapel Hill. Under Question 1, these include:

- Responsible Conduct of Research (RCR) course.
- Conflicts of Interest (COI)
- Clinical Trial Agreement (CTA)
- Clinical Trials Billing Compliance (CTBC)

- Clinical Research Coordinator (CRC) - Foundation
- Clinical Research Coordinator (CRC) - Advanced
- Good Laboratory Practice (GLP)
- Essentials of Grant Proposal Development
- Essentials of Research Administration
- Elective Modules - Select this option if you want to enroll in the 'Elective Modules' course.

## Conflict of Interest Training

Please note that this Conflict of Interest training offered by CITI is only required for UNC Health Network Entity Researchers:

> **Attention UNC Researchers:** If you are employed by UNC CH or UNC Health Medical Center, you must complete the UNC Chapel Hill COI training. Log in at http://coi-training.unc.edu. Completion of COI training is valid for 4 years.
>
> **Attention UNC Health Network Entity Researchers:** If you are employed by one of the UNC Health Network Entity hospitals (excludes UNC Medical Center), in addition to the trainings described above, CITI-based COI training is also required of individuals engaged in the planning, conduct (including obtaining informed consent), or analysis of human subjects research. Completion of COI training is valid for 4 years, after which a refresher course is required.

Contact the Office of Research Support & Compliance at ORSC@unchealth.unc.edu if you have questions about COI training.

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## More Information

For more information, please visit: https://research.unc.edu/human-research-ethics/getting-started/training/