

Compliance Advisory Services

NIH-Funded Studies and GCP Training Requirement

GCP Training Requirements

On September 16, 2016, the National Institutes of Health (NIH) issued a new policy, entitled “Policy on Good Clinical Practices for NIH Awardees Involved in NIH-funded Clinical Trials,” Notice Number NOT-OD-16-148. This policy was effective as of January 1, 2017.

Per NIH Policy, “all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practices (GCP), consistent with principles of the International Conference on Harmonisation (ICH) ER (R2).1.”

For additional information regarding the NIH policy, please see the full policy here:

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-148.html>

CITI Program GCP Module Revisions

The Collaborative Institutional Training Initiative (CITI Program) offers several GCP courses that fulfill the NIH policy for GCP training requirement. CITI Program’s GCP modules that reference ICH E6 were revised January 2017 to reflect the [Integrated Addendum to ICH E6 \(R1\): Guideline for Good Clinical Practice E6 \(R2\)](#) updated guideline.

CITI Program modules in a GCP FDA or ICH course completed after the revision date include the ICH E6 (R2) material. Learners who have completed the module after the revision date have satisfied the NIH GCP training requirement.

Review the CITI Program module effective dates here:

<https://support.citiprogram.org/customer/en/portal/articles/2468008-transcelerate-mutually-recognized-gcp-training#read>

The CITI Program courses are available to all UC San Diego employees and students free of charge. For additional information regarding the CITI program GCP training modules, visit: <https://about.citiprogram.org/en/series/good-clinical-practice-gcp/>

How to Expire a CITI Training Module

If your GCP Training Module hasn’t expired and you need to retake it in order to be compliant with NIH regulations, please send your name, UCSD email address, and your CITI member ID number to Compliance at rcp@ucsd.edu.

We will submit your information to CITI and your course will be manually expired. An auto email from CITI will alert you that your course has expired and you will then be able to retake the course.

Do I need to take CITI GCP training?

- You are NOT involved in the conduct, oversight, or management of an NIH-funded clinical trial
- OR
- You have taken the required modules after the January 2017 revision date

No

- You ARE involved in the conduct, oversight, or management of an NIH-funded clinical trial
- AND
- You have NOT taken the required modules after the January 2017 revision date

Yes

If you have any questions, please contact Compliance at (858) 657-7487, email rcp@ucsd.edu, or visit the Compliance Intranet <https://pulse.ucsd.edu/departments/research-compliance/Pages/default.aspx>

Contact Us

Please send your questions, comments, and feedback to the Compliance Advisory Services at (858) 657-7487 or rcp@ucsd.edu.