GCP Training and the New NIH Policy

On September 16, 2016, the **National Institutes of Health (NIH)** issued a *new policy* (Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials; NOT-OD-16-148) that specifies **NIH-funded investigators and staff should be trained in Good Clinical Practice (GCP)**.

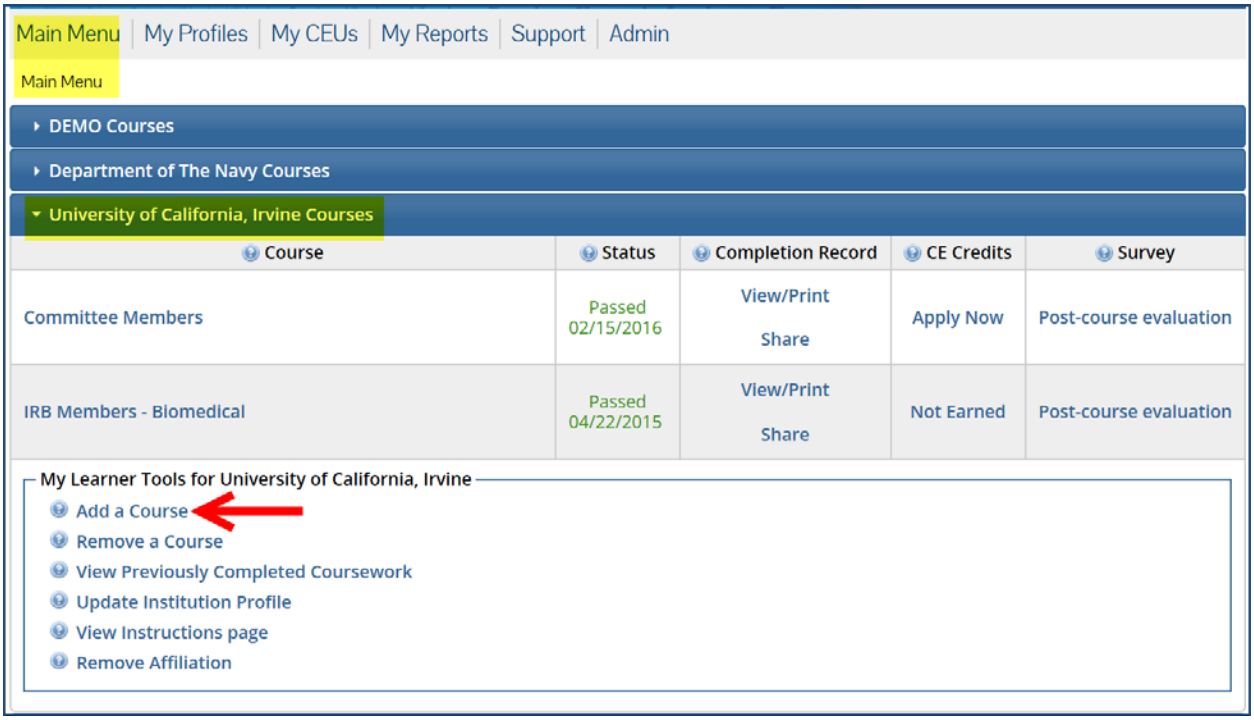
Who does this new policy apply to?	The NIH (2016) policy states that **all NIH-funded investigators and staff "who are involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonisation (ICH) E6 (R2)."**
Is GCP training the same as human subjects protection training?	No. GCP training is an additional separate training and is not basic human subjects protection training. GCP principles are specific to clinical trials and include international ethical and scientific quality standards for designing, conducting, recording, and reporting clinical trials.
Does CITI Program offer GCP training that is compliant with the NIH policy?	Yes. CITI Program offers GCP courses that are acceptable GCP training for the NIH policy. Acceptable GCP Training for NIH Policy on Good Clinical Practice Training - Good Clinical Practice (US FDA focus), and Refresher Course - GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus), and a Refresher Course - GCP for Clinical Investigations of Device, and a Refresher Course
When is this policy effective?	This policy takes effect January 1, 2017. **A refresher GCP course should be completed every 3 years.**
Who else requires GCP compliance?	The U.S. Food and Drug Administration (FDA) requires *GCP compliance* for studies conducted under an investigational new drug application or investigational device exemption.

Finding GCP Courses in CITI

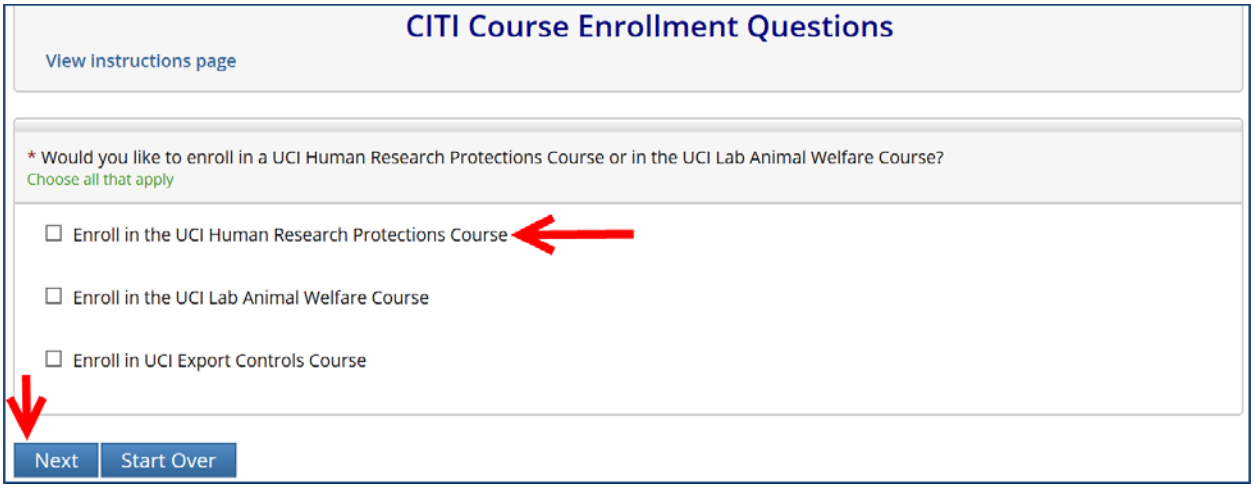
Step 1: Login: https://www.citiprogram.org/

** Be sure to affiliate with **UC Irvine**, and use your **UCI email address** for your CITI profile*

Step 2: Main Menu – select ***"Add a Course"***



Step 3: Course Enrollment Questions - select ***"Enroll in the UCI Human Research Protections Course"***



Step 4: Select the course(s) [or refresher] appropriate for your study

RESEARCHERS/RESEARCH PERSONNEL
OPTIONAL

- ☐ Research with Children - SBE
- ☐ Vulnerable Subjects - Research Involving Children
- ☐ Consent in the 21st Century
- ☐ Tools used by Researchers
- ☐ Informed Consent and Incidental Findings in Research with Human Subjects
- ☐ Non-US Centric Modules for the International Research Community
- ☐ Recognizing and Reporting Unanticipated Problems involving Risks to Subjects or Others in Biomedical Research
- ☐ Unanticipated Problems and Reporting Requirements in Social and Behavioral Research
- ☐ Community Based Researchers course
- ☐ Social & Behavioral Investigators in Spanish
- ☐ Good Clinical Practice (GCP)
- ☐ GCP for Clinical Trials with Investigational Drugs and Medical Devices
- ☐ GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus)
- ☐ GCP FDA Refresher
- ☐ GCP ICH Refresher
- ☐ GCP Device Refresher
- ☐ Clinical Research Coordinator (CRC)