

New Good Clinical Practice Training Requirements

The NIH's National Center for Advancing Translational Sciences (NCATS) is leading an initiative to promote Good Clinical Practice (GCP) training to ensure that investigators who conduct clinical trials are appropriately trained. Indiana University Health Ball Memorial Hospital, Inc. supports this training initiative as an essential step toward further ensuring the protection of trial participants and the quality of clinical trial results.

Accordingly, effective January 1, 2017, the IU Health Ball Memorial Institutional Review Board (IRB) will require Good Clinical Practice (GCP) training for Principal Investigators of interventional clinical studies. This requirement will apply to new interventional clinical studies and renewals of interventional clinical studies submitted after January 1.

For the purposes of consistency and tracking, GCP training must be completed through the CITI program. CITI GCP training is valid for three years, and CITI GCP training completed within the last three years will be accepted. A GCP refresher course is now available in CITI for expired GCP courses. Sponsors may accept completion of CITI GCP training in lieu of sponsor-provided GCP training.

How can I access this course?

1. Login in to your CITI account at www.citiprogram.org.
2. Select "Indiana University/IU Health Courses"
3. Under Select Curriculum-Indiana University/IU Health, Question #3, Would you like to take the CITI GCP course? Choose: "Yes, I would like to enroll in the GCP course."
4. Scroll to the end and select "Submit."
5. The GCP course is now added to your list of available courses.
6. Click on Good Clinical Practice (in blue) and the required modules will appear. (There are 14 modules)

If you have any trouble logging in or gaining access to CITI courses, contact Alfreda Bright at abright@iuhealth.org or 765.747.8458.



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