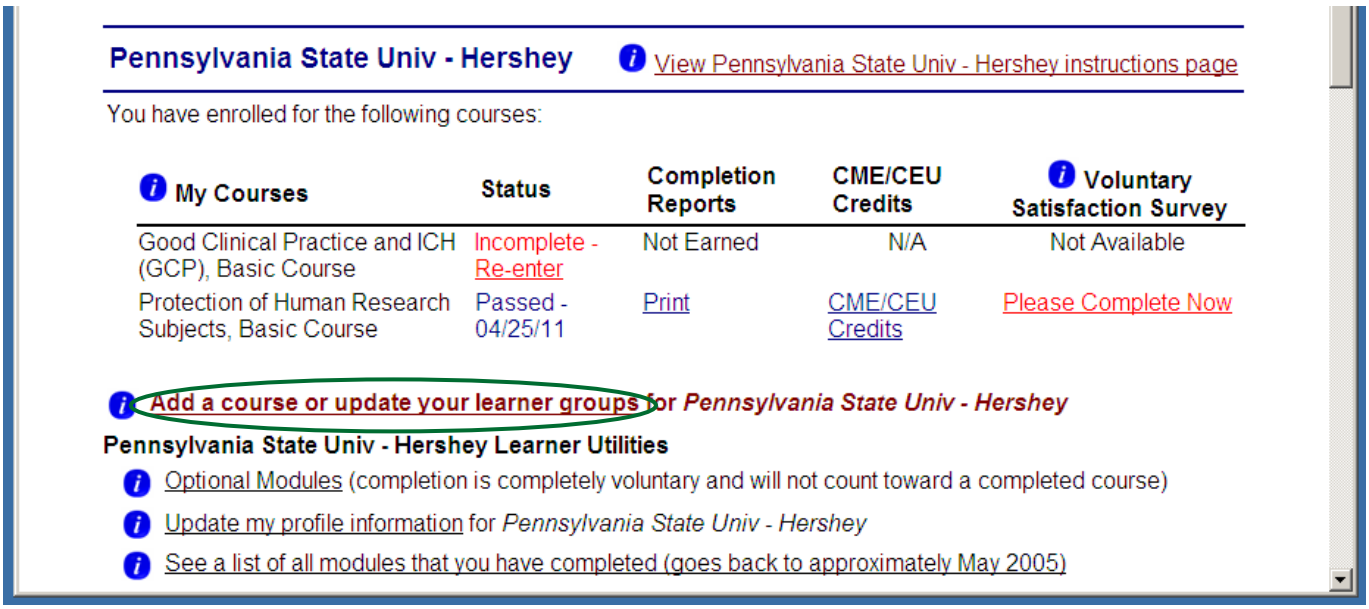
July 2011 HSPO Update

Good Clinical Practice Course Required for FDA-Regulated Research

As previously announced, effective July 1, the CITI Good Clinical Practice (GCP) course is required for all key personnel on research that is regulated by the Food and Drug Administration (FDA). This is in addition to the 'Protection of Human Subjects (HSP)' course. Personnel on FDA-regulated research must complete both courses, and meet the 3-year continuing education requirement when applicable. The requirements must be met before the Institutional Review Board (IRB) will accept new submissions or modifications to add personnel to a study. The GCP course is available in the Penn State Hershey online curriculum, CITI - Collaborative Institutional Training Initiative. Detailed CITI Course Instructions are provided on the web, and brief steps are listed below to add a course to existing curriculum. For login assistance or a forgotten *user name* call the HSPO at 531-5687. (Also, the CITI login page provides a forgotten *password* link, if needed.)



To Add a Course or update your learner groups

- Log in at www.citiprogram.org, for Penn State Univ – Hershey, and select 'Add a course or update …'
- Under the Human Research Protection courses, select the desired one (only the following are required courses):
  - *Protection of Human Research Subjects – Biomedical course*
    - *If you are asked to confirm the level it means your renewal is due soon, so choose the Refresher level*
  - *Good Clinical Practice and ICH Course (GCP)*
- On the next screen, you may decline 'Responsible Conduct of Research (RCR)' courses, which are optional
- Back on the CITI Main Menu, the newly selected course(s) will load with a red link to enter a course

Tip: Under Learner Utilities, you can also select 'Click Here to See Your Previously Completed Coursework' and print certificates.

For questions or CITI login assistance, please call the HSPO at 531-5687.