

DF/HCC GCP Training Requirement Update

Guidance

January, 2017

Important components of the updated Good Clinical Practice (GCP) training requirement per [EDU-100](#) (effective 2/28/17)

1. GCP training will be required for Research Personnel conducting human subject research overseen by the DF/HCC. Individuals who only participate in Not Human Subject Research (NHSR) and IRB-Exempt research are excluded from the GCP requirement*
2. Individuals must complete GCP training at least every 3 years. (Previously, DF/HCC only required Investigators to complete this training as a one-time requirement.)
3. The GCP training requirement is in addition to the current Human Subject Protection (HSP) training requirement that applies to all research personnel. Both trainings may be accessed through the CITI website. Please refer to the DF/HCC website site for up to date information and instructions on both trainings: <http://www.dfhcc.harvard.edu/research/clinical-research-support/clinical-research-education/>

**Note: Researchers working on NHSR and IRB-Exempt research are still required to complete the appropriate Human Subject Protection training through CITI (Group 3: Exempt/NHSR Research)*

GCP Training FAQs

Why is the GCP training requirement changing?

DF/HCC policies were revised to align with enhanced GCP training requirements from the NIH that became effective on January 1, 2017. Please see: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-148.html>

How is Research Personnel defined? Who falls under this requirement?

Research personnel includes individuals, identified by the Principal Investigator, who participate in study design, coordination, data collection and data management. The research team includes, but is not limited to, subinvestigators, research coordinators, study coordinators, research nurses, research pharmacists and clinical research biostatisticians. Typically, if someone was required to take Human Subject Protection Training [e.g., Biomedical Research (Group 1), Social/Behavioral Research (Group 2), or Combined Biomedical and Social/Behavioral Research (Group 4) through CITI], they will also require GCP training going forward.

Who may be excluded from this requirement?

Research personnel who work exclusively on Not Human Subject Research (NHSR) or IRB-Exempt research are not required to complete GCP training at this time.

Additionally, individuals that support the research by performing routine procedures (e.g., laboratory and pharmacy technicians, infusion nurses, radiologists, pathologists), are generally not required to complete GCP training unless the PI determines that an individual makes a direct and significant contribution to the research.

What GCP trainings are accepted by DF/HCC?

Primarily, DF/HCC offers GCP and HSP training through the CITI program. Through CITI, researchers can meet the requirement by initially completing the basic GCP, and then completing the refresher GCP course every three years. Other equivalent GCP training may be accepted with approval from the Office of Data Quality.

If your CITI account is linked with DFCI, we offer a combined HSP/GCP course. For instructions on completing CITI HSP and GCP under the DFCI affiliation, please see: http://www.dfhcc.harvard.edu/crs-resources/ODQ_Documents/07_Education/CITI_Step_by_Step_Instructions.pdf. You do not need to enter a DFCI email address to affiliate with DFCI.

If you take a GCP course outside the CITI program, or through the CITI program affiliated with an institution other than Dana-Farber Cancer Institute (e.g., MGH or BIDMC), please be sure to send your completion certificate to ODQEducation@dfci.harvard.edu. Those taking CITI GCP linked with DFCI do not need to forward a separate copy of their completion certificate as they are sent automatically.

The CITI GCP course focuses on drug and device trials; is there a Social-Behavioral Research GCP course that is acceptable in lieu of the CITI course?

The following Social-Behavioral specific GCP course meets DF/HCC requirements: <http://www.sbm.org/training/good-clinical-practice-for-social-and-behavioral-research-elearning-course>

You will need to create an account with the Society of Behavioral Medicine (SBM) to complete this training, if you don't already have one. Be sure to send your certificate to ODQEducation@dfci.harvard.edu if you complete training through this option.