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GCP Training –New NIH Policy Reminder

- The NIH issued a new GCP training requirement effective January 1, 2017
- Investigators and clinical trial staff* (including study coordinators, research nurses, sub-investigators) must complete GCP training at least every 3 years.
- If you have not completed formal GCP training with the past 3 years, please do so through the CITI website. See: GCP Training Instructions Step-By-Step.
- Please send a copy of GCP training records to ODQEducation@dfci.harvard.edu.
- DF/HCC is currently reviewing and revising our internal policies to ensure we are aligned with the new NIH requirement. The updated DF/HCC policy and corresponding compliance tracking of GCP training will not be effective until February, 2017; however, research staff that will require GCP training under the NIH policy should immediately take steps to ensure compliance prior to January 1, 2017.

* The NIH defines investigators and clinical trial staff as follows:

Investigator: The individual responsible for the conduct of the clinical trial at a trial site. If a clinical trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

Clinical trial staff: Individuals, identified by the investigator, who are responsible for study coordination, data collection and data management. The central focus of clinical trial staff is to manage participant recruitment and enrollment, to maintain consistent study implementation, data management, and to ensure integrity and compliance with regulatory and reporting requirements. These individuals may also seek informed consent from prospective participants, enroll and meet with research participants, and collect and record information from research participants. Clinical trial staff may also be called the research coordinator, study coordinator, research nurse, study nurse or sub-investigator.