TITLE: Documenting Study-Specific Training	
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Applicable Regulations & Guidelines:

21 CFR 312.53	Selecting Investigators and Monitors
Sections 4.1, 4.2	International Conference on Harmonization; Good Clinical Practice: Consolidated Guideline, May 1997

Other References: Delegation of Responsibility and Study Training Log (template)

Responsible Personnel: DF/HCC Principal Investigator (PI) or study staff designee

Policy Statement: The PI or study staff designee is responsible for ensuring training on study-specific tasks and documentation of this training.

Procedure:

1) The PI or study staff designee will provide study-specific training for research protocols **as appropriate**.

2) Training includes, but is not limited to:
   - Initial training delivered at the site initiation visit
   - Consenting process
   - Ongoing training for modifications to study procedures
   - Training of new or replacement staff added after the site initiation visit
   - Study staff of all protocols utilizing electronic data capture (eDC) through the QACT must have training in Phase Forward "Inform" conducted by the QACT office.

3) The method to document study-specific training will vary according to the mechanism provided by the sponsor.
   - For industry sponsored studies, use the document(s) provided by the company.

   - For cooperative group or PI-initiated studies there is no document provided by the sponsor. The *Delegation of Responsibility and Study Training Log* template must be utilized. It is located on the DF/HCC Clinical Research Operations website (http://www.dfhcc.harvard.edu/clinical-research-support/clinical-research-operations-cro/).