

Dear DF/HCC Research Community,

The following revised policies have been posted to the Clinical Research Unit website. Most updates are administrative.

PM-401: Clinical Research Records Maintenance and Storage:

Responsible Personnel: Was revised The first sentence of item 1) has been revised to: "The PI or designee is responsible for contacting the study sponsor in order to determine how long study records must be maintained and **must obtain sponsor approval** prior to the destruction of any records. If there is no sponsor and **no IND then the records retention is per institutional policy. If the study is a sponsor-investigator IND trial, then** the FDA 21 CFR Part 312 (c) is followed..."

QA-705: Responsibilities of the Audit Subcommittee:

References and Responsible Personnel were updated. Item 5) was revised to include "**When the subcommittee determines audit findings are unacceptable, the CLINPOC Chair and Co-Chair are notified and can take immediate action if needed. At the next full committee meeting,...**"

QA-706: Notifying DF/HCC of External Audits for Clinical Research

References were updated, item 4) now reads "**The Audit Subcommittee** and the Clinical Investigation Policy and Oversight Committee (CLINPOC) reviews external audits and their findings **quarterly**, and determines if **an internal** re-audit or other action is required."

QA- 713: Centralized National Cancer Institute (NCI) Annual Investigator Registration:

This SOP was updated to update the references and item 4) and the management of this process has changed from QACT to CTEO.

QA-718: QACT Data Monitoring:

Updated Responsible Personnel and other minor administrative changes.

QA-719: Audit Preparation and Response:

Clarification on when a written corrective action is required plus minor administrative updates.

QA-720: Internal Auditing of Clinical Trials

References and Responsible Personnel were updated along with other minor administrative changes.

To access this site from the Clinical Trials Portal, click on Clinical Research Unit which is located just below OPRS on the Portal Menu.

To access this site directly from the DF/HCC intranet: [<http://www.dfhcc.harvard.edu/clinical-research-support/clinical-research-operations-cro/policies-and-procedures/>](http://www.dfhcc.harvard.edu/clinical-research-support/clinical-research-operations-cro/policies-and-procedures/)

Please contact Jane or Nancy below with any questions.

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