Summary of Revisions
DF/HCC Policies, Operations, and Related Documents
Changes Effective: August 1, 2019

No formal documentation of training on the following policy updates is required. Below is a summary of key revisions. Tracked versions are available for review on the DF/HCC website – Policy Updates Page.

RCO-100: Investigator-Sponsored Research

- Combined with RCO-101 (to be retired effective 8/1/19)
- Content, language and definitions expanded to include all DF/HCC investigator-sponsored research, including non-IND/IDE research
- Added language regarding requirements for investigators collaborating with external parties on DF/HCC-sponsored research
- Removed language on IND Safety Reports (moved to RCO-204)
- Procedural language about obtaining and maintaining and IND and IDE moved to two new DF/HCC Operations:
    - *RCO-OP-4: Obtaining and Maintaining an IND*
    - *RCO-OP-5: Obtaining and Maintaining an IDE*

RCO-204: Reporting Adverse Events

- Sections 5.13. and 5.14. Language regarding IND Safety Reports added (moved from RCO-100)
- Updated to clarify investigator responsibilities regarding IND Safety Reports for DF/HCC-sponsored research
- Section 5.4. Language revised to state that clinically significant test results must be documented as adverse events, but abnormal results that are not clinically significant are not considered adverse events.

RCL-100: Preparation for Site Close Out

- Revised to encompass all DF/HCC research rather than limited to FDA-regulated (IND/IDE) research
- Language reorganized and edited to clarify requirements for both investigator-sponsored and externally sponsored research

Minor/Administrative Updates

AUD-100: Audits and Inspections

- Section 5.2.2.2. Language added to clarify that DF/HCC is unable to host external sponsor or their representatives during on-site regulatory inspections

RCL-101: Record Retention for Completed Research

- Section 5.1. Language moved from previous section 5.5. to clarify investigator (or designee) responsibilities for teams without dedicated or centralized disease programs

Other New/Revised Documents:

- Requirements for DF/HCC Collaborations with External Parties (NEW)
- Transfer of Obligations Template (NEW)
- Regulatory File: Required Document List (REVISED)

Newly Retired Policies – Effective 8/1/19

- RCO-101 (Combined with RCO-100)
