Summary of Revisions
DF/HCC Policies, Operations, and Related Documents
Changes Effective: January 31, 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.

Updates to Policy Content and Requirements

ADM-100: Creation and Maintenance of DF/HCC Policies and Operations

- Added comprehensive definition of Human Subject Research as it applies to DF/HCC research and policies.

DATA-100: Data Management of Investigator-Sponsored Therapeutic Protocols

- Combined with DATA-103 (to be retired as of 1/31/19) to create one comprehensive policy for data management and compliance for investigator-sponsored therapeutic trials.
- Updated to reflect current data request, missing forms report, and data management requirements. Language regarding paper CRFs removed.
- Updated/New DF/HCC Operations
  - *DATA-OP-1: Data Requests*
  - *DATA-OP-2: Obtaining Missing Forms Reports* (new)

MULTI-100: DF/HCC Investigator-Sponsored Multi-Center Research

- Updated with single IRB requirements from the revised Common Rule.
- Clarified what is considered an External Site engaged in human subject research and the requirements for training and approval.

RCO-204: Reporting Adverse Events

- Clarified IND safety report review language. Note that the use of portals is acceptable to DF/HCC when accompanied by direct notification. DF/HCC recognizes that sponsors may use different methods to communicate the unanticipated problem determination and fulfill their regulatory obligations.

RCO-205: Reporting of Protocol Deviations, Violations and Exceptions

- Updated with single IRB requirements from the revised Common Rule.

REGIST-100: Eligibility Checklists

- Section 5.2: ODQ will now create standardized eligibility checklists using the IRB-approved protocol document. For more information, please see the FAQ on this change.
- Combined with REGIST-104 (retired as of 1/31/19)
- New DF/HCC Operation:
  - *REGIST-OP-3: Eligibility Checklist Development*

REGIST-101: Subject Registration

- Combined REGIST-101A and 101B (centralized vs. decentralized registrations)
- Section 5.5.: Clarified the study team's responsibility for updating subject information in OnCore for randomized trials where the initial registration/randomization is performed centrally by ODQ.
- Section 5.7.: Updated to allow for summary accrual reporting in limited situations
- Updated DF/HCC Operation:
    - *REGIST-OP-1: Subject Registration*

Reorganized and Combined Policy Language

AUD-100: Audits and Inspections

- Combined with AUD-101 (retired as of 1/31/19) to create one comprehensive policy for both internal audits and external regulatory inspections.
- Updated/New DF/HCC Operations and documents:
    - *AUD-OP-1: Internal Auditing Procedures*
    - *AUD-OP-2: FDA and Other Regulatory Inspections*
    - *DF/HCC External Regulatory Inspections Contact List*

COM-100: Human Research Oversight and Operations Committees

- Combined with COM-101, COM-102, and COM-103 (retired as of 1/31/19) to create one comprehensive policy for DF/HCC oversight and operations committees.
- New DF/HCC Operations:
    - *COM-OP-2: Accrual Monitoring Procedures and Criteria*
    - *COM-OP-3: CLINOPS Procedures*
    - *COM-OP-4: CLC Procedures*
    - *COM-OP-5: DSMC Procedures, Review and Data Compliance*
    - *COM-OP-6: DSMB Procedures and Review*

DOC-100: Research Subject Documentation

- Combined with DOC-100, DOC-101 and DOC-102 (retired as of 1/31/19) to create one comprehensive research documentation policy.
- Clarified requirements regarding confidential questionnaires in section 5.2.1.2

RCO-100: Responsibilities of the Sponsor Conducting Research Involving a Drug

- Minor administrative updates throughout to update references and policy language.

RCO-101: Responsibilities of the Sponsor Conducting Research Involving a Device

- Minor administrative updates throughout to update references and policy language.

RCO-102: Responsibilities of Investigators

- Combined with RCO-206 (retired as of 1/31/19)
- Minor administrative updates throughout to update references and policy language.

RCO-103: Confidentiality and Secondary Use of Research Information

- Combined with CON-103 (retired as of 1/31/19).

- Title updated to reflect combined content.

RCO-203: Regulatory Documentation

- Combined with RCO-200, RCO-201, RCO-202 (retired as of 1/31/19) to create one comprehensive policy on regulatory documentation.
- Section 5.2.1.1: IRB-determined minimal risk research is exempt from delegation of authority log requirement.
- New Operations and Documents:
    - *RCO-OP-3 Completing the FDA Form 1572.*
    - *DF/HCC Regulatory File – Required Document List*

Other New/Revised Documents:

- REGIST-OP-4: NCI Clinical Trials Reporting Program (CTRP) Compliance
    - Converted to operation from REGIST-202(retired as of 1/31/19)
- RCO-OP-3: Performance of Protocol Specified Procedures at Non-DF/HCC Sites
    - Converted to operation from RCO-207 (retired as of 1/31/19)
- DF/HCC Site Management Plan
    - Updated throughout to align with current DF/HCC Policies and institutional practices.

Retired Policies – Effective 1/31/19

- COM-101 (Combined with COM-100)
- COM-102 (Combined with COM-100)
- COM-103 (Combined with COM-100)
- DATA-103 (Combined with DATA-100)
- RCO-200 (Combined with RCO-203)
- RCO-201 (Combined with RCO-203)
- RCO-202 (Combined with RCO-203)
- RCO-206 (Combined with RCO-102)
- RCO-207 (Converted to DF/HCC Operation)
- REGIST-104 (Combined with REGIST-100)
- REGIST-202 (Converted to DF/HCC Operation)

Notice of Administrative Update: All DF/HCC Policies and supporting documents were updated to reflect the departmental name change of Research Informatics Operations (RIO) *[formerly the Clinical Trials Research Informatics Office (CTRIO)]* and job title for Office of Data Quality (ODQ) Clinical Research Systems Specialist *[previously Protocol Systems Coordinator (PSC)]*.