**Summary of Policy Updates**
**Changes Effective: September 30, 2022**

*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.*

# Summary of Policy Updates

## Significant Updates

### RCO-204: Safety and Event Reporting

- Updated the requirement for documentation of expectedness to better align with recent changes to DFCI IRB policy.
- Clarified the expectations for timely review and documentation of adverse events.
- Added statement regarding review and use of central lab results when local lab results are used for patient care determinations.

### MON-101: Research Conduct Oversight by External Sponsors

- Site qualification language updated to reflect changes to onsite tours and use of virtual tours.
- Updated expectations for monitors and monitoring visits, including receipt of monitoring reports and scheduling remote monitoring activities.

### INV-103: Protocol Mandated Drug Taken at Home

- Updated to clarify that standard of care/ancillary medications provided by the sponsor typically do not qualify as protocol mandated drug, and therefore documentation for dispensation and return of these medications is not required
- Language added to include pertinent information to be included in the drug diary, and clarify that both paper and electronic drug diaries are acceptable tools of documentation

## Minor Updates/Clarifications

### COM-100: Research Oversight and Operations Committees

- Administrative updates to roles and responsibilities, and language added to clarify who appoints SRC chairs.

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

- Updated to clarify that ODQ and RIO are only able to provide central data management support when DF/HCC data capture systems are used.

### DATA-101: Case Report Form Development

- Minor updates to bring policy language in line with current CRF development processes.

### DOC-100: Research Subject Documentation

- Minor clarifications for how to correct a documentation error, and documenting sponsor/IRB approval of deviations, exemptions, and waivers.

**EDU-100: Training Requirements for Research Personnel**

- Minor edits to references, and to remove "interventional" from definitions as not used in policy.

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

- Minor grammatical and reference updates throughout.

**RCL-100: Preparation for Site Close Out**

- Minor clarifications throughout, including removing Research Nurse as responsible personnel and updating the definition of completed protocol.

**RCO-100: Investigator-Sponsored Research**

- Added a statement that the sponsor-investigator of research under an IND/IDE must submit new projects or changes to FDA prior to submitting them in iRIS for SRC/IRB review.

**RCO-103: Confidentiality and Secondary Use of Research Information**

- Added a statement that all research staff are responsible for ensuring that staff have appropriate access and that access be removed when an individual leaves or changes roles.
- Added that breaches of confidentiality should be reported to the appropriate Privacy Officer and the DFCI IRB, even if the study is under an external IRB.
- Clarified that data sharing restrictions do not apply to an established DSMB or similar committee specified in the protocol.

**RCO-203: Regulatory Documentation**

- Added definition for the delegation of authority, and updated examples of staff typically not listed to include phlebotomists, dermatologists and ophthalmologists.

**REGIST-101: Subject Registration**

- Updates to the required timing of subject registrations.
- Minor updates to clarify when summary accrual reporting is allowed

**REGIST-200: Registration of Clinical Trials on ClinicalTrials.gov**

- Minor updates to outdated references/links