Summary of Policy Updates

Changes Effective: May 31, 2023

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.

INV-100: Research Pharmacy Standard Policy

- Section 5.9.1. Language added to clarify that pharmacists with Collaborative Drug Therapy Management (CDTM) qualifications may be delegated additional tasks, and must be listed individually on the delegation log.
- The DF/HCC Delegation of Tasks key has also been updated to include CDTM Pharmacist column with additional delegated tasks.

RCO-203: Regulatory Documentation

- Section 5.2.1. Language added to allow for the use of institutionally approved electronic delegation logs.

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

- Section 5.1. New Clinicaltrials.gov records will be created in each institution's PRS account going forward. The policy has been updated to refer sponsor-investigators to their institution's requirements and processes.
  - Note that institutional policies regarding Clinicaltrials.gov registration may differ.
    - For DFCI, BCH and BIDMC sponsor-investigators, ODQ will continue to assist with initial registration in Clinicaltrials.gov, but all new records will be created in the home institution's PRS account.
    - However, the Clinicaltrials.gov registration process for new protocols will change on April 30, 2023 for BWH and MGH sponsor-investigators conducting DF/HCC research. MGB requires that records be created in the home institution's PRS account, and that sponsor-investigators create the Clinicaltrials.gov registrations themselves. ODQ will notify MGB sponsor-investigators when a clinicaltrials.gov record is required.

REGIST-101: Subject Registration

- Section 5.2. Language added to allow for retrospective registration on protocols reporting summary accrual data only.
- Section 5.3. Language added to clarify requirements for prospective registration, including when registration records and on-study statuses must be created/updated in OnCore.
- Section 5.6. Language updated to clarify when ODQ will perform centralized randomization, and the study team's responsibilities in those cases.
