Summary of Policy Updates

Changes Effective: January 3, 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.

EDU-100: Training Requirements for Research Personnel

- Section 5.5. Added a **new** training requirement for all investigators holding an IND for research submitted under DF/HCC.
    - Appropriate training on IND responsibilities and requirements will be provided by the investigator's home institution, and documentation of completion must be provided to the Office of Data Quality (ODQ) for centralized tracking.

How to fulfill this new training requirement:

- Information has been added to the DF/HCC New Research Staff Checklist and the DF/HCC Training and Education Page outlining the appropriate institutional contact for completing this training.

- If an investigator has questions regarding prior completion of training and/or adherence to this policy requirement, they should reach out to their designated institutional contact.

Rollout and timing:

- **As of January 3, 2023**: The policy update and training requirement will go into effect, and investigators/teams may begin to receive conditions noting this requirement for any pending or newly submitted studies.

- **As of March 1, 2023**: Investigators must be in compliance with this requirement prior to activation of any newly submitted studies and/or amendments changing the IND holder for an existing study.

RCO-203: Regulatory Documentation

- Section 5.1.2.1. Language added to clarify that data stored in central DF/HCC systems (e.g., OnCore, iRIS, OncPro) are not considered part of the Trial Master File or Investigator Regulatory File. Regulatory documents must be separately filed in a distinct Trial Master File/Investigator Regulatory File.

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