Summary of Policy Updates

Effective September 1, 2021

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

- Section 5.5. revised to clarify that for all investigator-sponsored studies using InForm EDC, a formal data request must be submitted to and approved by the Office of Data Quality (ODQ) prior to the release, sharing, or publication of research data.

Related Resource:

- **e-Learning:** Please find additional guidance on when and how to submit an InForm data request to ODQ in this new 7 minute micro-learning: ***Submitting InForm Data Requests***

RCO-102: Responsibilities of Investigators

- Sections 5.8. and 5.9. revised to clarify the requirements and process for the transfer of Principal Investigator responsibilities when there is a PI departure or extended leave of absence from a DF/HCC institution.
    - A PI who will no longer be primarily employed at a DF/HCC institution must complete and close out all active research projects with the IRB and OHRS **or** transition active research projects to a new, appropriately qualified PI. The current PI must prospectively report a planned change in site PI to the Core Site and institutional officials as applicable.
    - A PI who will be taking a leave of absence and will not be reachable by telephone or email, or the leave of absence will exceed three consecutive months, must transition active research projects to a new, appropriately qualified PI.

RCO-204: Safety and Event Reporting

- Sections 5.3.1.1. and 5.3.1.2. revised to clarify that for combined phase studies that include a pilot or phase I component (i.e., phase I/II), the requirement for the PI to review all IND/IDE safety reports only applies while the study is in the pilot phase or phase I.

REGIST-100: Eligibility Checklists

- Section 5.3.5.2. updated to allow for the screening staff and/or enrollment monitor to confirm subject eligibility via email prior to registration under limited circumstances only. Email confirmation is only acceptable when it is otherwise not feasible to obtain a physical or electronic signature prior to registration, and a delay may impact subject safety or patient care.
    - When utilized, email approval must be sent from a validated institutional email account and must be filed with the completed eligibility checklist in the subject's research chart.

Summary of Updated DF/HCC Operations and other Guidance Documents

Please note that these documents may have different effective/posted dates, as indicated

RCO-OP-1: Documenting Delegation of Authority *(effective 9/1/21)*

- Sections 3.1., 3.2.1.3., and 3.3.1.3. revised to remove the requirement to list an individual start date for each person on the delegation log, clarifying that the date of PI signature (required on each page of the log) serves as the start date for each individual listed to begin performing delegated research tasks.

- Per DF/HCC Policy, individuals may not begin performing research procedures on a protocol until they have completed all required training (per EDU-100) and have been delegated and approved on the DOA log via the PI's signature.

Related Resources:

- **DF/HCC DOA Log Template** (revised to remove start date column – study teams may begin using this version for new and existing studies on 9/1/21)
- **e-Learning:** Please find additional guidance on the DF/HCC DOA documentation process in this updated 6 minute micro-learning: ***Documenting Delegation of Authority***

COM-OP-5: Data and Safety Monitoring Committee (DSMC) Procedures, Review, and Data Compliance *(previously posted and effective as of 4/27/21)*

- Section 3.3.4. revised to clarify data compliance thresholds, areas of committee focus (toxicity), and action(s) that will be taken by the DSMC at each level of data non-compliance. A table has been inserted that clearly outlines these details for quick reference.

DF/HCC New Researcher Checklist *(revised and previously posted)*

- This updated version of the checklist provides additional guidance on who needs to complete certain training requirements, and clarifies systems access requirements (e.g., when OnCore access is needed vs. an OnCore profile).
- The checklist has also been reformatted into expandable/collapsible sections to allow researchers to drill down on only the section they need.

DF/HCC Guidance – Maximum Blood Draw for Research Purposes *(new)*

- This new guidance document outlines the acceptable amount of blood to be drawn from subjects solely for research purposes and states that exceptions to the recommended volume must receive prior approval by the IRB of record.