

## Summary of Policy Updates

Effective: August 1, 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](#).*

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### **NEW** RCO-104: New Protocol Submission Requirements

- This is a new policy outlining:
  - Requirements for submission of a new research study to DF/HCC
  - Expectations for responding to conditions in a timely manner and escalation steps that may be taken when condition responses are not received
  - Criteria for the withdrawal of new research studies that do not move forward

### RCO-100: Investigator-Sponsored Research

- Section 5.1.5.1. Updated to align with requirements in new policy RCO-104. When a DF/HCC investigator will hold an IND, FDA approval must be obtained before the new research study is submitted to DF/HCC for review.
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