

Summary of Policy Revisions Changes Effective: February 28, 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](#).

RCO-204: Safety and Events Reporting

- Significant updates to section 5.3. IND Safety Reports received from external sponsors, including:
 - Removal of the different process for IND/IDE Safety Report (INDSR) Review for phase I and I/II studies. Consistent policy language now applies to studies of all phases.
 - PIs may delegate review of INDSRs to an appropriately qualified subinvestigator.
 - Documentation of INDSR review and receipt can occur either per institutional practice or via a sponsor- or CRO-provided online portal/system RCO-204: Reporting Adverse Events

Rolling Implementation

- Researchers may begin implementing the updated version 12 of RCO-204: Safety and Event Reporting as early as January 1, 2022.
- Investigators and teams that choose to implement prior to February 28, 2022 should retain this [Note-to-File](#) with their regulatory documents.

Educational Resources

- Program leaders are asked to share this information with all research personnel who work on FDA-regulated research.
 - **NEW 9-minute e-Learning:** [Investigator Review of External IND Safety Reports](#)
 - **UPDATED:** [FAQ: DF/HCC Policy on Receipt and Review of IND Safety Reports](#)

CON-100: Informed Consent Process

- Clarification only: When additional documents are required to be given to subjects as part of the consent process (e.g., conflict of interest information sheets), the consent process documentation must indicate whether they were provided.

RCL-101: Record Retention for Completed Research

- Revised to indicate that institutional record retention requirement timelines may be longer than otherwise required under DF/HCC policy.

ADM-100: Creation and Maintenance of DF/HCC Policies and Operations

Version 12.1 effective as of 12/1/2021

- Administrative update to remove the title of DF/HCC Associate Director of Administration from the responsible personnel.
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