

Summary of Policy Revisions

Effective: September 1, 2025

Tracked versions are available for review on the [DF/HCC website – Policy Updates Page](#).

RCO-204: Safety and Event Reporting (Version 14)

- **Section 5.2. IND Safety Reports**
 - Reformatting of IND Safety Reporting (INDSR) policy section to clearly delineate the responsibilities of the sponsor vs. investigator related to INDSRs, also emphasizing that when a DF/HCC investigator holds the IND and serves as Sponsor-Investigator, they hold both sponsor and investigator responsibilities.
 - Sub-sections now clearly outline review and reporting responsibilities as tied to each specific role as they apply to DF/HCC investigators.
- **Section 5.2.2. Sponsor Responsibilities Related to INDSRs**
 - Apply to DF/HCC investigators that hold the IND and are serving as the Sponsor-Investigator.
 - 5.2.2.3.1. Clarifies the reporting timeline for Sponsor-Investigators to notify the FDA within 15 calendar days of determining the UAP constitutes a significant risk.
 - 5.2.6.1.2. New language clarifying that the Sponsor-Investigator does not need to duplicate reporting to the FDA for INDSRs received from external entities (e.g., drug manufacturers) that have already been submitted to the FDA.
- **Section 5.2.3. Investigator Responsibilities Related to INDSRs**
 - Apply to DF/HCC investigators serving as the PI on an externally sponsored trial, or as the Sponsor-Investigator of an investigator-sponsored trial.
 - 5.2.3.3.1. Updated to allow for the delegation to qualified study team members, as defined in the updated DF/HCC Key: Delegation of Tasks, the review of INDSRs sent from external sponsors to identify those that are clearly indicated by the sponsor as UAPs.
 - Note that for DF/HCC investigator-sponsored trials, the Sponsor-Investigator may not delegate Sponsor responsibilities related to the review and assessment of INDSRs, as outlined in section 5.2.2.
- **Definition: Unanticipated Problems Involving Risk to Subjects or Others (UPRSO)**
 - Updated to include common shorthand “Unanticipated Problem (UAP)” as is used throughout the policy.
- **Section 5.3. IDE Safety Reporting (UADEs)**
 - New section added to clarify DF/HCC Investigator and Sponsor-Investigator safety reporting responsibilities for device studies under an IDE.

Additional Updated Documents

- [DF/HCC Key: Delegation of Tasks](#) (version: July 21, 2025)
- [Guidance & FAQ: DF/HCC Policy on Review of INDSRs from External Sponsors](#)
- [DF/HCC Operation RCO-OP-4: Obtaining and Maintaining an IND](#)
- [DFCI IRB Policy: SAE and INDSR Reporting](#) (previously updated and effective March 17, 2025)

Early Implementation of RCO-204 Version 14

- Researchers may begin implementing version 14 of RCO-204: Safety and Event Reporting, along with the updated version of the DF/HCC Key: Delegation of Tasks as of July 21, 2025. Teams who choose to implement prior to September 1, 2025 should retain this [Note to File](#) with their regulatory documents.

Implementing New Version of the Key: Delegation of Tasks

- Principal Investigators that choose to apply the updated Key: Delegation of Tasks; Version: July 21, 2025 (including the additional delegated responsibilities to the Coordinator role) to their *active* DF/HCC Delegation of Authority Logs, may utilize this [Note-to-File Template](#) by signing and retaining it with their regulatory documents in lieu of individually updating each existing DOA log with the new version of the Key.