

Summary of Policy Updates

Effective: January 31, 2025

No formal documentation of training on the following policy updates is required. Below is a summary of key revisions. Tracked changes are available for review on the [DF/HCC website – Policy Updates Page](#).

Consent-Related DF/HCC Policies

CON-100: Informed Consent Process

- **Witness definition** updated to clarify the role of, and who may serve as witness.
- **Section 5.1.2.** updated to include radiation and surgery to types of interventional trials that require an attending physician to obtain consent (when greater than minimal risk).
- **Section 5.3.** Edits throughout to clarify considerations in the presentation of consent information.
- **Section 5.4.6.** Requirement update – a copy of the signed ICF must be uploaded to the EMR for interventional drug, device, biologic, radiation, and surgery trials.
- **Section 5.5.** Language simplified to outline overarching DF/HCC requirements for updating participants of new information and when applicable, obtaining reconsent in a timely manner. Language outlining certain plan specifics (exact timing, method, etc.) that are ultimately the determination of the IRB of record has been removed and is now captured in the DFCI IRB guidance (see below).
- **Section 5.6.** Duplicative information that is already captured in policy CON-101: Consent of Non-English-Speaking Participants has been removed.
- **Sections 5.7. and 5.8.** Reorganized and updated for clarity; DFCI IRB-specific policy for use of a LAR was moved to OHRS policy.
- **Sections 5.9. and 5.10.** Language updated to clarify requirements for seeking assent from minor participants, as well as more clearly defining requirements for when a minor participant reaches the age of majority during the course of research.
- **Updates throughout** to reorganize subsections for clarity, and to remove gender-specific language.

CON-101: Obtaining Informed Consent of Non-English Speakers

- **Interpreter definition** updated to allow for a family member only when a professional interpreter is not available.
- **Section 5.1.** Removed requirement for a separate witness when a qualified study team member acts as interpreter.
- **Section 5.2.5.1.1.1.** Updated to clarify that when a remote interpreter is used and is also acting as witness, institutional policy *may* require a physical witness signature.
- **Section 5.2.8.** New requirement – When a short form is used in lieu of a fully translated ICF, the investigator must subsequently obtain a translated copy of the long form consent to be provided to the participant, and it must be documented that this has occurred.
- **Section 5.4.** Language simplified to outline overall requirements for notifying subjects of new information in a timely manner, in accordance with CON-100 and the plan approved by the IRB of record.
- **Updates throughout** to remove gender-specific language.

Consent-Related OHRS - DFCI IRB Policy, Guidance, and Templates

- **DFCI IRB Guidance: Reconsent and New Risk Notification: Guidance for Study Teams** (*posted and effective immediately*)
 - New guidance for teams in developing and submitting a notification/reconsent plan to the DFCI IRB for review and approval.
 - Outlines new process for notifying participants after IRB approval but prior to activation (when activation is delayed).
 - *Note* - This document has been combined with previous DF/HCC operation CON-OP-1: Reconsent, which has been retired.
- **DFCI IRB Policy: Use of Legally Authorized Representatives (LAR)** (*updated version to be posted in December*)
 - Updated IRB policy to clarify and expand on the criteria and considerations for using a LAR, and the process for obtaining DFCI IRB approval.
- **DF/HCC Consent Form Templates** (*Updated versions to be posted in December*)
 - Multiple updates, including to the signature block to clarify role of interpreter and witness when applicable.

Additional DF/HCC Policy Updates – Minor Revisions and Clarifications

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

- Updated to adjust language from “therapeutic” to “treatment” to align with current regulatory guidance.

DATA-101: Case Report Form Development

- Updated to adjust language from “therapeutic” to “treatment” to align with current regulatory guidance.
- DF/HCC operation **DATA-OP-3: EDC Receipt** also updated to align language.

RCO-104: New Protocol Submission Requirements

- **Section 5.1.** updated to clarify requirements for the pre-submission form process which went into effect in April 2024.

REGIST-101: Subject Registration

- Updated to adjust language from “therapeutic” to “treatment” to align with current regulatory guidance.

REGIST-200: Registration of Clinical Trials on ClinicalTrials.gov

- **Section 5.2.** Language added to define the requirements and process for transferring clinical trial records between institutions (e.g., when a PI changes institutions).