TITLE: Creation and Maintenance of DF/HCC Policies and Operations		
POLICY #: ADM-100	**Page:** 1 of 4	**Effective Date:** 12/1/2021

1. POLICY STATEMENT:

DF/HCC Policies and Operations apply to all human subject research conducted within the Dana-Farber/Harvard Cancer Center (DF/HCC). There is a standard method for writing, revising and approving DF/HCC Policies and DF/HCC Operations.

2. BACKGROUND:

The International Conference on Harmonisation ICH – E6 recommends implementing systems with procedures that assure the quality of every aspect of research.

3. RESPONSIBLE PERSONNEL:

3.1. Executive Committee for Consortium Clinical Research (ECCCR) Chair
3.2. Clinical Research Operations Subcommittee (CLINOPS) Chair
3.3. DF/HCC Associate Director of Clinical Trials
3.4. Office of Data Quality (ODQ) Director
3.5. ODQ Clinical Trials Education Manager
3.6. Office for Human Research Subjects (OHRS) Director
3.7. Research Informatics for Operations (RIO) Director

4. DEFINITIONS:

4.1. **DF/HCC Policies:** A collection of rules and requirements that govern the conduct of human subject research within DF/HCC. All personnel participating in human subject research within the DF/HCC must comply with DF/HCC policies.

4.2. **DF/HCC Operations:** Procedural documents that must be followed by DF/HCC research personnel to standardize the performance of certain research activities within the DF/HCC in order to comply with DF/HCC policies and other applicable regulatory requirements.

4.3. **Human Subject Research:** Any systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge, that involves human subjects, whereas a human subject is defined as a living individual about whom an investigator (whether professional or student) conducting research:

(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. (§46.102)

For additional information as to whether DF/HCC research constitutes human subject research under both the FDA and DHHS regulations, see OHRS Info Sheet – Policy: Determining if a Project is Human Subject Research**.**

5. POLICY:

5.1. DF/HCC Policies

5.1.1. Writing and Revising Policies

5.1.1.1.Policies are reviewed formally by CLINOPS at least every 3 years. Revisions are made accordingly to account for changes in federal regulation, procedure or institutional policy. Policies may be revised more frequently if necessary.

5.1.1.1.1. The CLINOPS and/or the ECCCR Chairs may identify the need for a new/modified DF/HCC policy. The ECCCR Chair may delegate the drafting of the policy edits to CLINOPS.

5.1.1.1.1.1.Policy edits or modifications identified by the CLINOPS or ECCCR Chairs as significant and/or substantial must be reviewed and approved by the ECCCR before they are finalized.

5.1.1.1.1.2.Policy edits or modifications identified by the CLINOPS or ECCCR Chairs as administrative or minor content changes require approval by CLINOPS before they are finalized.

5.1.1.1.2. If CLINOPS determines that no changes are required, the review and signatory process are documented. The policy is labeled with a new last reviewed date.

5.1.1.2.Polices must be consistent with federal regulations, guidelines, and the current DF/HCC Policy Template and DF/HCC Guidance on Format

Requirements.

5.1.1.3. During the revision process (prior to approval), the policy is a controlled document. It is confidential and proprietary.

5.1.2. **Approval and Release of New and Revised Policies**

5.1.2.1. DF/HCC policies must be reviewed and approved by the Associate Director of Clinical Trials.

5.1.2.2. The effective date and training requirements are assigned by the Associate Director of Clinical Trials.

5.1.2.3. Effective dates are assigned based on the criticality of the policy and the training requirements. Effective dates must provide sufficient time to conduct and document training (typically set for two months from the approval date).

5.1.2.4. ODQ will develop and distribute training materials (when applicable) to the DF/HCC research community to supplement institutional training on the release of new or updated policies.

5.1.2.5. ODQ will notify the DF/HCC research community of new and revised policies using the DF/HCC Research Listserv email distribution list.

5.1.2.6. ODQ will post the updated policy to the DF/HCC website for use on its effective date, with an updated version number, effective date, and last reviewed date.

5.1.3. All previous versions of the policies, including the signature pages and documented changes, will be maintained by the ODQ.

5.1.4. Substantial and immediate issues with a policy are addressed with the DF/HCC Associate Director of Clinical Trials. The decision to change or make exceptions to a policy is at their discretion. Interim policy changes will be communicated using the DF/HCC Research Listserv email distribution list.

5.2. **DF/HCC Operations**

5.2.1. The Associate Director of Clinical Trials will designate offices or departments to develop and maintain DF/HCC Operations.

5.2.1.1. Revisions to DF/HCC Operations require review and approval from the Associate Director of Clinical Trials.

5.2.2. DF/HCC member institutions may also develop and maintain institutional procedures to standardize research processes within an institution. Institutional procedures may not conflict with DF/HCC Policies or DF/HCC Operations. The review and approval process for institutional procedures is at the discretion of the institution.

6. APPLICABLE REGULATIONS & GUIDELINES:

21 CFR 50 – Protection of Human Research Subjects
21 CFR 54 – Financial Disclosure by Clinical Investigators
21 CFR 56 – Institutional Review Boards
21 CFR 312 - Investigational New Drugs – Drugs for Human Use
21 CFR 812 – Investigational New Device Exemptions
45 CFR 46 - Protection of Human Subjects
FDA Industry Guidelines and Information Sheets
FDA Compliance Policy Guidance Programs: 7348.809, 7348.810, and 7348.811

7. RELATED REFERENCES:

International Conference on Harmonisation – E6

8. RELATED RESOURCES:

DF/HCC Policy Training and Signature Record
OHRS Info Sheet – Policy: Determining if a Project is Human Subject Research