DANA-FARBER / HARVARD CANCER CENTER
~~STANDARD OPERATING PROCEDURES~~POLICIES FOR THE CONDUCT OF HUMAN SUBJECT RESEARCH

TITLE: ~~Writing~~Creation and ~~Revising~~Maintenance of DF/HCC ~~Standard Operating Procedures~~ Policies and Operations		
~~SOP~~POLICY #: ADM-100	**Page:** 1 of 5	**Effective Date:** 5/15/18~~08/31/2016~~

1. POLICY STATEMENT:

There is a standard method for writing, revising and approving ~~the~~ DF/HCC ~~Standard Operating Procedures (SOPs) for Human Subject Research~~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. Clinical Research Operations Committee (CLINOPS) Chair
~~3.2. Clinical Trials Education Coordinator~~
~~3.3.~~3.2. DF/HCC Associate Director of Administration
~~3.4.~~3.3. DF/HCC Medical Director for Clinical Trials Operations
~~3.5.~~3.4. Office of Data Quality (ODQ) Director
3.5. ODQ Education Coordinator
3.6. Office for Human Research Subjects (OHRS) Director
3.7. Clinical Trials Research Informatics Office (CTRIO) Director

4. DEFINITIONS:

~~4.1. None~~
4.1. **DF/HCC Policies:** A collection of rules and requirements that govern the conduct of research within the Dana-Farber/Harvard Cancer Center (DF/HCC). All personnel participating in research within the DF/HCC must comply with DF/HCC policies.

4.2. **DF/HCC Operations:** General procedures that must be followed 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.

5. POLICY:

5.1. **DF/HCC Policies**

Version: ~~9~~10
Effective Date: ~~08/31/2016~~
Last Reviewed Date: ~~06/30/2016~~

~~5.1.0.~~5.1.1. Writing ~~SOPs~~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 ~~Clinical Research Operations Committee (~~CLINOPS~~)~~ ~~chair~~ Chair identifies the need for a new/modified DF/HCC ~~SOP and assigns an author to~~policy.

~~5.1.1.~~ If CLINOPS determines that no changes are required, the ~~task.~~

5.1.1.1.2. review and signatory process are documented. The ~~author prepares the draft SOP in accordance~~policy is labeled with a new last reviewed date.

~~5.1.2.0.~~5.1.1.2. Polices must be consistent with federal regulations, guidelines, and ~~institutional policy using~~ the current DF/HCC ~~SOP~~Policy Template and DF/HCC Guidance on Format Requirements ~~for Standard Operating Procedures. Tools are designed (and attached where applicable) to be used with the SOP.~~.

~~5.1.3.0.~~5.1.1.3. During the revision process (prior to approval), the ~~SOP~~policy is a controlled document. It is confidential and proprietary.

~~5.1.4. The draft SOP is~~Draft policies must be reviewed by CLINOPS for accuracy and feasibility. The CLINOPS chair determines if the ~~SOP~~policy requires input from additional entities or departments.

~~5.1.5.0.~~5.1.1.4. ~~All comments and revisions are evaluated and are included in the final draft as appropriate.~~

~~5.2.0.~~5.1.2. Approval and Release of New and Revised Policies

~~5.2.1. The final draft is completed and submitted to the DF/HCC Medical Director for Clinical Trials Operations and the DF/HCC Associate Director of Administration for review and approval.~~

~~5.2.1.1.~~5.1.2.1. ~~The SOP is finalized when~~DF/HCC policies must be reviewed and approved by the DF/HCC Medical Director for Clinical Trials Operations and the DF/HCC Associate Director of Administration ~~reach agreement and approve the procedure~~.

~~5.2.1.2.The DF/HCC Medical Director for Clinical Trials Operations and the DF/HCC Associate Director of Administration sign the SOP as the approving officials.~~

~~5.2.2.0.~~5.1.2.2. ~~Effective dates~~The effective date and training requirements are assigned by the DF/HCC Medical Director for Clinical Trials Operations and the DF/HCC Associate Director of Administration.

~~5.2.2.1.~~Effective dates are assigned based on the criticality of the ~~SOP~~policy and the training requirements. ~~Therefore, the effective date may be somewhat later than the approval date.~~

~~5.2.2.2.~~5.1.2.3. ~~Unless the SOP must take effect immediately to address safety concerns, effective~~ Effective dates ~~are generally set for 2 months from the approval date to~~must provide sufficient time to conduct and document training (typically set for two months from the approval date) .

~~5.3. **Implementation**~~

5.1.2.4.~~After the effective date~~ODQ will develop and ~~training requirement are assigned, the ODQ Director signs the SOP and releases it to the Clinical Trials Education Coordinator for development of~~ distribute training materials (~~if~~when applicable~~). The approved SOP and training materials (if applicable) are distributed~~) to the DF/HCC ~~sites. The approved SOP is posted~~research community to supplement institutional training on the release of new or updated policies.

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

~~5.3.1.~~ ODQ must post the updated policy to the DF/HCC website ~~prior to the effective date to facilitate review and training.~~

~~5.3.2. The approved SOP is posted to the DF/HCC website for current~~ for use on its effective date~~. SOPs are protected documents. They are posted in a "read only"~~, with an updated version~~.~~

~~5.4. Revising SOPs~~

~~5.4.1. SOPs are reviewed formally by the CLINOPS every 3 years. Revisions are made accordingly to account for changes in federal regulation, procedure or institutional policy. SOPs may be revised more frequently if necessary.~~

~~5.4.2.0.~~5.1.2.6. ~~Revisions follow the procedure described above. Revisions are labeled as such with new~~ number, effective date, and last reviewed ~~dates and a new version number.~~date.

~~5.4.3. If no changes are required, the review and signatory process are documented. The SOP is labeled with a new last reviewed date.~~

~~5.4.4.~~5.1.3. All previous versions of the ~~SOPs~~policies, including the signature pages and documented changes, ~~are~~must be maintained by the ODQ.

~~5.4.5.~~5.1.4. Substantial and immediate issues with ~~an SOP~~a policy are addressed with the DF/HCC Medical Director for Clinical Trials Operations or the DF/HCC Associate Director of Administration. The decision to change ~~procedures~~or make exception to a policy is at their collective 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 DF/HCC Medical Director for Clinical Trials Operations and the DF/HCC Associate Director 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 DF/HCC Medical Director for Clinical Trials Operations and the DF/HCC Associate Director of Administration.

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 ~~FORMS & TOOLS~~RESOURCES:

DF/HCC Policy Training and Signature Record
~~Guidance on Format Requirements for Standard Operating Procedures (SOPs)~~