| **TITLE:** Writing and Revising DF/HCC Standard Operating Procedures | | |
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| **SOP #:** ADM-100 *(formerly GA-101)* | **Page:** 1 of 4 | **Effective Date:** 9/17/12 |

## 1. POLICY STATEMENT:

There is a standard method for writing, revising and approving the DF/HCC Standard Operating Procedures (SOPs) for Human Subject Research.

## 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 Office (CTEO) Director
3.3. DF/HCC Associate Director of Administration
3.4. DF/HCC Medical Director for Clinical Trials Operations
3.5. Quality Assurance for Clinical Trials (QACT) Director

## 4. DEFINITIONS:

4.1. None

## 5. PROCEDURE:

### 5.1. **Writing SOPs**

5.1.1. The Clinical Research Operations Committee (CLINOPS) chair identifies the need for a new/modified DF/HCC SOP and assigns an author to the task.

5.1.1.1. The author prepares the draft SOP in accordance with federal regulations, guidelines and institutional policy. Tools are designed (and attached where applicable) to be used with the SOP. While in draft form, the SOP is a controlled document. It is confidential and proprietary.

5.1.2. The draft SOP is reviewed by CLINOPS for accuracy and feasibility. The CLINOPS chair determines if the SOP requires input from additional entities or departments.

5.1.3. All comments and revisions are evaluated and are included in the final draft as appropriate.

5.1.4. 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.

5.1.4.1. The SOP is finalized when the DF/HCC Medical Director for Clinical Trials Operations and the DF/HCC Associate Director of Administration reach agreement and approve the procedure.

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

5.1.5. Effective dates are assigned by the DF/HCC Medical Director for Clinical Trials Operations and the DF/HCC Associate Director of Administration.

5.1.5.1. Effective dates are assigned based on the criticality of the SOP and the training requirements and therefore may be somewhat later than the approval date.

5.1.5.2. Unless the SOP must take effect immediately to address safety concerns, effective dates are generally set for 2 months from the approval date to provide sufficient time to conduct and document training.

5.2. **Format**

5.2.1. The author prepares the draft SOP using the current DF/HCC SOP Template and DF/HCC Guidance on Format Requirements for Standard Operating Procedures.

5.3. **Implementation**

5.3.1. After the effective date and training requirement are assigned, the QACT Director signs the SOP and releases it to the CTEO Director for development of training materials (if applicable). The final SOP and training materials (if applicable) are distributed to the DF/HCC sites.

5.3.2. The final SOP is posted to the DF/HCC website on its effective date. SOPs are protected documents. They are posted in a “read only” 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. Revisions follow the procedure described above. Revisions are labeled as such with new effective and last reviewed dates and a new version number.

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. All previous versions of the SOPs, including the signature pages and documented changes, are maintained by the QACT Administrative Office.

5.4.5. Substantial issues with an SOP 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 is at their collective discretion.

## 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
CLINOPS Purpose and Organization

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## 8. RELATED FORMS & TOOLS:

DF/HCC SOP Signature Page
DF/HCC SOP Template
Guidance on Format Requirements for Standard Operating Procedures (SOPs)

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| **Version:** 6 |
| **Effective Date:** 9/17/12 |
| **Last Reviewed Date:** 3/13/12 |