


Standard Operating Procedures for Clinical Research at USF Health Morsani CRC			
	<b>DOCUMENT CONTROL MANAGEMENT</b>		
<b>SOP#: 105</b>	<b>Effective Date:06/01/2016</b>	<b>Version: 1.0</b>	<b>Page 1 of 6</b>

**PURPOSE:** The purpose of this Standard Operating Procedure (SOP) is to ensure that controlled documents related to clinical research are appropriately managed at the CRC. The purpose of "control" is to assure that documents used in more than one location are a) properly situated where needed, and b) can be withdrawn and re-issued when changed, assuring that only current, non-obsolete versions of the documents are in place.

**SCOPE:** This SOP encompasses all documents used to control the management and processes associated with clinical research studies at the CRC.

**RESPONSIBILITY:** The **Principal Investigator** is responsible for determining which documents need to be controlled. The **Research or Regulatory Coordinator** is responsible for implementing and maintaining document control system that includes the following:

- Coordinates reviews and revisions of quality system documents
- Maintains Master File to ensure active and revised documents are provided to staff that must contain Document Number, Title, Revision Level and Review date
- Archives superseded or obsolete documents
- Reviews SOP prior to use
- Ensures that all routine operations and activities are documented by SOPs
- Creates or delegates creation of documents

**Other Designated Research Personnel** are responsible for the following:

- Verifying that the official version of the document is used
- Review and determine need for new procedures or its revision and to convey that need to their immediate supervisor


## DEFINITIONS:

**Controlled Document:** A document is considered "controlled" when its distribution is identified by means of a written list or log that gives the document a title and the identity of the location where it is situated (which may be a list of names or physical locations).

## PROCEDURE:

1. Research staff will be knowledgeable of various types of controlled documents used for clinical research. Examples of controlled documents include the following:

- Clinical protocol (including monitoring plan)
- Protocol amendments
- Case report forms (CRFs)
- Informed consent form (ICF)
- Investigator Brochure


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		<b>DOCUMENT CONTROL MANAGEMENT</b>	
<b>SOP#: 105</b>	<b>Effective Date:06/01/2016</b>	<b>Version: 1.0</b>	<b>Page 2 of 6</b>

**PROCEDURE (cont.):**

- Equivalent medical device study documents (Investigational Plan, Report of Prior Investigations)
- Adverse event (AE) reporting form
- Certain other FDA documents: All other documents that are developed for clinical study purposes are considered non-controlled.

**2. Version Control and Naming Convention:**

- 2.1. All controlled documents need to be dated and/or versioned in sequential order and systematically named, especially if they belong to a series or set of documents e.g. protocol, informed consent form.
- 2.2. The first draft of the protocol should be labelled with a version number and dated, for example 'Draft version 0.1 and dated. Further draft versions should be labelled 'Draft version 0.2, 0.3' etc. and dated.
- 2.3. The final original version of the protocol may be labelled 'Final Version 1.0' and dated before being submitted for the appropriate approvals.
- 2.4. If amendments are necessary following review of the protocol then subsequent versions of the protocol may be labelled 'Draft Version 1.1, 1.2' while still being drafted and reviewed and the version re-submitted for approval should be labelled 'Final Version 2.0' and dated.
- 2.5. If the protocol is then amended again during the study then the version submitted for approval of the amendment will be labelled 'Final Version 3.0' and so on.
- 2.6. Other considerations that should be on the document when appropriate:
  - Effective date and expiry date or next review dates if applicable. It may be necessary to also include date issued and date printed.
  - Page numbers – It is recommended that pages are numbered as "Page X of Y"
  - Confidential – If the document is confidential, mark "Confidential"
  - Document identification- e.g. a title, department name
  - Approvals - It may be necessary to include signature and date of Author, Reviewer and Authorizer with titles of signatories e.g. for SOPs, protocols.
  - Copyright as appropriate – Insert copyright information if necessary.
  - Reason for Change – If it is a revision of the control document, state reason for change and list changes.


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		<b>DOCUMENT CONTROL MANAGEMENT</b>	
<b>SOP#: 105</b>	<b>Effective Date:06/01/2016</b>	<b>Version: 1.0</b>	<b>Page 3 of 6</b>

**PROCEDURE (cont.):**

- Referencing - When reference is made to another controlled document, you may use the instruction “see/refer to *Document Title*”. The version number may be excluded.

**3. Document Initiation and Approval Procedures:**

- 3.1. The PI or designated research personnel will use the procedures below for the drafting, review, approval and revision of controlled documents.
  - 3.2. Determine which documents are needed for developing regulatory submissions, collecting data or other study information, and/or performing any other study-related function.
  - 3.3. Determine who will draft the first version of a given document (the author) and any related appendices (list of attachments) to be included with the document.
  - 3.4. Determine who must review and approve the first and succeeding draft
  - 3.5. Use templates or other available guidelines for developing new documents where available, and initiate the document drafting process.
  - 3.6. Complete the document control noting version date in the document number section and in the footer of the document.
  - 3.7. Circulate the draft if it needs continued review securing signature/review date, comments and suggestions from all specified reviewers.
  - 3.8. Revise the document per initial review process, and if any revisions are not incorporated, he/she will notify the affected reviewer(s) of the reason(s) for not including the revision(s), and negotiate a resolution, documenting any significant differences in the space provided on the Document Control Form.
  - 3.9. Continue to circulate the revised document to all signatories until the review process is complete. The document will have a version date for each review and then a final version date.
  - 3.10. Ensure all required reviewer approvals are indicated by entries in the Signature and Approval Date boxes on the controlled document.
  - 3.11. Upon final signature of the last reviewer, the authorized person should sign and date the controlled document in the space provided to indicate responsibility for that document.
4. Following final approval, the research designee will assign all newly approved documents a version number and effective date.
  5. The original approved document and Document Control Form(s) will be retained in the appropriate archive file or section of the Regulatory Master File.
  6. For new, non-controlled documents, there are no specific required procedures to follow for development, but department administration must approve the development of new documents and their final version.

Standard Operating Procedures for Clinical Research at USF Health Morsani CRC			
		<b>DOCUMENT CONTROL MANAGEMENT</b>	
<b>SOP#: 105</b>	<b>Effective Date:06/01/2016</b>	<b>Version: 1.0</b>	<b>Page 4 of 6</b>

**PROCEDURE (cont.):**

**7. Document Review/ Change Procedures:**


- 7.1. Each respective department will review controlled documents periodically or as needed by circumstances (e.g., new federal or state regulation, new University or institutional policy or procedure, or need for update of Investigational Brochure, etc).
- 7.2. If revisions are needed in a controlled document, the research designee will do the following:
  - Have the author of the change(s) circulate the revised draft with a copy of the original, clearly noting the changes, using the Document Control Form as its cover
  - Continue to give updated and revised controlled documents a new version number (01, 02, etc.) and a current effective date
  - Document periodic review and updating by maintaining an accurate Table of Modifications Form for each controlled document
  - Watermark prior version of the controlled document "Obsolete" and save copy for the appropriate archive file or section of the Regulatory Master File
  - Update any related tables or indices, as appropriate (refer to the current OHR policy for details).

**8. Revision of Non-Controlled Documents:**

- 8.1. When revisions are needed in a non-controlled document, the author of the non-controlled document or a designee will do the following:
  - Make the change(s) and circulate the revised draft with a copy of the original, clearly noting the changes and why they are needed.
  - Continue to give updated and revised non-controlled documents a new version number (01, 02, etc.) and current effective date. .
  - Mark prior version of the document "Obsolete" and save copy for the appropriate archive file (see specific SOP for location).
  - Update any related tables or appendices, as appropriate

**9. Document Implementation Procedures:**

- 9.1. The Investigator will ensure that all appropriate staff is trained in the proper use of the new or revised document.
- 9.2. The Investigator will make a list of all affected parties and appropriate regulatory authorities (IRB, FDA) who must be notified of changes to applicable documents and notify them in writing when the changes are implemented (or prior to implementing, if appropriate).
- 9.3. The research designee will provide the updated version of appropriate documents to affected parties.

Standard Operating Procedures for Clinical Research at USF Health Morsani CRC			
	DOCUMENT CONTROL MANAGEMENT		
	SOP#: 105	Effective Date:06/01/2016	Version: 1.0
		Page 5 of 6	

**PROCEDURE (cont.):**

**10. Storage and Archiving:**

- 10.1. Controlled documents should be stored in an area or room restricted to authorized individuals only. If the controlled documents are part of essential documents, they should be part of the Research Master/Regulatory File (see SOP 201: Regulatory Documentation) and archived appropriately (see SOP: 504 Archiving Study Records).
- 10.2. Old versions of controlled documents must be archived in a separate file.
  - Obsolete documents that are retained for reference or legal obligations are water marked "OBSOLETE" and kept separate from active documents. Obsolete electronic documents are removed from the network and stored in media that are only accessible to authorized personnel. Any obsolete documents that need to be reactivated must be reviewed, approved and released in the same manner as newly established documents.
  - At least one copy of all obsolete documents must be archived.
- 10.3. The OCR will maintain a master list of all SOPs specific to the CRC. This file or database will indicate the SOP number, version number, effective date, title, author, status, and any historical information regarding past versions.
- 10.4. Documents will be archived in electronic storage to:
  - Prevent their continued use
  - Facilitate easier access for retrieval purposes
  - Limit documents to a read-only format to protect them against unauthorized changes made to the document as well as to be available for historical data review

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**SOP#: 105**

**Effective Date:06/01/2016**

**Version: 1.0**

**Page 6 of 6**

REFERENCES:	21 CFR 812.100 General Responsibilities of Investigators ICH E6, 2.13 The Principles of ICH GCP ICH E6, 5.1 Quality Assurance and Quality Control ICH E6, 5.5 Trial Management, Data Handling and Record Keeping	
RELATED POLICIES:		
APPENDICES:	Appendix E: Document Control Process Flow	
REVISION HISTORY: Keep a running history of all revision dates.		
Approval Date	Effective Date	Review/Revision Date
01/01/2015	06/01/2015	06/15/2016