1 PURPOSE
This procedure describes the steps to be followed for developing, revising and approving controlled and non-controlled documents for investigator-initiated, FDA- and DHHS-regulated, human subject research documentation within Memorial Healthcare System (MHS) regardless of whether and IND or IDE is in place.

2 GENERAL INSTRUCTIONS AND RESPONSIBILITIES
The Investigator or designee is responsible for reviewing, approving, distributing, rendering obsolete and archiving all revisions to investigator-initiated controlled and non-controlled documents.

3 SPECIFIC PROCEDURES
3.1 Process Requirements for Specific Documents
a) The following documents are controlled documents:
   - Clinical protocol
   - Protocol Amendments
   - Case Report Forms (CRFs)
   - Informed Consent Form (ICF)
   - Investigator Brochure (IB)
   - Equivalent medical device study documents (Investigational Plan, Report of prior Investigations)
Investigator Standard Operating Procedures  

- Standard Operating Procedures  
- Other FDA Documents  
  
b) All other documents that are developed for clinical study purposes are considered non-controlled.  

c) Refer to other specific SOPs when developing the content of a specific document.  

3.2 Documentation Initiation and Approval Procedures  

  a) The investigator or designee will determine which controlled documents are needed for developing regulatory submissions, collecting data or other study information, and/or performing any other study-related function.  

  b) The investigator or designee will determine the author of the first version of a given document template.  

  c) The author may use templates or other available guidelines as resources for developing new documents, where available.  

  d) The author should use a good version control method in the footer of the document template. The author should send the draft controlled document template to OHR for review.  

  e) The author will revise the draft document template per the OHR review recommendations. If any revisions are not incorporated, the author should notify OHR with the reason(s) for not including the revisions and negotiate a resolution.  

  f) Upon final approval from OHR, the author must obtain original signatures and dates on the document and the footer should clearly state the final version date of the controlled document template.  

  g) A copy of the document template should be kept in the Document files at the OHR.  

3.3 Document Change Procedures  

3.3.1 Revision of Controlled Documents  

  a) The investigator or designee will review controlled documents periodically or as needed by circumstances (e.g. federal or state regulation, new Memorial Healthcare System policy or procedure, or need for update of IRB etc.)  

  b) If revisions are needed in a controlled document, the following should happen:  

    - Have the author of the changes compile a list of changes that have been made to the document stating the reason for each change (via track changes).  

    - Keep good version control in the footer of the document.  

    - Obtain IRB approval for the document.  

    - Once IRB approval has been obtained, archive the prior version and save the copy in the appropriate regulatory binder.  

    - The updated document should be circulated to all appropriate research staff and the necessary training provided prior to use (Attachment B).  

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3.3.2 Revision of Non-Controlled Documents

a) The following are examples of non-controlled documents:
   - Documentation of Consent Process
   - Internal templates and/or logs
   - Checklists
   - Forms
   - Management Plans

b) Keep good version control in the footer of the document.

c) Mark the prior version of the document “obsolete” and save the copy in the Shared Drive at the research site.

d) The updated document should be circulated to all appropriate research staff for use.

e) Non-controlled documents do not need IRB approval prior to use.

3.4 Document Implementation Procedures

a) The Investigator will ensure that all appropriate staff are trained in the proper use of the new or revised document and that the training is appropriately documented either through the use of Attachment A, or provided during the monthly meetings with the relevant members of the research team.

b) The Investigator or his designee will make a list of all appropriate research staff and regulatory bodies (e.g. FDA, IRB) who must be notified of the changes in the documents and notify them in writing. If applicable, the new documents should be provided for approval, and only implemented once approval has been obtained.

4 REFERENCES TO OTHER APPLICABLE SOPS

- This SOP affects all SOPs except 101.

5 ATTACHMENTS

A. Training Documentation Form

6 APPLICABLE REGULATIONS AND GUIDELINES

- General Responsibilities of Investigators (21 CFR 312.60)
- Quality Assurance and Quality Control (ICH E6, section 5.1)