1 PURPOSE

This procedure describes the steps that are necessary for developing, revising and maintaining standard operating procedures (SOPs) for regulated human subject research within Memorial Healthcare System (MHS).

2 GENERAL INSTRUCTIONS AND RESPONSIBILITIES

DHHS & FDA Regulations recommend that all FDA-regulated human subject research be conducted under written procedures. This is interpreted to mean Standard Operating Procedures (SOPs), which are written guidelines for the conduct of a specific process. They provide a standardized roadmap describing how a procedure should be done in order to maintain consistency across different users. SOPs should be modified and revised periodically to reflect the current, acceptable practice of the institution or the site.

a) MHS personnel engaged in FDA-regulated human research are responsible for adherence to this SOP to ensure uniform practices.

b) All SOPs must be reviewed and approved by the following prior to implementation:
   i. Chief Medical Research Officer for the Office of Human Research (OHR)
   ii. Senior Vice President and Chief Medical Officer (MHS)

c) When an Investigator follows OHR approved SOPs for Good Clinical Practices (GCPs), the OHR acts as the designee for SOP maintenance and management.

d) When the Investigator creates separate SOPs, which are to be used in conjunction with OHR's SOPs, the Investigator is responsible for approval of said SOPs from the OHR per (b) listed above.
   i. SOPs should specifically be created and adhered to when the Principal Investigator is also the sponsor of the study (physician initiated research).

e) The Investigator is responsible for staff knowledge and training on all applicable SOPs.
3 SPECIFIC PROCEDURES

3.1 SOP initiation and Approval Procedures

a) The investigator or designee will determine the need for any additional (study specific) SOPs and confer with OHR.

b) The OHR may decide to implement new SOPs at any time if deemed necessary for the overall research program.

c) An author (person who is knowledgeable in the scope of work being covered) will be designated to write the draft.

d) The investigator and/or the author will also determine who, within the OHR, should review and approve the draft SOP.

e) The author will use the approved SOP template (Attachment A).

f) The author should use a good version control method in the footer of the SOP.

g) The author should send the draft SOP to OHR for review, if not initiated by the OHR.

h) The author will revise the draft SOP 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.

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

j) The original signed SOP should be kept in the SOP files at the OHR, and a pdf created for distribution, review and training purposes. The new SOP should be circulated to all research staff at MHS. They will be posted electronically by the OHR on the MHS research webpage (www.mhs.net/research).

3.2 SOP Change Procedures

a) The OHR will review SOPs periodically and as needed by circumstances (e.g. new state or federal regulation, new MHS policy or procedure).

b) A log of the changes made to the SOP (via track changes) should be kept at OHR documenting each of the SOPs, the date of review, if a revision was needed and a brief description of the revision.

c) The original, revised SOP should have original signatures and be placed in the OHR SOP binder to REPLACE the existing SOP.

d) The older version of the SOP should be marked “Obsolete” and placed in the SOP archive binder by the OHR.

e) Indices will be updated by OHR.

3.3 SOP Implementation Procedures

a) The investigator or OHR designee will ensure that all appropriate personnel are trained in the proper use of the new/revised SOP. All training should be documented and signed off on a formal training log (Attachment C), and filed within the department.

b) All new and revised SOPs will be made available on the MHS research webpage.
c) The OHR designee will provide updated versions of all appropriate SOPs to research staff and will request that all outdated versions of SOPs be disposed of or archived.

4 REFERENCES TO OTHER APPLICABLE SOPS
   • All SOPs are affected by and must follow this SOP

5 ATTACHMENTS
   A. SOP Template
   B. SOP Training Documentation Form

6 APPLICABLE REGULATIONS AND GUIDELINES
   • General Responsibilities of Investigators (21 CFR 312.60 and 21 CFR 812.100)
   • The Principles of ICH GCP E6 Section 2.13
   • Quality Assurance and Quality Control (ICH E6, Section 5.1)
   • FDA Compliance Program Guidance (CPG) Manual, Program 7348.810