1 PURPOSE
This procedure describes the process for conducting and documenting training of the Investigators and other designated individuals who participate in the conduct of all human subject research within Memorial Healthcare System.

2 GENERAL INSTRUCTIONS AND RESPONSIBILITIES
   a) The Investigator assumes the responsibility for the conduct of a clinical study and the protection of human subjects and has the authority to delegate portions of that responsibility to other study personnel (Reference SOP 103). He/she is responsible for ensuring that study personnel to whom those responsibilities are delegated also are qualified by training, experience, and if appropriate, licensing, to perform their study-related duties.

   b) All personnel are responsible for completing the appropriate training to conduct study-related duties, to document protocol training, and to demonstrate they can apply training in the conduct of their duties.

3 SPECIFIC PROCEDURES
3.1 Investigator's Employee Training Plan
   a) Memorial Healthcare System (MHS) complies with federal directives to educate key research personnel and requiring those personnel to complete training on MHS research policies and procedures.

   b) The Investigator's study personnel who are working on or overseeing human subject research programs should receive initial and ongoing training regarding the ethically and scientifically sound conduct of human subject research.

   c) Training for study personnel will be scheduled and supervised by the Investigator and/or his/her designee.
d) The Investigator will ensure that study personnel attend mandatory MHS research training programs.

e) The initial training program should familiarize key personnel with the development and specifications of the protocol, investigator's brochure, investigational products, including preclinical safety information, and pertinent regulatory requirements on conducting clinical studies in accordance with Good Clinical Practice (GCP).

f) Designated training of staff should take place on site or via commercially sponsored courses. The curriculum should consist of at least the following elements:

1. Standard Operating Procedures (SOPs)
2. Investigational New Drug (or Investigational Device Exemption) Process
3. Applicable Regulatory Requirements (Investigational Product Accountability, Reporting Requirements)
4. Protection of Human Subjects (IRB, Informed Consent, Other Internal or External Regulatory Groups)
5. HIPAA

g) For sponsored investigator initiated studies, the curriculum should also include the following:

1. Study Design and Conduct
2. Protocol and Case Report Form (CRF) Development
3. Entering information on the CRF
4. Study Documentation and Files
5. SAE/AE Collection, Analysis, Interpretation and Reporting
6. Data collection, analysis, interpretation and reporting

h) For continuing education purposes, the Investigator's designee should schedule ongoing in-house GCP and human subject protection updates (Attachment A).

i) Online GCP training (Collaborative Institutional Training Initiative (CITI)) must be completed before key personnel participate in the conduct of a clinical study or engage in contacts with study participants.

j) The Investigator should provide an appropriate period of time, no greater than three months, for new employees to cover the topics in this curriculum.

3.2 Site Team Training

a) Participating Investigators and all study personnel who are working on or overseeing research on human subjects should receive initial and ongoing training regarding the responsible conduct of research (Attachment B and C).

b) All personnel will support required training activities by taking an active part in their own professional development in relevant content areas.

c) Memorial physicians who are Principal Investigators, as well as other key members of the research team such as the study and/or regulatory coordinators, may travel to an offsite Investigator meeting and/or other study related training at the sponsor's expense.
3.3 Supplemental Training
   a) Investigators and other study personnel should attend periodic workshops and seminars to acquire timely information about topics relevant to the field of human subject investigations or to their therapeutic area.

   b) Attendance at national conferences is also encouraged so that current, pertinent information is provided.

   c) It is highly recommended that all staff hired through the OHR obtain research certification through a national organization (e.g., SOCRA, ACRP, etc) within 3 years of their hire date, if not already obtained.

3.4 Protocol Training
   a) The Investigator must ensure that appropriate study personnel are knowledgeable about all protocol-specific regulatory requirements for ongoing study protocols, study procedures and investigational products.
      a. When protocol training is provided via self study materials, staff should sign off on Attachment D.

   b) For sponsor initiated studies, a sponsor representative will typically be responsible for providing training to site study personnel on the protocol requirements, drug accountability, GCP and electronic data capture requirements either in person, via webinar/teleconference or by means of a PowerPoint presentation.

   c) In those cases where an initiation visit from the sponsor is not possible, or the study is investigator-initiated, the Principal Investigator will be responsible for training research personnel on the specific requirements of the protocol and clearly documenting the name of the trainer, persons who attended, date of the training and the topics covered (Attachment E).

3.5 New Hires
   a) All new hires to the OHR will be required to go through comprehensive research training (Attachment B) prior to commencing participation in any research related activities. The form is modifiable per the research role.

   b) New Hires will also be required to review the most current version of all OHR SOPs, policies and procedures and Research Manual before receiving approval from their Manager to actively begin working on research projects (Attachment C).

3.6 Revised SOPs
   a) Once revisions to current SOPs are made, or new SOPs created, relevant research staff will be informed of the changes and provided with the new document to review and sign-off. If the SOP is more involved, it will be presented at the monthly OHR Departmental meeting with adequate training provided.

   b) To reinforce the importance of the SOPs, all OHR staff will be required to review the most current version of the SOPs annually. This should be signed off by their manager and placed in their personnel file.
3.7 Documentation of Training/Training Files

a) The OHR will maintain copies of training program certificates of completion for all research employees in their appropriate personnel files.

b) SOP training must be documented and filed using the SOP Review Sheet.

c) Research personnel are also encouraged to keep a copy of all their training certificates for reference.

4 REFERENCES TO OTHER APPLICABLE SOPS

• This SOP affects adherence to all other SOPs

5 ATTACHMENTS

A. Staff Training Form
B. Orientation Schedule for New Employees
C. SOP Review Sheet
D. Protocol Self-Study Training Document
E. Internal SIV Checklist

6. APPLICABLE REGULATIONS AND GUIDELINES

• General Responsibilities of Investigators (21 CFR 312.60)
• General Responsibilities of Investigators (21 CFR 812.100)
• Specific Responsibilities of Investigators (21 CFR 812.110)
• The Principles of ICH GCP (ICH E6, section 2.8)
• Investigator’s Qualifications and Agreement (ICH E6, section 4.1 )
• Adequate Resources (ICH E6, section4.2)
• Trial Management, Data Handling, and Record Keeping (ICH E6, section 5.5 )
• NIH Notice OD-00-039 Required Education in the Protection of Human Research Participants (June 5, 2000)
• Clarification on June 5, 2000 Notice, OD-01-061 (Sept 5, 2001)