1 PURPOSE
This procedure describes the steps for fulfilling the Sponsor’s instructions and other applicable regulatory and clinical requirements involved in specimen collection, shipping and handling.

2 GENERAL INSTRUCTIONS AND RESPONSIBILITIES
   a) The Sponsor is responsible for ensuring that all participating clinical study sites have the requisite capability and training for collecting, handling, storing, shipping and/or retaining specimens collected from subjects before, during and after the completion of a study.

   b) The Monitor is responsible for assessing each potential Investigative site for their ability to comply with the Sponsor’s specimen management requirements.

   c) The Sponsor and Investigator or their designees are responsible for carrying out all study-related specimen collection procedures according to the clinical protocol and for ensuring that specimen storage and retention requirements are fulfilled per shipping and handling guidelines.

3 SPECIFIC PROCEDURES
3.1 Assessing Specimen Management Capability
If applicable, the Study Monitor will:
   a) Visit the site’s laboratory facilities during the qualification visit.

   b) Ascertain the laboratory’s policies for receiving, handling, storing, disposing, and shipping research specimens.

   c) Assess the laboratory’s ability to process the additional expected specimens from study subjects.

   d) Assess storage space and/or requirements for alternative storage arrangements for specimens collected for the purpose of the study.
3.2 Specimen Collection, Labeling and Handling
   a) Investigative site study personnel involved in the receiving, handling, storage, disposing, and shipping of research specimens are required to receive the appropriate IATA training and certification, as required by Memorial Healthcare System and/or the Sponsor.
      i. A copy of the current training completion certificate should be provided to the OHR for the personnel training file and for tracking purposes. This should be completed before any shipping of specimens takes place.
   b) The Sponsor will include instructions in the protocol for receiving, handling, storage, disposing, and shipping of all study specimens, as applicable, and provide the necessary equipment or supplies where appropriate.
   c) Designated study personnel will collect the appropriate specimens identified in the protocol from each subject while observing appropriate precautions based upon applicable regulatory guidelines (e.g. those of the Occupational Safety and Health Administration or OSHA), the infection control manual, and/or the institutional procedure manual for the handling of body fluids.
   d) When appropriate, the Sponsor will provide study personnel with:
      i. A Specimen Preparation Checklist during site training (See Attachment A for use as a template in investigator-initiated trials).
      ii. A Specimen Shipping Log for recording specimen shipments (See Attachment B for use as a template in investigator-initiated trials).

3.3 Specimen Retention Requirements
   a) The Sponsor and site Investigator will periodically verify that specimen processing, storage, shipping and retention is within the capability of their site’s laboratory facilities, with assistance from the Office of Human Research, if needed.
   b) If laboratory policies or space prohibit the retention of specimens for the protocol-specified period of time, the Investigator will establish alternative storage space for specimens and advise the Sponsor of those arrangements.
   c) The performance of equipment for specimen storage (refrigerator, freezer) will be monitored (e.g. daily temperature charts) per the protocol, with documentation of equipment monitoring retained for the Monitor’s examination as requested.
   d) The Investigator or designee will periodically verify that specimen storage requirements (e.g. storage temperature) are being met and ensure that alternatives are available in case of emergency, e.g. power failure.

4 REFERENCES TO OTHER APPLICABLE SOPS
   • 301 Clinical Protocol Development, Implementation and Compliance
   • 401 Initiation Visit and Site Training
   • 503 Documentation and Records Retention
   • 504 Routine Monitoring Visits
5 ATTACHMENTS
   A. Specimen Preparation Checklist
   B. Specimen Shipping Log

6 APPLICABLE REGULATIONS AND GUIDELINES
   • General Responsibilities of Sponsors (21 CFR 312.50)
   • General Responsibilities of Investigators (21 CFR 312.60)
   • General Responsibilities of Sponsors (21 CFR 812.40)
   • General Responsibilities of Investigators (21 CFR 812.100)
   • Adequate Resources (ICH E6, Section 4.2)
   • Compliance with Protocol (ICH E6, Section 4.5)
   • Trial Management, Data Handling, and Record Keeping (ICH E6, Section 5.5)