1. INTRODUCTION AND PURPOSE

The proper collection and processing of specimens obtained from study subjects is an important factor impacting the integrity of data collected in a clinical study and protecting against the spread of infection at MMC as well as during transport to and arrival at off-site locations. To ensure accurate data, specimens must be collected in specified tubes, quantities, and at the specified time points. In addition, specimens must be processed, possibly preserved, and shipped as appropriate. Research, laboratory, and ancillary staff must adhere to appropriate lab practices when collecting, processing, and arranging for shipment of the specimens. This standard operating procedure (SOP) describes the steps for fulfilling the regulatory and clinical requirements involved in specimen collection and handling.

2. APPLICABLE REGULATIONS AND GUIDELINES

49 CFR 173.199	Diagnostic specimens and used health care products
49 CFR 173.217	Carbon dioxide, solid (dry ice)
21 CFR 312.62	Investigator record keeping and record retention
29 CFR 1910.1030	Bloodborne pathogens
May 9, 1997	International Conference on Harmonization: Good Clinical Practice: Consolidated Guideline
FDA website:	U S Food and Drug Administration Home Page
OHRP website:	HHS - Office for Human Research Protections
ICH website:	ICH
OSHA website	Occupational Safety and Health Administration - Home
DOT website	PHMSA - Home

3. PROCEDURES

If utilizing NorDx services, ensure that the Request for Nordx Support of Clinical Research Studies procedure has been reviewed and the NorDx Green Sheet has been completed and reviewed with NorDx personnel prior to collecting any study specimens.

Collection

Collect specimens according to the protocol while observing appropriate precautions based upon the "Occupational Safety and Health Administration (OSHA) bloodborne pathogens guidelines, and the Institutional Infection Control Manual".

Label the tubes, other containers, and study required forms with subject ID, date, and time.

Utilize sponsor provided supplies, labels, and processing documents*

Processing and Shipping

* May not apply to non-industry sponsored trials

Process the specimens according to the procedure defined in the protocol (for example, centrifuge speed, duration, temperature requirements).

Prepare and package specimens being sent to an outside laboratory according to the instructions specified in the protocol or the laboratory procedure manual*and in accordance with legal requirements.

Complete the appropriate laboratory requisition slip. If using a central or outside laboratory follow the instructions in the protocol or lab manual* (if provided).

Personnel responsible for shipping specimens must be properly trained according to the type of specimen being shipped. Identify if the specimen is an Infectious Substance, Category A or a Biological Substance, Category B as this will dictate the training required to satisfy federal regulations. For more information regarding Category A and Category B differentiation, refer to the Sample Training Module Pertaining To The Requirements Set Forth In 49CFR173.199 and 49CFR173.217.

Required Shipping Training- Infectious Substances, Category A
Complete the Saf-T-Pak™ Shipping Division 6.2 Dangerous Goods Compliance Training CD-ROM on shipping hazardous materials.

Repeat training prior to the date of expiration noted on the Saf-T-Pak™ training certificate.

Upon completion of training, forward a copy of the training certificate to the Research Education and Compliance Officer at MMCRI.

Required Shipping Training- Biological Substance, Category B
Complete the Packaging Biological Specimens, Category B training module Sample Training Module Pertaining To The Requirements Set Forth In 49CFR173.199 and 49CFR173.217.

Complete the training module post-test.

Retain the training module and return a copy of the signed and dated post-test to the Clinical Trials Unit Manager.

A score of 100% is required. Individuals who score below 100% will be notified and instructed to repeat the post-test.

Repeat this training in 3-years.

4. LINKS AND RESOURCES

Request for Nordx Support of Clinical Research Studies Attachment A

* May not apply to non-industry sponsored trials

Nordx Green Sheet Attachment B
Occupational Safety and Health Administration (OSHA) bloodborne pathogens guidelines (link)
Procedure Manual for the handling of bodily fluids (link)
Sample Training Module Pertaining To the Requirements Set Forth In 49CFR173.199 and 49CFR173.217 Attachment C