Procedure Name: Specimen Collection and Handling Procedure	**Number:** SOP 8 v3.0
Subject: Clinical Research	**Effective Date:** July 01, 2004
Linked Policy: Clinical Research Operations & Compliance Policy	**Revised Date:** June 08, 2023

PURPOSE:

To establish the GW Medical Faculty Associates ("MFA") procedure for collecting and handling specimens from research subjects including certification in hazardous shipping and adhering to good laboratory practices when collecting, processing and arranging for shipment of specimens.

SCOPE:

This standard operating procedure ("SOP") applies to all research team members responsible for the collection and handling of human subject specimens.

RESPONSIBILITY:

This SOP sets forth responsibilities for research team members involved with collection and handling specimens from subjects involved in clinical research studies conducted at the MFA. The Principal Investigator ("PI") retains this responsibility unless the PI has expressly delegated this duty to another research team member and the delegation is documented on a study specific Delegation of Authority Log.

PROCEDURES:

Study specific specimen collection and handling are provided by clinical trial sponsor or their vendor that is running the analysis on the labs. Any deviation from the guidelines should be appropriately documented and reported to the sponsor real time. In general, coordinators should follow the steps listed below:

<u>Collecting the Specimens</u>

1. Research team members responsible for the shipping of hazardous goods (research specimens) must receive International Air Transport Association (IATA) certification prior to being delegated this duty. IATA training certifies that research staff on how to safely transport hazardous materials by air in accordance with the Dangerous Goods Regulations

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2. Collecttheappropriateresearchspecimensasperprotocolfollowingprecautionsbasedupon OSHA guidelines, infection control, and policies and procedures for the handling of body fluids.
3. Document the collection into the research subject's record, noting the date and time of collection and any relevant information concerning the subject's status at time of collection. Data elements for clinical trials sponsors may vary. At minimum you must include the protocol, the subject unique ID, date and time of collection and the labs being sent for analysis
4. Maintain a central record of the protocol specified retained body fluids/tissue samples to document the location and identification of retained samples if assays need to be repeated.
5. Labelthetesttubesorothercontainerswithresearchsubjectidentifiersandtheshortname for the lab being sent, as per protocol or per laboratory instructions (i.e. LabCorp).
6. Collect specimens following universal precautions including the use of appropriate personal protective equipment.

<u>Processing the specimens</u>

1. Process specimens per protocol specifications (e.g. centrifuge speed, duration, temperature specifications).
2. Process specimens and when required transfer into the appropriate transport tube(s) following the proper precautions, and in the proper location.
3. Label the study-specific test tubes or other containers with research subject identifiers, date, time and any other required information.
4. Complete laboratory requisition as appropriate. Enclose one copy with specimens and retain one copy for the subject's study file.

<u>Preparing specimens for shipping to the test laboratory</u>

1. Prepare specimens per protocol specifications and/or central laboratory procedure manual.
2. Complete and maintain a specimen shipment log as appropriate.
3. Retain a copy of shipping receipt/air bill tracking number.

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Storing of specimens

1. Some clinical trial sponsors ask sites to store samples in a freezer for a certain duration. Always refer to your clinical trial protocol for storage instructions.
2. If you are required to store specimens for one night or greater, you must keep a temperature log of the freezer temperature daily.
3. If there are any temperature excursions, those must be reported to the clinical trial sponsor within 24 hours

Retaining Clinical Specimens after a study has Completed

1. Once a study has been completed and a final report submitted, consult sponsor regarding relocation, destruction, anonymization of any remaining clinical specimens.
2. Unused specimens must be destroyed unless consent has been granted for future use of stored specimens.
3. If consent for future use has not been granted, a destruction method and documentation must be part of the regulatory file.
4. If consent for future use is granted, then a list of subject numbers and a certified copy of the consent granted future use needs to be maintained in the regulatory file.

Review and Revision

This SOP shall be reviewed every 2 years. This SOP may be reviewed more frequently if it does not reflect current operations.

REFERENCES:

21 CFR 312.62	Investigator recordkeeping and record retention.
21 CFR 812.140	Records.

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IATA DGR	Dangerous Goods and Regulations: International Air Transport Association 40 Code of Federal Regulations (40 CFR) Transportation of Dangerous Good Regulations
ICH E6 (R2)	Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2)
	Section 8.3.25
MFA Clinical Research SOPs	SOP 6- Source Documentation Procedure