THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

SOP-14: Research Specimen Management

1. Objective

To ensure that the Principal Investigator (PI) and all research team members assisting in the conduct of clinical research are informed about their obligations and responsibilities as they pertain to Good Clinical Practices (GCP), the investigational plan, applicable regulations, guidances, and institutional policies. This Standard Operating Procedure (SOP) applies to the written procedures followed by all members of a clinical research team involved in the conduct of human subjects' research at The Ohio State University Wexner Medical Center (OSUWMC), hereafter called the investigational site. These detailed instructions promote compliance in conducting clinical research.

SOP-14 describes the process for the proper collection, handling, and management of biospecimens for clinical research. Attachment templates include:

A: Research Specimen Shipping Log

2. Responsibility

The College of Medicine Clinical Trials Management Organization (COM-CTMO) develops, implements, and maintains SOPs. The need to write a new or revise an existing SOP is based upon changes to federal regulations, guidelines, institutional policies, or procedures. These documents will be provided to departments and research teams conducting human subjects' research. Departments or research teams may develop additional research SOPs or a Research Procedure Addendum (RPA) to expand on an existing SOP, however this need should be limited.

The PI is ultimately accountable for all clinical research activities and is responsible for the appropriate delegation of tasks to individuals with adequate training and education to perform such tasks. It is the responsibility of all members of the clinical research team involved in supervising, managing, or conducting study-related activities to follow the SOPs. The clinical research team may include but is not limited to the following members:

Research Team Members

Principal Investigator (PI)	Clinical Research Coordinator (CRC)
Sub-Investigator (Sub-I)	Clinical Research Assistant (CRA)
Clinical Research Manager (CRM)	Other Research Staff as appropriate
Clinical Research Specialist (CRS)	Administrative and Support Staff

3. Definitions

Please refer to the SOP Glossary document for detailed definitions of commonly used clinical research terminology.

4. Procedures

All research team members that will be in direct contact with patients, biohazardous materials or work in the clinical setting will complete appropriate biosafety and occupational health training and obtain appropriate tests and immunizations related to their specific job requirements from employee health prior to engaging in delegated tasks for a clinical research study. For a complete list of required trainings go to COM/OHS Training and Assessment Checklist.

Clinical research studies that produce results (either qualitative or quantitative) from biospecimen research tests that impact clinical decision making are recorded in the subject's electronic health record or that are communicated to the subject directly, must be conducted in a CLIA approved laboratory or have appropriate CLIA certificate waivers. This includes point of care testing such as pregnancy, glucose, creatinine, urine testing, etc. The PI or research team members will contact the medical center Pathology CLIA compliance team at CLIA.compliance@osumc.eduto determine if the research testing requires CLIA oversight.

The PI and delegated research team members will ensure that the facilities and equipment utilized for obtaining, processing and storing biospecimens is reviewed at regular intervals by Environmental Health and Safety (EHS).

If equipment needs to be calibrated (e.g., centrifuges, scales, refrigerators, etc.) it is the responsibility of the research team members to arrange at a minimum yearly calibrations and maintenance with an approved OSU vendor.

A. Specimen Collection, Processing, Storage, Shipping and Transportation

Collection

The PI or delegated research team members will have appropriate training and practice the necessary precautions when collecting biospecimens from subjects by following OSHA safety guidelines and institutional policies and procedures.

The PI or delegated research team members will appropriately document the subject name, study ID number, date and time of collection, type of specimen collected, and any relevant information pertaining to the subject's status at the time of the specimen collection. Appropriately label the specimen with subject identifiers, date, time, type of specimen and any other protocol-required information. Any protected health information (PHI) will be kept confidential and secured per institutional policies.

Processing

The PI or sponsor provides specimen processing guidelines (outlined in either the protocol or a lab manual), which must be followed by the investigational site. This may include instructions related to centrifuge settings, temperature, time, speed, and number of aliquots.

When handling or processing specimens, research team members must have access to personal protective equipment (PPE). PPE includes but is not limited to gloves, protective face shields, and lab coats. Lab coats worn to process samples should not be the same coats worn in patient care clinics.

Storage

Storage requirements, specified in the PI or sponsor provided protocol or lab manual, must also be followed by the investigational site. This may include required labels for specimens, appropriate storage containers, temperature, and duration of storage. Research specimens should not be stored with investigational products, food, or beverages.

Shipping

Shipping requirements, specified in the PI or sponsor provided protocol or lab manual, will also be followed by the investigational site. This may include completing the laboratory requisition slip to send with the specimens, specific preparations and packaging requirements of the specimens, and acceptable days to ship specimens.

Transportation
If samples are transported by research team members to another location, it is required that they are placed in a biohazard bag and transported within a closed container that is sealable to reduce accident and exposure risk.

The PI and delegated research team members will maintain a research specimen collection, processing, and shipping log *(See Attachment A: Research Specimen Shipping Log).* A copy of all shipping records for biospecimens will be maintained at the investigational site. Any deviations from the protocol specific collection, processing, or storage requirements will be documented and reported to the sponsor.

5. Applicable Regulations, Guidances and Policies

Regulation/ Guidance/Policy	Title
21 CFR 50	Protection of Human Subjects
21 CFR 312	Investigational New Drug Application
21 CFR 812	Investigational Device Exemptions
45 CFR 46	Protection of Human Subjects
45 CFR 160	HIPAA Privacy Rule
45 CFR 164 Subparts A and E	HIPAA Privacy Rule
49 CFR 107	Transportation: Hazardous Materials Program Procedures
49 CFR 171	Transportation: General Information, Regulations, and Definitions
OSU Environmental Health & Safety	Research/Biosafety Programs and Services
OSU Office of Responsible Research Practices HRPP	Privacy and Confidentiality
OSU Office of Responsible Research Practices HRPP	Research Involving Data and or Biological Specimens
OSU Office of Responsible Research Practices HRPP	Research Involving Human Subjects
OSU Office of Responsible Research Practices HRPP	Research Involving Investigational Drugs
OSU Office of Responsible Research Practices HRPP	Research Involving Medical Devices
OSU Office of Responsible Research Practices HRPP	Responsibilities of Principal Investigators, Co-Investigators, and Key Personnel

OSU Office of Research	Institutional Biosafety Policy
OSUWMC	Use of Patient Information by Hospitals and Medical Staff
OSUWMC	Patient Information & HIPAA Requirements
OSUWMC	OSU Clinical Laboratories
COM Office of Human Resources	Training & Assessment Requirements
FDA Guidance for Industry	Investigator Responsibilities- Protecting the Rights, Safety, and Welfare of Study Subjects, October 2009
ICH GCP E6(R2)	Guideline for Good Clinical Practice: E6 Integrated Addendum

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