West Virginia Clinical and Translational Science Institute Center of Excellence

STANDARD OPERATING PROCEDURE

Title:		COE-116.00	
Biospecimen Management		Page 1 of 4	
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Purpose:

This standard operating procedure (SOP) describes the standard operations followed by the Morgantown, West Virginia University (WVU) Health Science Center (HSC) and affiliated health systems regarding biospecimen management.

Scope:

This SOP describes the process for the collection, storage, tracking and shipment of biospecimens involving human subjects to ensure that ethical principles and regulatory compliance are maintained regarding human biospecimens used for research.

Materials:

Attachment 1- Biospecimen Chain-of-Custody Tracking Form Template

Responsibility:

This SOP applies to the clinical research personnel responsible for the biospecimen maintenance involving human research subjects.

Definitions

Biospecimen: A collection of human specimens and associated data for research purposes such as but not limited to, blood and blood products, bone marrow, tissue obtained from transplants, surgery, or autopsy, urine, saliva, placental tissue, cord blood and feces.

Identifiable biospecimen: A biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen (45 C.F.R. 46.102(6)).

Individually Identifiable: The identity of the subject is or may readily be ascertained by the investigator or associated with the information or biospecimen. (45 C.F.R. 46.102(6)).

Coded specimen: The specimen contains (1) identifying information (such as name or social security number) that would enable the investigator access to the identity of the individual to whom the specimen was obtained, has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and (2) a key to decipher the code exists, which enables the linkage of the identifying information to the private information or biospecimens.

Unidentified: The process of removing identifiers from samples to prevent traceability to the original subject.

Procedure

There are restrictions for accessing and using the personal identifying data that may be associated with human biospecimens. Researchers who manage human specimen data, and other investigators who have access to it, are legally and ethically obligated to protect data that is considered private information. The type and extent of private information that can be transferred with shared specimens must be consistent with the IRB-approved research protocol, HIPAA authorization from the participant, data use agreements, and, if applicable, Clinical Trial Agreements.
Only limited PHI should be associated with specimens collected and sent externally as part of clinical trials. The specimens should be coded and direct identifiers (e.g. name, medical record number) must not be associated with specimens unless specifically documented in the signed consent form.

A. The PI or delegated research team members shall have the appropriate training for biospecimen collection and handling according to OSHA safety guidelines, institutional policies, protocol and/or laboratory requirements. Research staff must also obtain biosafety training from the WVU Environmental Health and Safety Department or equivalent alternative.

B. The PI or delegated research team may consult with the WVU Institutional Review Board (IRB) and/or the IRB of record to determine how Federal and State regulations and policies apply in regard to the requirements for IRB approval, informed consent process and biospecimen repository.

Note: Some HHS conducted or supported research involving coded private information or specimens may be subject to Food and Drug Administration (FDA) regulations. The FDA regulatory definitions of human subject (21 CFR 50.3(g), 21 CFR 56.102(e)) and subject (21 CFR 312.3(b), 21 CFR 812.3(p)) differ from the definition of human subject under HHS regulations at 45 CFR 46.102(f).

1. Collection and processing

    a. Specimens collected for research purposes or clinical specimens to be used for research purposes, should be collected, and processed according to the type of the specimen being collected, protocol, lab manual and/or

their intended use. Documentation of the biospecimen collection and processing should be maintained for research purposes.

b. Specimens collected should be categorized as either identified or unidentified.

c. Protected health information (PHI) shall be kept confidential and secured per WVU and WVUH institutional policies.

2. Storing

a. Individual types of biospecimens should be stored according to the protocol or laboratory guidance specific to the biospecimen type and the purpose for the collection.

3. Specimen Banking

a. Refer to WVU HSC Data and Biospecimen Repositories guidance.

4. Shipping/Final disposition

a. Shipping requirements depend upon the type of sample and the intended use. When shipping specimens consider the shipping time, distance, climate, season, method of transportation. It should also be consistent with all applicable laws, regulations, policies, and terms for transfer of those particular materials. Shipment should also be performed in accordance with the protocol and/or laboratory guidance specific to the study/biospecimen type.

b. Documentation of the shipment may include information such as recipient (or source), date shipped (or received), courier name and package tracking number, sample description, number of samples shipped (or received), condition on arrival, study name and number if applicable, investigator's name, and signature of biospecimen recipient. Documentation of shipment should be maintained for research purposes.

c. Chain of custody procedures that allow for tracking the biospecimens from collection or receipt to shipment/processing/final disposition should be followed and associated documentation retained.

d. A materials transfer agreement may be required when receiving or sending identifiable information, including when related to biospecimens.

e. In some cases, biospecimens can also be stored in a bank for future research use or disposed and procedures from IRB approved protocols and/or laboratory methodologies should be followed.

References

HHS OHRP Guidance, Engagement of Institutions in Human Subject Research, 2008
HHS Regulation Subject Protection, 45 C.F.R. 46.102(6)
U.S. Occupational Safety and Health Administration's Bloodborne Pathogens Standard (OSHA Standards, Booklet 3186-06R, 2003)
WVU HSC Data and Biospecimen Repositories guidance
WVU Health System policies
WVU HSC Biospecimen Processing policies

History of Revisions to SOP

Effective Date	Nature of Revision
14 FEB 2022	New SOP