



The biorepository defines the types of specimens submitted based on the following:

- 1. Purpose (intended use of specimen)**
- 2. Required specimen data**
- 3. Biosafety/risk level (laboratories are suitable for the type of specimen/pathogen requiring processing)**
- 4. Duration of storage (may be indefinite)**

NOTE: This may be an overarching statement that defines the criteria required for all collections held in the biorepository. This may include the receipt or transfer of an entire collection.

REFERENCES

- 1) Department of Health and Human Services. Biosafety in Microbiological and Biomedical Laboratories, 6th ed. June 2020.

BAP.01700 Collection/Processing Oversight

Phase II

A pathologist or designee assigned to the management of the biospecimens ensures that collection policies and processes reflect published best practices.

NOTE: Blood and other body fluids not required for the diagnosis or prognosis must be collected with approved protocols and may not require pathologist review. To determine remnant tissue at the site of the collection, the appropriate medical/legal designee must be involved in the decision. This does not apply to downstream processing.

If samples are acquired according to sponsor-driven protocols, the sponsor makes all decisions about sample usability. The biorepository carries out the instructions provided by the sponsor. In this instance BAP.01700 is not applicable.

REFERENCES

- 1) International Society for Biological and Environmental Repositories (ISBER). ISBER best practices recommendations for repositories. 5th ed. ISBER; 2023.

BAP.01703 Disease Control Import Permit

Phase II

If the biorepository receives specimens that are considered infectious biological agents imported from outside of the United States and its territories, the biorepository has obtained the Centers for Disease Control Import Permit.

NOTE: The Office of Public Health Preparedness and Response CDC Import Permit Program regulates the importation of the following into the United States:

- *Naturally occurring or bioengineered infectious biological agents capable of causing disease in a human;*
- *Any material that is known or reasonably expected to contain an infectious biological agent;*
- *Vectors, including animals/animal products that are known to transfer or are capable of transferring an infectious biological agent to a human.*

If the material being imported is rendered sterile (eg, thermal, chemical or irradiation treatment) or it has been confirmed not to contain infectious agents for humans, a CDC-issued import permit is not required for importation. Information, guidance documents, and resource materials may be found on the following website: <http://www.cdc.gov/import-permit-program/php/index.html>. The application may be obtained from <http://www.cdc.gov/import-permit-program/php/eipp/index.html>.

BAP.01704 Chain-of-Custody Procedures

Phase II



The biorepository follows a defined process for chain-of-custody specimen collection, accessioning, and handling.

NOTE: If specimens are referred to another laboratory, the collection site must follow chain-of-custody instructions provided by the referral laboratory.

REFERENCES

- 1) Clinical and Laboratory Standards Institute (CLSI). *Toxicology and Drug Testing in the Medical Laboratory*. 3rd ed. CLSI guideline C52. Clinical and Laboratory Standards Institute, Wayne, PA; 2017.

BAP.01706 Biospecimen Chain of Custody**Phase II**

The biorepository has a system to track biospecimen chain of custody.

NOTE: Chain of custody is used to maintain the integrity of the biospecimen by providing records of the control, transfer, and analysis of biospecimens.

The intent of this requirement is to have a system in place to ensure adequate records of the "life history" of the biospecimen. Chain of custody provides a traceable record that guarantees unbroken control over biospecimens and its containers from initial collection to final disposition. This is achieved with accurate and effective labeling, tracking and reporting.

Chain of custody requires that from the moment the biospecimen is received every transfer between departments be recorded.

Evidence of Compliance:

- ✓ Logs or message boards showing specimen movement through biorepository **AND**
- ✓ Work flow diagrams

BAP.01709 Surgical Pathology Specimens Release for Research**Phase II**

A sample of a surgical pathology gross specimen may be submitted for research only if all of the following criteria are met:

1. The pathologist determines that the sample(s) is not necessary for diagnostic purposes.
2. For laboratories subject to US regulations, formal written authorization is obtained in accordance with the requirements of HIPAA if identifiable patient information is released.
3. The biorepository meets other relevant requirements, including but not limited to, the requirements of the institution, the directives of any applicable institutional review board (IRB) or similar entity, and national, federal, state (or provincial), and local laws and regulations.
4. De-identified/anonymized sample of a surgical pathology gross specimen may be submitted for research if a waiver of consent has been obtained.

BAP.01712 De-identification for Research**Phase II**

For specimens that are released for research, the biorepository follows a defined process for de-identifying/blinding or anonymizing specimens without compromise to research-related demographic information, when required.

BAP.01715 Coding**Phase II**

There is a defined coding system for sample identification.

BAP.01718 Participation/Donor Informed Consent**Phase II**

For specimens that are released to a biorepository, appropriate participant/donor informed consent is secured.

NOTE: This is not applicable when specimens are obtained under waiver of consent.