



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.