NOTE: This could include: 1) a sponsor-investigator (such as a pharmaceutical company seeking samples for an internal research project or as part of a multi-site clinical trial); 2) a biobank seeking biosamples to fulfill the needs of its research clients; 3) a cooperative oncology group that sets criteria (such as disease type, specific samples required, accompanying medical data, informed consent specifications) for inclusion into a biobank and that cooperative oncology group confirms all criteria have been met (directly or through a contracted biobank) before submitted samples are accepted into the biobank.

BIOSPECIMEN COLLECTION AND HANDLING

SPECIMEN COLLECTION AND HANDLING

The collection and handling for all biospecimens is critical to the overall quality and diversity of the sample inventory.

Inspector Instructions:

	• Sampling of policies and procedures for sample collection and handling, including sample types, samples with potentially infectious materials, preservation, de-identifying or anonymizing, aliquoting, specimen storage conditions, and chain-of-custody • Policy for the type of samples suitable for submission to the biorepository • Storage temperature records • Sampling of biospecimen QA reports for key elements of processing and preservation of solid and fluid specimens • Records of informed consent and IRB releases
	• Sampling of stored specimens for temperatures required by protocols • If collection occurs on-site, observe the processing/preservation procedure • Specimen storage conditions during sample receipt
	• How does your biorepository capture variables that could impact biospecimen usage? • How/when would the biorepository communicate pre-analytic variables to researchers? • How do you ensure accuracy of pre-analytic data capture? • What is your specimen coding system for sample identification? • How do you confirm patient consent prior to processing and banking? • What do you do if the sample size is too small relative to the requirements or it does not meet researchers' needs? • Do you receive specimens considered infectious biological agents from outside the United States?
	• Follow a tissue sample released for research from the pathologist to storage

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.