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