INTRODUCTION

A biorepository is defined as an entity that collects, processes, stores, manages, and/or distributes biospecimens, their derivatives and relevant data, as needed, for research purposes. It encompasses the physical location as well as the full range of activities associated with its operation. The term biorepository used within the checklist may be considered synonymous with biobank and repository.

The term laboratory may also be used to describe a biorepository. When the term "patient" is used within the checklist, it may also refer to donors, clients, and study participants.

This checklist covers a broad range of activities that occur in biorepositories. Not all checklist requirements will apply to every biorepository.

The scope of services of the biorepository must be clearly recorded.

 *Policy/Procedure icon - The placement of this icon next to a checklist requirement indicates that a written policy or procedure is required to demonstrate compliance with the requirement. The icon is not intended to imply that a separate policy or procedure is required to address individual requirements. A single policy or procedure may cover multiple checklist requirements.*

***Laboratories not subject to US regulations:** Checklist requirements apply to all laboratories unless a specific disclaimer of exclusion is stated in the checklist. When the phrase "FDA-cleared/approved test (or assay)" is used within the checklist, it also applies to tests approved by an internationally recognized regulatory authority (eg, CE-marking).*

*References used in the development of this checklist were the CAP Accreditation Checklists, 2023 ISBER * Best Practices for Repositories, and the NCI Best Practices for Biospecimen Resources.*

*ISBER — International Society for Biological and Environmental Repositories is an international forum that addresses the technical, legal, ethical, and managerial issues relevant to repositories of biological and environmental specimens.

DEFINITION OF TERMS

Aliquot - Process wherein a specimen is divided into separate parts which are typically stored in separate containers as individual samples. The term aliquot may also be used as a noun to denote a single sample.

Anonymization - The process of removing particulars from samples, test results, or records to prevent traceability to the original patient.

Blinding - An action taken to prevent access to information that might affect the outcome of an observation.

Coded specimen - Identifying information (such as name or social security number) that would enable the investigator to ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (ie, the code); and a key to decipher the code exists, enabling linkage of the identifying information to the private information of specimens.

De-identify - The removal from a specimen of all 18 elements that could be used to identify the individual or the individual's relatives, employers, or household members; these elements are enumerated in the HIPAA Privacy Rule.

Derivative - A substance that can be made from another substance.

Function check - The set of routines that show an instrument to be ready for operation.

Legacy specimen - Biospecimens available for research once all protocol-specified endpoints, including clinical and biorepository studies, have been completed. These remaining biospecimens could be made available by the biorepository for correlative studies (subject to application, scientific review, and approval).

Material Transfer Agreement (MTA) - An agreement that governs the transfer of tangible research material and associated clinical data between two organizations, when the recipient intends to use it for his/her own research purposes.

Pathologist - A physician who has successfully completed an approved graduate medical education program in pathology.

In the US, a physician is defined as a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine who is licensed by the state to practice medicine, osteopathy, or podiatry within the state in which the laboratory is located. In jurisdictions not subject to US regulations, a physician is defined as an individual who has a primary medical school degree (eg, MBBS, MBChB, MD, DO) in keeping with the standards of that particular jurisdiction.

Qualified pathologist - A pathologist who has training in the specific functions to be performed (eg, an anatomic pathologist for anatomic pathology functions, a clinical pathologist for clinical pathology functions, or an anatomic pathologist or dermatopathologist for skin biopsies).

Quality assurance - The systematic monitoring and evaluation of the various aspects of a project, process, service or facility to maximize the probability that minimum standards of quality are being attained.

Quality control - An integral component of quality management composed of the aggregate of processes and techniques used to detect, reduce, and correct deficiencies in an analytical process.

Quality control (QC) is a surveillance process in which the actions of people and performance of equipment and materials are observed in some systematic, periodic way that provides a record of consistency of performance and action taken when performance does not conform to standards set by the biorepository. QC is a set of procedures designed to monitor the test method and the results to assure test system performance; QC includes testing control materials, charting the results and analyzing them to identify sources of error, and determining, performing and recording any corrective action taken as a result of this analysis.

Remnant specimens - Remaining portion of a specimen obtained for clinical purposes that is no longer needed for its original purpose and that would otherwise be discarded.

Sample - A single unit containing material derived from one specimen.

Source Facility - Those sites that contribute specimens to the biobank. The source facility may be a clinic, hospital or individual investigator, and, in some instances, the biorepository may be the source facility, (eg, when the biorepository does blood or specimen collections for normal controls).

Specimen - A specific tissue, blood sample, etc. taken from a single subject or donor at a specific time.

Sponsor - The person, organization or biorepository that seeks and is responsible for the initiation, maintenance, and governance of the biospecimen collection. The sponsor typically provides the financial support to create and maintain the collection.

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