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.