SECTION 1.

Glossary and definitions

Unless otherwise defined in another context in this book, important terms are defined below.

Some of the definitions are according to the 2012 International Society for Biological and Environmental Repositories (ISBER) guidelines (ISBER, 2012).

It should be noted that the International Organization for Standardization (ISO) standards that are currently under development and will be released within 2 years (ISO/TC 276 Biotechnology) will include a section on biobanking definitions.

Adverse event
Any event that caused harm or had the potential to cause harm to any biobank personnel or visitors, including but not limited to breach of security of the premises and its contents, or harm to biospecimens or data integrity or linkage.

Aliquot
Aliquoting is a process in which a specimen is divided into separate parts, which are typically stored as individual samples. The term "aliquot" may also be used as a noun to denote a single sample. It is advisable to store aliquots in separate containers, to minimize loss due to unexpected equipment failure.

Analyte
A substance or chemical constituent that is determined in an analytical procedure.

Annotation
Additional information associated with a particular point in a document or other piece of information.

Anomaly
An unexpected event occurring within the quality management system, usually detected by staff of the area in which the event occurred, which may result in non-compliance with the quality management system or with the requirements of the user.

Anonymization
The process in which identifying information or details are removed from the data collected with a sample, so that the sample donor remains anonymous.

Associated data
The clinical, pathological, and epidemiological information related to patients who provided a sample. The information relates to characteristics of the sample, the study participant, and biological experiments that can be used to generate knowledge.

Autopsy
The postmortem examination of

organs and tissues of a body, to determine cause of death or pathological conditions.

Biobank
Infrastructure for the collection, archiving, and storage of biospecimens and their associated data, and the procedures and related services connected to the biospecimens and associated data. The services include informing individuals who are approached to participate in a study, obtaining their consent, collecting and processing specimens for secure long-term storage, accessing and retrieving specimens appropriate for analysis, processing for preparation of biomaterials (e.g. DNA, RNA, proteins), quality control, and packaging and shipping of specimens. Many types of biobank are relevant to cancer research. They include, among others, tumour and tissue biobanks for specimens and data obtained in the course of normal clinical procedures; specialized collections of specimens and data developed in the context of clinical trials, mechanistic studies, or diagnostic or prognostic studies; and collections of specimens and data developed in epidemiological studies and biomarker studies. Biobank samples include tissues, blood, cell lines, DNA, and proteins derived from individuals with a history of hereditary or familial cancer. Biobanks are also known as biorepositories.

Biobanking
The process of storing material or specimens and associated data for future use.

Biohazard
An organism, or a substance derived from an organism, that poses a threat to (primarily) human health. This can include medical waste and samples of a microorganism, virus, or toxin (from a biological source) that can affect human health. It can also include substances harmful to animals.

Biological resource
A collection of biological specimens and associated data that are acquired for a defined purpose. The custodian of the collection is responsible for the management of the biological resource. Biological resources may be stored in a biobank or laboratory and in databases, depending on the number of samples, the volume of information, and the governance structure of the biobank.

Biological safety hood
A cabinet designed to provide a microbe-free work environment, which enables work on samples in an isolated area.

Biorepository
See “Biobank”.

Coding
Substituting a code for personally identifying information in such a way that linkage is only possible through a key.

Cold chain
A temperature-controlled supply chain.

Cold ischaemia
The condition of a tissue sample after its removal from the body until its stabilization or fixation.

Collection
The practice or technique of collecting a specimen, or a specific sample or group of samples, that has been isolated for future research purposes.

Consignee
Any individual, agency, institution, or organization that receives specimens and assumes responsibility for storing, dispensing, and tracking the disposition of specimens.

Container
An enclosure for one or more units of a specimen or specimens.

Controlled areas
Restricted work areas of low microbial and particulate content in which non-sterile materials are prepared.

Custodian
The person responsible for the management of a biological resource. The custodian works with other key stakeholders in the management of the resource, including the tracking of all relevant documentation for the resource, and is responsible for ensuring that policies on access to the resource are in place and are implemented according to appropriate guidelines.

Database
A structured collection of records or data that is stored in a computer system so that a computer program or a person using a query language can consult it to answer queries.

Dehydration
The removal of water from a tissue.

De-identification
A process that ensures that a person’s identity cannot be connected with information or samples donated by them.

Desiccant
A desiccant is a hygroscopic substance that induces or sustains a state of dryness (desiccation) in its vicinity. Commonly encountered pre-packaged desiccants are solids that absorb water.

Deviation
An intentional or unintentional event that departs from a set procedure or normal practice.

Dewar
A specialized container that holds

liquefied gases. A dewar may also be referred to as a dewar flask or dewar vessel, or a liquid nitrogen tank.

Distribution
A process that includes receipt of a request for specimens, selection of appropriate specimens, and final inspection, in conjunction with subsequent shipment and delivery of specimens to another biobank, specimen collection centre, or laboratory.

Donor
A person who donates or gives an organ, blood, or blood products to another person.

Dry ice
Solid-phase carbon dioxide (CO_2). CO_2 solidifies at −78.5 °C.

End user
A health-care practitioner, scientist, or laboratory staff member who performs an appropriate procedure, test, or archival function.

Error
A deviation from a standard operating procedure (SOP) during specimen retrieval, processing, testing, quarantining, labelling, storage, or distribution that might adversely affect the specimen.

Ethical, legal, and social issues (ELSI)
The ethical, legal, and social issues associated with the development and operation of a biobank.

Identifier
Information (e.g. name, social security number, medical record number, or pathology accession number) that would enable the identification of the subject. For some specimens, this information might include the taxon name and the collection number.

Incident
Any unplanned occurrence that deviates from standard operating procedures (SOPs) or applicable government laws and regulations during specimen retrieval, processing, labelling, storage, or distribution that may affect subsequent use of those specimens.

Individual
The person who is the subject of protected health information.

Informed consent
A decision to participate in research, taken by a competent individual who has received the necessary information; who has adequately understood the information; and who, after considering the information, has arrived at a decision without having been subjected to coercion, undue influence, inducement, or intimidation.

Institution
The body responsible for specimen collection and archiving that commits itself to the development, management, and long-term maintenance of a biobank. Although the organizational nature of such institutions may vary widely, they are primarily clinical cancer centres, academic medical centres, research institutes closely associated with clinical centres, or central organizations dedicated to the management of biobanks.

Institutional review board (IRB)
See “Research ethics committee (REC)”.

Label
Any written, printed, or graphic material on or affixed to a specimen container or package.

Liquid nitrogen (LN_2)
Coolant used to cool and store samples. Nitrogen becomes liquid at −196 °C. Samples stored in the vapour phase of liquid nitrogen are −190 °C and warmer, depending on the distance from the liquid phase.

Liquid nitrogen tank
See “Dewar”.

Lyophilized
Dehydrated for storage by conversion of the water content of a frozen specimen to a gaseous state under vacuum. Also called “freeze-dried”.

Material Transfer Agreement (MTA)/ Data Transfer Agreement (DTA)
An agreement or contract that governs the transfer of research materials and/or data between two organizations, when the recipient intends to use them for research purposes. It defines the rights and obligations of the provider and the recipient with respect to the use of the materials and/or data.

Monitoring system
A system that monitors the temperature and environmental conditions, including alarms, in conjunction with remote access, security features, and electronic data storage.

Participant
A person who takes part in a trial. Participants must usually meet certain eligibility criteria.

Patient
A person who receives medical attention, care, or treatment.

Pre-analytical data
Factors that may have an impact on the integrity of the sample during the collection, processing, and storage processes. These data include information on the treatment of the sample, including the conditions and the duration of the treatment.

Preservation
The use of chemical agents, alterations

in environmental conditions, or other means during processing and storage to prevent or retard biological or physical deterioration of a specimen.

Procedure
A series of steps that, when followed in order, are designed to result in a specific outcome.

Processing
Any procedure used after specimen collection but before distribution, including preparation, testing, and releasing the specimen to inventory and labelling.

Pseudo-anonymization
The process whereby identifiable personal information is anonymized, but in such a way that the personal identifiers are replaced by one pseudonym, which can be linked across multiple data records without revealing the identity of the person.

Quality
Conformance of a specimen or process with pre-established specifications or standards.

Quality assurance (QA)
An integrated system of management activities involving planning, implementation, documentation, assessment, and improvement to ensure that a process or item is of the type and quality needed for the project.

Quality control (QC)
The system of technical activities that measures the attributes and performances of a process or item against defined standards, to verify that the stated requirements are fully met.

Quality management system (QMS)
The organizational structure, procedures, processes, and resources needed to implement quality management.

Re-identification
A reversible process that allows data from which identifiers have been removed, and replaced by a code, to be re-identified and linked to a specific individual by, for example, using the code or linking different data sets.

Removal
See “Retrieval”.

Repository
An entity that receives, stores, processes, and/or disseminates specimens, as needed. This term encompasses the physical location as well as the full range of activities associated with its operation. A repository may also be referred to as a biorepository or a biobank.

Research ethics committee (REC)
A board, committee, or other group formally designated by an institution to review the ethical, legal, social, scientific, and financial implications of biomedical research involving humans as subjects, to approve the initiation of the research, and to conduct periodic reviews of such research. In some countries, this body is known as an institutional review board (IRB) or a research ethics board (REB).

Retrieval
The removal, acquisition, recovery, harvesting, or collection of specimens.

Safety
Processes, procedures, and technologies to ensure freedom from danger or harm.

Sample
A single unit containing material derived from one specimen.

Shipping manifest
A written description of the contents of a shipped package.

Snap-freezing
The process by which the temperature of samples is lowered very rapidly to below −70 °C using dry ice or liquid nitrogen.

Specimen
A specific tissue sample, blood sample, and so on taken from a single subject or donor at a specific time.

Standard operating procedures (SOPs)
A set of detailed written instructions to achieve uniformity of the performance of a specific function.

Storage
Maintenance of specimens under specified conditions for future use.

Subject
A living or deceased individual who is the source of the specimen in accordance with established medical criteria, procedures, and privacy regulations. In some countries, the term “Donor” or “Individual” may be used in the same context as “Subject”, especially in the context of human specimens.

Traceability
The ability to locate a specimen during any step of its donation, collection, processing, testing, storage, and disposition.

Warm ischaemia
The condition in which the tissue is deprived of its normal blood supply, containing oxygen and nutrients, while the tissue is at body temperature.