Preamble

The International Agency for Research on Cancer (IARC) published *Common Minimum Technical Standards and Protocols for Biological Resources Centres Dedicated to Cancer Research*, known as the "Green Book", in 2007. The recommendations and protocols in that publication were largely based on guidelines, procedures, and documentation on biorepositories developed by several working groups, institutions, regulatory bodies, and organizations, including the World Health Organization.

However, biobanking has developed at a rapid pace over the years, driven mainly by the push for personalized medicine, the need for high-quality biological resources and associated data for scientific research, and technological advancement of analytical platforms for molecular and genetic research. These developments have enabled the collection and analysis of large numbers of biospecimens in combination with epidemiological and clinical data collected across populations and involving multiple biobanks.

In response to these developmental changes and to promote collaborative projects, a wide range of biobanking stakeholders are establishing approaches and mechanisms for the harmonization of resources, including data. These stakeholders include international organizations, societies, and institutions, such as the United States National Cancer Institute (NCI), the International Society for Biological and Environmental Repositories (ISBER), the European, Middle Eastern and African Society for Biopreservation and Biobanking (ESBB), and the Biobanking and BioMolecular resources Research Infrastructure–European Research Infrastructure Consortium (BBMRI-ERIC). Their activities include the improvement of biobanking protocols and standards to provide high-quality samples and to adequately address ethical, legal, and social issues (ELSI).

This IARC Technical Publication includes guidelines and recommendations for biobanks not only in high-income countries but also in low- and middle-income countries (LMICs). The recommendations are based on validated and/or evidence-based guidelines, taking into account the current knowledge of biobanking practices and standards resulting from projects such as Standardisation and Improvement of Generic Pre-analytical Tools and Procedures for In Vitro Diagnostics (SPIDIA), BBMRI–Large Prospective Cohorts (BBMRI-LPC), and the International Genomics Consortium (IGC), as well as the European Committee for Standardization (CEN) Technical Specifications for molecular in vitro diagnostic examinations and International Organization for Standardization (ISO) norm 15189 (ISO, 2012). ISO 15189 is currently under revision (https://www.iso.org/obp/ui/#iso:std:iso:15189:ed-3:v2:en), and the working groups of the Technical Committee of ISO 276 (http://www.iso.org/iso/home/standards_development/list_of_iso_technical_committees/iso_technical_committee.htm?commid=4514241) are dealing with biobanking quality issues, including terminology, bioresearch, bioprocessing, pre-analytical methods, isolation of

analytes, and data processing and integration.

This book also includes sections on sample sharing, ELSI, and harmonization guidelines important to support collaborative research efforts that make use of biological materials. In particular, the section on open access deals with the principles of sharing and provides recommendations for biobanks in relation to sample and data sharing, which is key to establishing research collaboration. The section on governance provides guidelines on governance structures for biobanks for transparent and effective running of the facilities. Templates for informed consent and Material and Data Transfer Agreements are available in the Annexes section.

This new book also benefits from the experience and knowledge gained by IARC from coordinating the LMICs Biobank and Cohort Building Network (BCNet) and managing an international biobank, which contains diverse collections of specimens and data drawn from studies across the world, including the European Prospective Investigation into Cancer and Nutrition (EPIC) collection.

The guidelines and recommendations are applicable to biobanks operating in different geographical locations, and although the book's focus is on biobanks dedicated to cancer research, the principles and guidelines outlined here are also applicable to non-cancer biobanks.

Table 1 presents a list of the main sources of information used to develop the recommendations presented in this book. Whenever appropriate, the book indicates references and links to more extensive documentation and protocols.

Table 1. Guidelines, procedures, and documentation on biobanks

Title	Authors/origin
Tissue banking for biomedical research	National Cancer Centre Singapore
Biorepository protocols	Australasian Biospecimen Network (ABN)/Australia
Standardizing tissue collection and quality control procedures for a European virtual frozen tissue bank network	European Human Frozen Tumour Tissue Bank (TuBaFrost)
Human tissue and biological samples for use in research: operational and ethical guidelines	Medical Research Council (MRC)/United Kingdom
2012 Best practices for repositories: collection, storage, retrieval, and distribution of biological materials for research	International Society for Biological and Environmental Repositories (ISBER)/International
NCI best practices for biospecimen resources	National Cancer Institute (NCI)/USA
Guidance on regulations for the transport of infectious substances	World Health Organization (WHO)/International
United Nations recommendations on the transport of dangerous goods, model regulations, 19th revised edition	United Nations Economic Commission for Europe (UNECE)/ International
Recommendation Rec(2006)4 of the Committee of Ministers to Member States on research on biological materials of human origin	Council of Europe Committee of Ministers
Collection, transport, preparation, and storage of specimens for molecular methods: approved guideline	Clinical and Laboratory Standards Institute (CLSI)/USA
The Human Proteome Organization	Human Proteome Organization (HUPO)
Case studies of existing human tissue repositories: "best practices" for a biospecimen resource for the genomic and proteomic era	RAND Corporation/USA
Biological resource centres: underpinning the future of life sciences and biotechnology	Organisation for Economic Co-operation and Development (OECD)/ International
OECD best practice guidelines for biological resource centres	Organisation for Economic Co-operation and Development (OECD)/ International
Standard operating procedure for the collection of fresh frozen tissue samples	European Organisation for Research and Treatment of Cancer (EORTC)