

PREAMBLE

Biological Resource Centres (BRCs), as defined by the Organisation for Economic Co-operation and Development (OECD), are service providers and repositories of living cells, as well as genomes of organisms, of archived cells and tissues, and of information relating to these materials (Organisation for Economic Co-operation and Development and Directorate for Science, 2001). Collection, annotation and use of human biospecimens are essential activities of cancer research. These processes are becoming critical in allowing patient access to molecular-based diagnosis and prognosis. BRCs need to comply with strict ethical and technical requirements and may be subject to regulation and/or legislation at various levels (institutional, local or national governmental, international). The aim of this document is not to replace such regulations. It is limited to tissue collections not needed for diagnosis or transplantation. The present document focusses on developing recommendations towards common minimum technical standards in order to stimulate the creation, development and networking of BRCs at the international level, and, through their use, enhance and improve cancer research worldwide. Ethical, legal and regulatory standards and recommendations will be addressed in a separate document, with the objective of promoting common standards while taking into account cultural and social differences among countries and states.

The International Agency for Research on Cancer (IARC) is working with a network of Directors of National Cancer Centres and organisations worldwide to develop this initiative. It aims to act as a catalyst and to provide a framework for the development and coordination of BRCs in all geographical regions. BRCs are essential for implementing a global description of cancer diseases based on molecular criteria. Developing such a description is key to further progress in descriptive epidemiology of cancer, understanding its causes, and working out novel preventive and cancer management strategies, the principal missions of IARC. Structuring, developing and harmonizing the calculation of the cancer-predictive value of biomarkers by means of prospective cohort studies is crucial to establishing the statistical parameters for cancer screening, and to give insights into cancer-causative mechanisms. This initiative is of particular importance given the central place of BRCs as a structural link between clinical practice, cancer registration and biological research aimed at understanding mechanisms and developing new treatments. A major priority in this initiative is the promotion of consensual standards acceptable and applicable in countries of different cultural, social and economical backgrounds, including training and the transfer of know-how, experience and technologies to centres located in low-resource countries, endowing them with a better capacity to develop research.

All researchers involved in biobanking activities are invited to consider and to adopt these recommendations which are applicable to different types of studies (prospective, retrospective or small collections).

This document has been developed in a stepwise manner, based on the recommendation of a group of experts of National Cancer Research Centres that met at the National Cancer Institute, Singapore, 19-21 April 2006. The first draft of this document was released on the IARC website (www.iarc.fr/goodscientificpractice.php) in December 2006 for a period of public consultation. The comments, remarks and criticisms contributed by many colleagues around the world have been taken into account in developing this first release of “Common Minimum Technical Standards and Protocols”.

The recommendations and protocols are largely based on guidelines, procedures and documentation on biorepositories developed by a number of working groups, institutions, regulatory bodies and organisations throughout the world. Table 1 presents a list of the main sources of information used for developing the recommendations presented in this document. Whenever appropriate, the document indicates references and links to more extensive documentation and protocols.

Table 1: Guidelines, procedures and documentation on biorepositories

Title	Authors/Origin	Link
Tissue Banking for Biomedical Research	Dr Oi Lian Kon, National Cancer Centre/Singapore	http://www.bioethics-singapore.org/resources/pdf/AppendixB-Dr%20Kon.pdf
Biorepository Protocols	Australian Biospecimen Network, (ABN)/Australia	http://www.abrn.net/pdf/ABN_SOPs_Review_Mar06_final.pdf
European Human Frozen Tumor Tissue Bank TUBAFROST	TUBAFROST/The Netherlands	http://www.tubarfrost.org/research/moreinfo/deliverables/TUBAFROST%20Deliverable%204.1.pdf
Human Tissue and Biological Samples for Use in Research: Operational and Ethical Guidelines	MRC/UK	www.mrc.ac.uk/consumption/idcpig?idcService=GET_FILE&dID=9051&dDocName=MR_C002420&allowInteru
Best Practices for Repositories I: Collection, Storage, and Retrieval of Human Biological Materials for Research	ISBER/USA	http://ehs.sph.berkeley.edu/Holland/Biorep/BestPractice%2005.3.5.pdf
National Cancer Institute: Best Practices for Biospecimen Resources	NCI/USA	http://biospecimens.cancer.gov/global/pdfs/NCI_Best_Practices_060507.pdf
Transport of Infectious Substances	United Nations Economic Commission for Europe, UNECE/International	http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2005_22r%20.pdf
UN Recommendations on the Transport of Dangerous Goods: Model Regulations.	WHO/International	http://www.unece.org/trans/danger/publi/unrec/rev13/13files_e.html
A Cold Greeting: an Introduction to Cryobiology	Bioteach/International	http://www.bioteach.ubc.ca/Bioengineering/AColdGreeting/
Specimen Collection, Preparation, and Handling	Labcorp/International	http://www.labcorp.com/datasets/labcorp/html/frontm_group/frontm/section/speccol.htm
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	https://wcd.coe.int/ViewDoc.jsp?id=977859&BackColorIntenet=9999CC&BackColorInttranet=FFBB55&BackColorLoggcd=FFAC75
The standard MM13-A "Collection, Transport, Preparation and Storage of Specimens for Molecular methods: Approved Guideline"	Clinical and Laboratory Standards Institute	http://www.clsi.org/source/orders/index.cfm?section=Shop&ETask=1&Task=1&SEARCH_TYPE=FIN&FindIn=0&FindSpec=MM13&x=9&y=2
The Human Proteome Organisation (HUPO)	Human Proteome	http://www.hupo.org/
Case Studies of Existing Human Tissue Repositories: "Best practices" of a Biospecimen Resource for the Genomic and Proteomic Era	RAND corporation	http://www.rand.org/pubs/monographs/2004/RAND_MG120.pdf
Biological Resource Centres: underpinning the future of life sciences and biotechnology	OECD/International	http://wcdm.nig.ac.jp/brc.pdf
OECD Best Practice Guidelines for Biological Resource Centres	OECD/International	http://www.wfcc.nig.ac.jp/Documents/OECD.pdf