

FOREWORD

This consultation document is intended to be used as a guideline for basic principles reflecting patient participation in both new and existing biobanks within an implemented European Biobanking and Biomolecular Resources Research Infrastructure (BBMRI).

This draft document has been distributed for consultation to European Patient Organisations as a mechanism by which they may wish to indicate their general support for the BBMRI initiative and for appropriate patient representation in the proposed infrastructure.

The text has been elaborated by a patient working group of the BBMRI Stakeholders' Forum and from the extensive consultation process with European Patient Organisations. The content does not provide a categorical summary of existing principles relating to patient participation, but attempts to highlight the more relevant principles laid down in the European and international instruments (EU, OECD, WHO, etc.) covering patient participation in networked biobanking activities as well as indicating existing examples of good practices to facilitate their implementation.

The status of this document is a working draft which may still be subject to modifications. A draft document was presented to the Steering Committee of the preparatory phase of BBMRI (2008-2010) at the BBMRI Stakeholders' Forum meeting on June 9th, 2010 in Brussels to assist in the drafting of policies and procedures for the implementation of the research infrastructure.

The Stakeholders' Forum of BBMRI recognises that biobanks within BBMRI operate under the control and within the jurisdiction of the national legislation of the member state within which they are established, and that these principles should be considered within those conditions.

This document has been drafted in the preparatory phase of BBMRI, on the understanding that the Stakeholders Forum, as an essential part of the implemented infrastructure will be provided with sufficient resources to facilitate continued participation of all stakeholders at optimal level.

MICHAEL GRIFFITH
Chairman
BBMRI Stakeholders' Forum

DERICK MITCHELL
Executive Manager
BBMRI Stakeholders' Forum

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Notes:

1. The term “Biobank” in this document refers to the OECD definition of the term;

“Biobanks or Biological Resources centres are an essential part of the infrastructure underpinning life sciences and biotechnology. They consist of service providers and repositories of the living cells, genomes of organism, and information relating to heredity and the functions of biological systems. Biobanks or BRCs contain collections of culturable organisms (e.g. micro-organisms, plant, animal and human cells), replicable parts of these (e.g. genomes, plasmids, viruses, cDNAs), viable but not yet culturable organisms, cells and tissues, as well as databases containing molecular, physiological and structural information (OECD, 1989).

2. The Term “Patient” in this document refers to the patient and his/her family or legal representative.

INTRODUCTION

Biobanks and Biobanking

Recently voted by [TIME magazine](#) as one of the “10 Ideas Changing the World Right Now”, Biobanks or Biobanking is thought of as a safe house for tissue samples, tumor cells, DNA and blood — that can be used for hold key resources for:

- basic research
- diagnostic purposes
- improved (molecular) classification of diseases
- development of new drugs and therapeutic concepts (personalized medicine)

BBMRI

Europe leads the world in biobanking. According to [Nature magazine](#), Europe has more than 400 biobanks, some involving samples from hundreds of thousands of individuals. However the diversity and lack of standardisation of these biobanks, and the differing ethical and legal landscape across Europe, have impeded their coordinated use. Since 2008, the European Commission has funded a preparatory study, the [Biobanking and Biomolecular Resources Research Infrastructure \(BBMRI\)](#), aimed at bringing cohesion to the European biobanking community and making existing and new high quality biological resources available for health research in Europe.

The BBMRI preparatory phase (2008-2010), which is funded within EU framework programme 7 (FP7), aims to provide the basis for the actual operational biobanking infrastructure and plans to provide a strategy and structure for aspects such as access rules and an ethical and legal framework in an effort to permit appropriate sharing of data and samples to maximise the potential healthcare gain. The major impact of BBMRI in the longer term will be the promotion of public health in the EU and the reduction in the burden of complex and rare diseases. BBMRI will speed up development of personalised medicine and will reduce some of the bottlenecks in drug discovery and development.

Stakeholders’ Forum

The [BBMRI Stakeholders’ Forum](#) is assembling the input and requirements of the broad and heterogeneous stakeholder community of BBMRI, comprising patients, clinicians, funding organisations, associated project partners, industry, and users. As part of a comprehensive consultation and engagement process, information and discussion meetings as well as working group workshops have been organised to allow for interactive communication and exchange of ideas. The BBMRI Stakeholders’ Forum aims to facilitate research by providing a forum for discussion; to exchange experience and knowledge; to be a think tank in the rapidly changing biobanking environment; and eventually to offer a platform for patients and users to interact systematically with investigators and industry.

Patient Participation

Representative patient organisations are a crucible of observation and experience which makes them a valuable partner and source of input in research. Indeed, an increasing number of patient organisations are working towards creating their own biobank. For most patients and patient organisations, the primary objective for their involvement is to find the cause of their disease or to improve their treatment options. The examples outlined in this document also show that it is invaluable to engage with patients and patient organisations as stakeholders in biobanking practices. It is in this context that a [patient working group](#) of the BBMRI Stakeholders’ Forum was established and has contributed to this consultation document.

**BASIC PRINCIPLES FOR
PATIENT PARTICIPATION
IN BBMRI**

1. ACTIVE PARTICIPATION

1.1 Partnership

Active participation by patients and patient organisations in BBMRI involves a partnership in the research process itself. Patient participation in the establishment of internal and external models of governance of biobanks and biobank networks within BBMRI should be surveyed against the background of the biobanking institution and the particular context in which it is embedded.¹⁻⁶

1.2 Quality of Research

BBMRI recognises that the quality of biobanking research is enhanced for the benefit of all stakeholders through the active participation of patients and patient organisations.

1.3 Training

In order to facilitate active participation of patients and patient organisations in research biobanking activities, appropriate training is necessary.⁷⁻⁹

1.4 Current Practices

Currently available practices of patient and patient organisation participation in healthcare, clinical research and biobanking around Europe¹⁻¹³ should be used by BBMRI as a foundation from which to develop clear guidelines for patient participation within the different levels of membership (Member State, Institution etc.) and different types of biobanks (disease-oriented, population-oriented, deceased persons, minors, etc.) within BBMRI.

1.5 Patient-Centered Approach to Healthcare

The integration of biobanking at all levels of disease-specific, epidemiological and applied biomedical research and healthcare will increase progress into health care research and decrease costs of both clinical trials and daily healthcare. Treating patients and patient organisations as full partners in this process is key in moving towards a patient-centered care model, thus building the foundation for patients to take responsibility for managing their care and overall health.

1.6 Active Engagement

Following the white paper on EU Health strategy (2008-2013) and as part of BBMRI's commitment to maintaining active engagement with patients and society in general, "Citizen Scientist" initiatives where patients and the public perform or manage research-related tasks such as observation, measurement or computation should be promoted by BBMRI in order to encourage empowerment of patients and the public and to ensure the long-term sustainability of biobanking initiatives.

1.7 Key Principles

The key principles for active participation of patients and patient organisations within BBMRI are *Inclusion*, *Engagement* and *Communication*. Translating these key principles into practice involves;

- a. Inclusion of patients and patient organisations as partners in the research effort, especially in the areas of communication, advocacy and recruitment.

- b. When establishing sample-, tissue- and data-banks the experience, knowledge and expertise of patients, families and carers should be considered.
- c. Listening to patients' voices/expectations on research needs from their experience from participating in biobanking as donors.
- d. Regular, general and reasonable feedback to patients regarding use, sharing and transfer of samples.

2. ETHICS

2.1 Ethical Governance

Active participation from patients and patient organisations prior to and during the ethical-decision-making process related to BBMRI is essential to ensure independent oversight of the BBMRI consent procedures as well as data and sample access policies.^{5,9}

2.2 Research Ethics Committees (RECs)

RECs already exist throughout Europe and elsewhere, to safeguard the interests of patients, and European guidelines for their members are currently in construction^{11, (e)}. If RECs are given the opportunity to give timely comment on, and approval of, processes involved in the donation of samples within BBMRI, they should also carefully consider the opinions of patient organisations.

2.3 Commercialisation

Commercialisation of human biological sample and medical data is prohibited in the European Convention ETS164 and in the national legislation of most Member States. The operators of biobanks within BBMRI should have a clearly articulated policy relating to the commercialisation of its own resources, research results derived from those resources, and/or commercial products, if any, that may arise from research using its resources. This policy should be communicated to the patient/donor at the point of obtaining their consent. Included should be a description of intellectual property issues and that patients relinquish any personal property rights through donation of samples (i.e. no fiscal return to patients).

2.4 Discontinuation Plan

Once a biobank within BBMRI is no longer required or is no longer of scientific value and it has been determined that it will be discontinued, the human biological materials should be disposed of in an appropriate manner, consistent with the principles of consent, privacy and confidentiality.

2.5 Death of Patient/Donor

The operators of biobanks within BBMRI should have a policy that addresses the situation where participants become legally incapacitated or die. It is essential that the biobank provides information on their policy to the participant or the appropriate substitute decision-maker at the time of consenting.

2.6 Key Principles

The key ethical principles for consideration for the active participation of patients and patient organisations within BBMRI include:

2.6.1 Transparency

BBMRI must strive to build a relationship of trust with participants and the wider public. Clear and transparent information must be used at all times in order to foster acceptance of the ways the infrastructure is developed and used. The responsibility to provide appropriate information in an understandable way should be a member-state requirement and should include a mechanism to check that the information provided is sufficient to enable a patient/donor to make an informed decision. Operators of biobanks within BBMRI should actively communicate relevant information to patients in a clear and transparent fashion. This appropriate information should be made publicly available before the process of donation and should be considered separate from the process of obtaining consent.

2.6.2 Consent

Consent is a fundamental ethical principle and appropriate procedures in relation to obtaining informed consent must be completed before samples are donated for research. The procedures involved and forms of such consent are a matter for national legislation based on the legal traditions of each country. Policies for the mutual recognition of the consent to donation provided in one culture, jurisdiction, or country are important and necessary.

2.6.3 Privacy and Confidentiality

Operators of biobanks within BBMRI should communicate to the patient/donor in an open and transparent manner, the privacy and confidentiality safeguards that are in place within an implemented BBMRI network.

2.6.4 Use

Operators of biobanks within BBMRI must inform patients/donors about all potential uses of the biobanking resource, including transfer to third parties and/or commercial entities.

2.6.5 Withdrawal

Operators of biobanks within BBMRI must inform patients/donors about their right to withdraw, of the nature of and modalities for exercising that right, as well as the implications of, and limits to, exercising that right.

3. ACCESS

3.1 Construction of Access Policies

The general guidelines for access policies and procedures involving use of the resources within BBMRI should be clear, flexible and openly communicated to the public. These guidelines should include an agreed procedure for reaching agreement among stakeholders on any future changes to the access policies. Patient organisations should be supported in order to make fair and equitable contributions to these access policies.

3.2 Access by Collaboration

As part of a more patient-centered approach to biomedical research, applications for access to the resources within BBMRI should be required to demonstrate appropriate consideration of patient participation in developing the protocol, formulating the research question, or justification as to why patient input was not deemed to be appropriate.

3.3 Collaboration with Industry

The ethical question of provision of access to biological resources for academia and industry within Europe and globally, must be clearly defined in the BBMRI access policies. The concept of Expert Centres in biobanking that would operate on a not-for-profit basis has been proposed by BBMRI as a possible solution to this question. In further exploration of this concept, patients and patient organisations must be consulted on the levels of standardization and quality management, as well as the integration and provision of appropriate counselling and services to facilitate ethically and legally compliant access.^(v)

3.4 Annotation

Following national and international recommendations, the maximum amount of relevant information should be provided with biological samples in a way that is interoperable between networked biobanks. However, in the absence of internationally standardized terminology for the identifiability of human biological materials, BBMRI must be satisfied that any research proposal for the use of samples understands what degree of identifiability is being proposed. The opinion and experience of patients and patient organisations can be very useful in this regard.

3.5 Return of Information

3.5.1 To the Biobank

In order to ensure transparency, and as part of the return of information to the individual biobank providing samples, all information that is learned as part of the analysis of that sample, including inconclusive results, should be returned in full to the biobank.

3.5.2 To the Public

The operators of biobanks within BBMRI should have a clearly articulated policy on feedback and the nature of the feedback, if any, that will be provided to patients/donors and the public.

3.6 Secondary use of research data

Where authorised by applicable law and the appropriate authorities, the operators of biobanks within BMRI should consider obtaining a consent form that will permit human biological specimens and/or data to be used to address unforeseen research questions. Participants should be fully informed of the breadth of such consent and additional safeguards should be in place to ensure that patients/donors are protected.

4. PATIENTS RIGHTS AND EXPECTATIONS

4.1 Patients' Rights

In order to assure the high quality of services provided by the various biobanks under BBMRI, and following European and International charters, appropriate consideration of the following rights must be part of BBMRI's mission in order to guarantee a "*high level of human health protection*" (Article 35 of the Charter of Fundamental Rights).

Patients have the Right to Healthcare

Patients have the Right to Autonomy in the context of the provision of samples.

Patients have the Right to Privacy and confidentiality of personal medical data

Patients have the Right of Access

Patients have the Right to Preventive Measures

Patients have the Right to Information

Patients have the Right to Consent

Patients have the Right to Free Choice

Patients have the Right to the Observance of Quality Standards

Patients have the Right to Safety

Patients have the Right to Innovation

Patients have the Right to Personalised Treatment

Patients have the Right to Complain

4.2 Cultural Autonomy

BBMRI should respect the autonomy (cultural beliefs, sensibility, sensitivities) of the country providing the samples and the perspectives and traditions of patients and families from whom samples are obtained, to minimize the risks to communities, populations, and groups.

4.3 Patients' Expectations

Operators of biobanks within BMRI should undertake reasonable efforts to properly manage the expectations of patients who participate in biobanking activities in terms of feedback and benefits.

4.4 Avoidance of Discrimination

The operators of biobanks within BBMRI should take reasonable measures to avoid discrimination against or stigmatisation of a person, family or group, whether or not they have contributed to the biobank.

4.5 Patients Rights on their donations

Patients have the absolute right that their donated samples are properly managed in a manner that protects their privacy and the confidentiality of their specimens and data. In the absence of an internationally certified management system, the operators of biobanks under BBMRI should develop and maintain clearly documented operating procedures and policies for the procurement, collection, labelling, registration, processing, storage, tracking, retrieval, transfer, use and destruction of human biological materials, data and/or information.

PRACTICES

1. [PatientPartner](#), a 3-year EU FP7 project, coordinated by the patient organisation VSOP in the Netherlands, is investigating, enforcing and advising on the role of patient organisations in clinical trials. This project will give rise to a facilitating structure that empowers, enables and mobilises European patient organisations to interact with the other European and international stakeholders in clinical trials.
2. In the Netherlands, the Dutch minister must consult donors and patients for setting policy for the Central Blood Bank Sanquin. Sanquin has instituted a [national donor council](#), representing all donors. This Donor Council gives advice and has to be consulted.
3. The [EuroBioBank](#) network, coordinated by [EURORDIS](#) (European Organisation for Rare Diseases, Paris, France) is the first operating network of biobanks in Europe providing human DNA, cell and tissue samples as a service to the scientific community conducting research on rare diseases. It has consulted with patient organizations in the construction of its ethical guidelines and consent forms.
4. The [Genethon DNA and Cell Bank](#) is one of the largest banks for genetic research in Europe and is driven by the patient organisation AFM.
5. The [Wales Cancer Bank](#) has an Ethics and Patient liaison group as part of its governing structure. It consists of representatives from patient groups across Wales and advises on patient information sheets and consent form compilation. The group continually monitors patient involvement and advises on recruitment procedures from the patient's perspective. It also has patient representation on its advisory board.
6. The [Public Population Project in Genomics \(P³G\)](#) is an international consortium dedicated to fostering collaboration between researchers and projects in the field of population genomics, and has patient representation in its international working group which focuses on issues of public engagement, governance, ethics, public policy, public health (prevention/promotion), commercialization, etc.
7. [Le groupe de réflexion avec les associations de malades](#) (GRAM) in INSERM promotes collaboration and partnership between researchers and patients' associations and outlines the importance of the role of patient associations in the definition of research policies.
8. [Macmillan Cancer Support](#) (UK) is a charitable organisation, which delivers research training courses specifically for cancer patients.
9. The EFGCP-EGAN [Patients' Roadmap to Treatment Working Party](#) provides information, tools, skills and funding for patients and patient organizations to improve patients' participation in clinical trials.
10. [UK Biobank](#) has embarked on an extensive consultation process with stakeholders, members of the public and the scientific community throughout the life of UK Biobank.

11. The [EUROREC Institute](#) (EuroRec) is an independent not-for-profit organisation whose main mission is to promote high quality Electronic Health Record systems (EHRs) throughout Europe. The coordination with healthcare authorities is done through the collaboration with the eHealth ERA consortium and its European Health Care Authorities (HCA) / Ministries groups. Both platforms (EuroRec and eHealth ERA) will assure the necessary bottom-up and top-down approaches for the adequate assessment of needs and for the optimal choice of methods for quality labelling and certification of EHRs in Europe.

12. [OnCore UK](#) launched a Donor Forum during its recruitment phase. It gave donors an ongoing connection with the biobank and the research they are supporting rather than the one off donation experience.

13. [Autocure](#), a 5-year FP6 research consortium is attempting to understand the origins and outcomes of some important rheumatic diseases, and has an active collaboration with patients.

14. [EUROPA DONNA](#), The European Breast Cancer Coalition, are members of the Steering Committee, the Legal/ethics Committee and the Spreading of Excellence Committee of the [MINDACT](#) clinical trial of the [Transbig consortium](#). EUROPA DONNA also serves on the Scientific Committee of [BIG Breast International Group](#).

15. [The Italian Association for Alternating Hemiplegia](#) (A.I.S.EA) is actively involved (definition of protocol, informed consent forms, provision of information and direct communication with patients about results) with the [I.B.AHC](#), an open repository by which the clinical information and the biological material of AHC patients with a validated diagnosis, are collected and made usable for any research project on AHC. The [I.B.AHC Biobank and the Clinical Registry](#) are fully integrated between each other and with the European Registry for AHC, under the responsibility of [ENRAH, the European Network for Research on AHC](#).

OTHER PRACTICES

This consultation document is actively seeking other examples of good practices, in regard to active participation of patients and patient organisations in biobanking or related activities. The linked document below provides the opportunity for organisations with specific experience in this area to contribute to this document in a fair and open manner. These examples will be considered in the next drafting of these principles.

To add your organisations' specific experience, click [here](#).

(or visit <http://docs.google.com/Doc?docid=0ARSrtjc7J5-AZGhrZ2o0NV80ZjN4ZDVodzU&hl=en>)

SOURCES

International Guidelines and Recommendations

- (a) [The OECD Guidelines on Human Biobanks and Genetic Research Databases](#) (2009).
- (b) World Medical Association Declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects (2000).
- (c) International Alliance of Patients' Organizations - [What is Patient-Centered Healthcare?: A Review of Definitions and Principles](#) (2005).
- (d) Council of Europe Oviedo-Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine. Recommendation 4 on research into biological materials of human origin (2006).
- (e) Council of Europe Steering Committee on Bioethics (CDBI) has drafted a [draft guide for research ethics committee members](#). The Guide has been elaborated by the Group of Specialists on Biomedical Research (CDBI-CO-GT2).
- (f) ISBER Best Practices For Repositories: Collection, Storage, Retrieval and Distribution of Biological Materials for Research
- (g) UNESCO general conference, Paris. International declaration on human genetic information (2003).
- (h) The [European Charter of Patients' Rights](#): states 14 patients' rights that together aim to guarantee a high level of human health protection and to assure the high quality of services provided by the various national health services in Europe (2002).
- (i) [White paper on EU Health strategy](#) (2008)
- (j) EU Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data (1995).
- (k) EU Directive 2001/20/EC relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (2001).

Relevant National Guidelines and Policies for Patient Participation

- (l) [INVOLVE and NRES joint statement: patient and public involvement in research and research ethics committee review](#) (2009).
- (m) [National strategy for service user involvement in the Irish health service](#) (2008).

Conference Proceedings

- (n) EPPOSI Recommendations on biobanking. Workshop on Patients Registries for Rare Disorders, organised by the European Platform for Patients' Organisations, Science and Industry (EPPOSI) (2009).
- (o) C. Smit. In: [EPPOSI conference, data-and bio-banking for research, towards joint ventures of patient organisations, science and industry on the road to validated expertise and new therapies](#). (2006).

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- p) Armstrong, V. et al. [Public Attitudes to Research Governance, A qualitative study in a deliberative context](#). Wellcome Trust (2007).
- q) Bauer K, Taub S, Parsi K. [Ethical issues in tissue banking for research: A brief review of existing organizational policies](#). Theor Med Bioeth 25(2):113-42 (2004).
- r) Bovenberg J, Meulenkamp T, Smets E, Gevers F. [Always expect the unexpected: Legal and social aspects of reporting biobank research results to individual research participants](#). Centre for Society and Genomics (2009).
- s) Cambon-Thomsen A, Rial-Seebag E, Knoppers BM. Trends in Ethical and Legal Frameworks for the use of human biobanks. Eur. Resp. J. 30: 373-382 (2007).
- t) Mayerhofer M. Patient organization as the (un) usual suspects. In: Herbert Gottweis and Alan Petersen, editor. Biobanks; Governance in comparative perspective. 1st ed. New York, USA: Routledge; p. 71,72-85 (2008).
- u) Salvaterra E. et al. Banking together. [A unified model of informed consent for biobanking](#); EMBO Reports;9(4): pages 307-313 (2004).

BBMRI-Referenced Outputs

- v) BBMRI Discussion Paper: “[Expert-Centres for Biobanking](#)” (2009)
- w) Report from the BBMRI Stakeholder’s Forum meeting “[Building a Biobanking Research Infrastructure for Europe](#)” (2009).
- x) Yuille M. et al. [Biobanking for Europe](#), Briefings in Bioinformatics; 9(1): pages 14-24 (2008).