Quality matters: A workshop for biobankers

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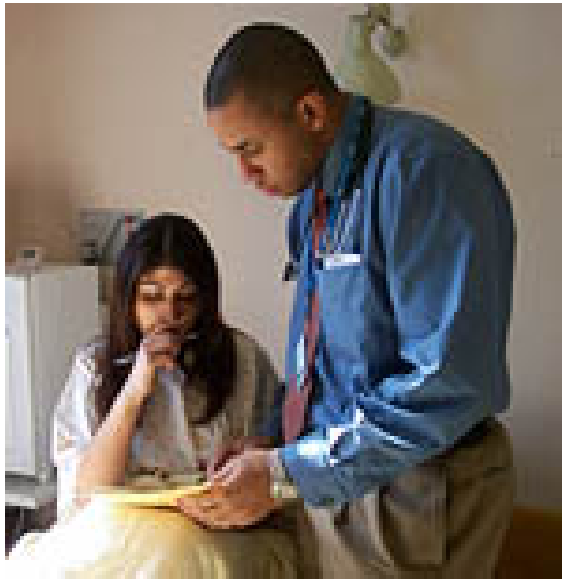
Introduction

BJ Clark

Quality *matters*

- Because:
  - We owe it to patients who donate samples.



Quality *matters*

- Because:
  - We owe it to researchers who use our services.

Quality *matters*

- Because:
  - Attention to quality is an ethical issue.

Quality *matters*

- Because:
  - It is required to comply with legislation and regulation.

Quality *matters*

- Because:
  - We have a duty to funders.

Quality *matters*

- Because:
  - **Biobanking and research is futile without it!**

"I've done a search for studies using quality samples and it turns out we haven't done any …."

CCB Guiding principles

7. Biosample resources exist to provide a quality service

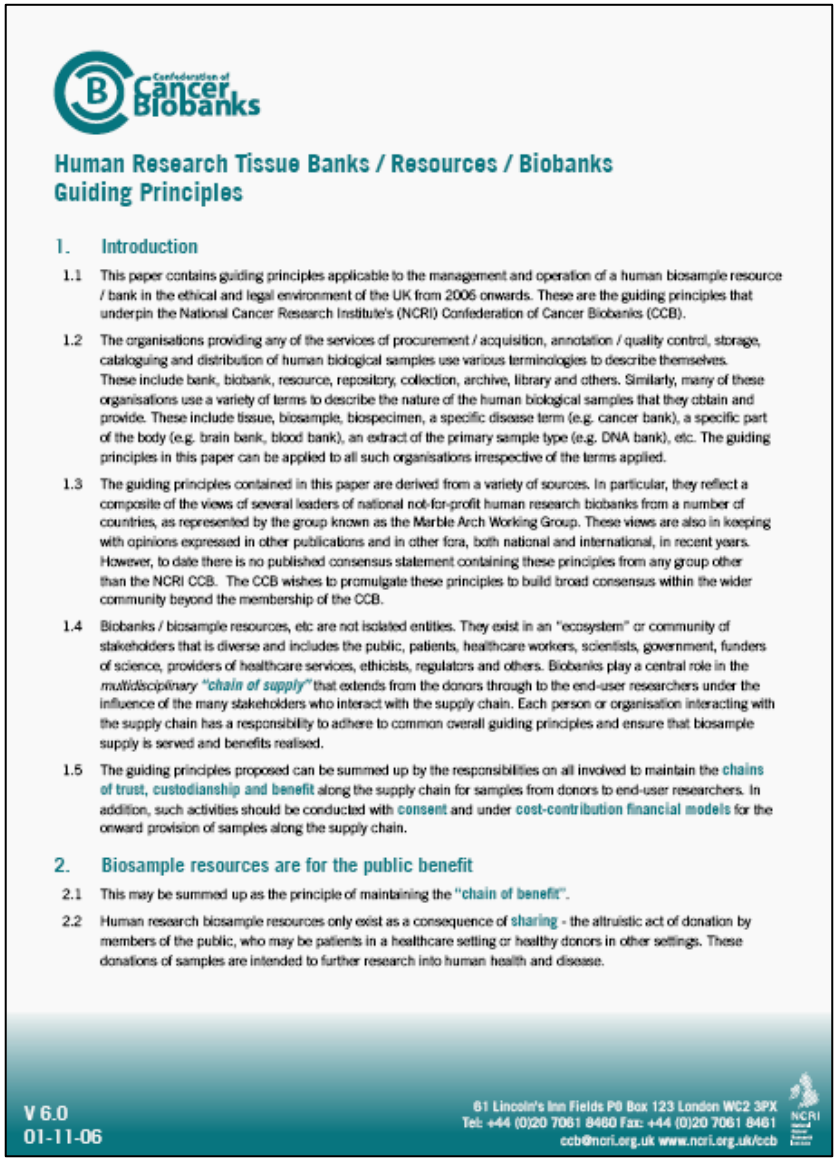
7.1 Quality management should be integral to the management of any biosample resource.

7.2 An individual or organisation who does not attend to quality management of the samples and overall resource diminishes the utility of the resource and thus disrupts the chains of trust and benefit.

7.3 A commitment to provide a service is necessary in the management of a biosample resource.

7.4 An individual or organisation that provides a poor service to donors upstream and researchers downstream diminishes the utility of the resource and disrupts the chains of trust and benefit.

7.5 Samples are best held in specifically designated facilities and premises to maintain quality and security and ensure that the integrity of the chains of trust, benefit and supply are best served.



Confederation of Cancer Biobanks

Human Research Tissue Banks / Resources / Biobanks
Guiding Principles

1. Introduction

1.1 This paper contains guiding principles applicable to the management and operation of a human biosample resource / bank in the ethical and legal environment of the UK from 2006 onwards. These are the guiding principles that underpin the National Cancer Research Institute's (NCRI) Confederation of Cancer Biobanks (CCB).

1.2 The organisations providing any of the services of procurement / acquisition, annotation / quality control, storage, cataloguing and distribution of human biological samples use various terminologies to describe themselves. These include bank, biobank, resource, repository, collection, archive, library and others. Similarly, many of these organisations use a variety of terms to describe the nature of the human biological samples that they obtain and provide. These include tissue, biosample, biospecimen, a specific disease term (e.g. cancer bank), a specific part of the body (e.g. brain bank, blood bank), an extract of the primary sample type (e.g. DNA bank), etc. The guiding principles in this paper can be applied to all such organisations irrespective of the terms applied.

1.3 The guiding principles contained in this paper are derived from a variety of sources. In particular, they reflect a composite of the views of several leaders of national not-for-profit human research biobanks from a number of countries, as represented by the group known as the Marble Arch Working Group. These views are also in keeping with opinions expressed in other publications and in other fora, both national and international, in recent years. However, to date there is no published consensus statement containing these principles from any group other than the NCRI CCB. The CCB wishes to promulgate these principles to build broad consensus within the wider community beyond the membership of the CCB.

1.4 Biobanks / biosample resources, etc are not isolated entities. They exist in an "ecosystem" or community of stakeholders that is diverse and includes the public, patients, healthcare workers, scientists, government, funders of science, providers of healthcare services, ethicists, regulators and others. Biobanks play a central role in the *multidisciplinary* ***"chain of supply"*** that extends from the donors through to the end-user researchers under the influence of the many stakeholders who interact with the supply chain. Each person or organisation interacting with the supply chain has a responsibility to adhere to common overall guiding principles and ensure that biosample supply is served and benefits realised.

1.5 The guiding principles proposed can be summed up by the responsibilities on all involved to maintain the **chains of trust, custodianship and benefit** along the supply chain for samples from donors to end-user researchers. In addition, such activities should be conducted with **consent** and under **cost-contribution financial models** for the onward provision of samples along the supply chain.

2. Biosample resources are for the public benefit

2.1 This may be summed up as the principle of maintaining the **"chain of benefit"**.

2.2 Human research biosample resources only exist as a consequence of **sharing** - the altruistic act of donation by members of the public, who may be patients in a healthcare setting or healthy donors in other settings. These donations of samples are intended to further research into human health and disease.

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61 Lincoln's Inn Fields PO Box 123 London WC2 3PX
Tel: +44 (0)20 7061 8460 Fax: +44 (0)20 7061 8461
ccb@ncri.org.uk www.ncri.org.uk/ccb

This workshop …

- Regulatory aspects
- Quality management systems
- Data management systems
- Technical aspects of repository and laboratory work

Why are we doing this?

- To allow **patients** to participate in research.
- To enable the highest quality and most relevant laboratory research.
- To help speed the benefits of research back to **patients**.

- Without patients and their willingness to donate samples and participate in research, the fight against disease would be far behind where it is today.
- It is imperative that we do a good job on their behalf and “quality” needs to be at the heart of everything we do.