Tissue Directory and Coordination Centre

BBMRI.uk
Biobanking and BioMolecular resources Research Infrastructure United Kingdom

The Role of the UKCRC Tissue Directory and Coordination Centre

- the UK National Node of BBMRI-ERIC

Anne Carter

Outline of the presentation

- History and background
  - Biobanking in the UK
  - UKCRC Funders' Vision for Human Tissue Resources
- The UKCRC Tissue Directory and Coordination Centre
  - The Call
  - The Centre
  - Plans – in brief
- BBMRI.uk
- What next?

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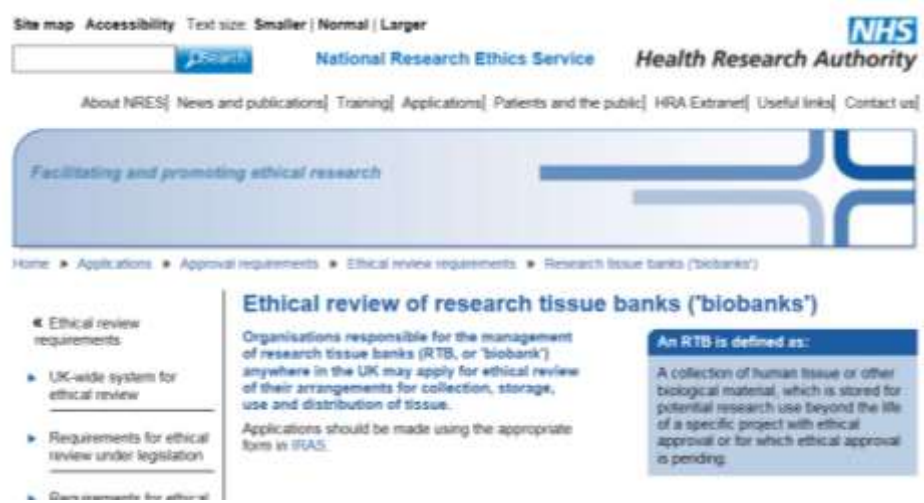
The UK's Biobanking Arena

HTA Human Tissue Authority
The regulator for human tissue and organs



Regulatory Support Centre

Support and guidance for those conducting research with human participants, their tissues or data.

Contact us on: info@rsc.mrc.ac.uk

Types of biobanks

- Cohort studies
  - UK Biobank; Life Study; CLOSER
- Disease specific
  - Wales Cancer Bank; Breast Cancer Now Tissue Bank; UK ME/CFS Biobank
- University or hospital focussed
  - All diseases; Multiple collections hosted
- Commercial biobanks
  - Pharma company
  - Commercial hosting services
- Bioresource
- Research project-specific collections
  - 100,000 genomes project

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Networking

closer
Promoting excellence in longitudinal research

Children's Cancer and Leukaemia Group
CCLG
Caring for children Curing their cancer

breast cancer now Tissue Bank

Greater Manchester Biobanking Network

Confederation of Cancer Biobanks

RD Connect

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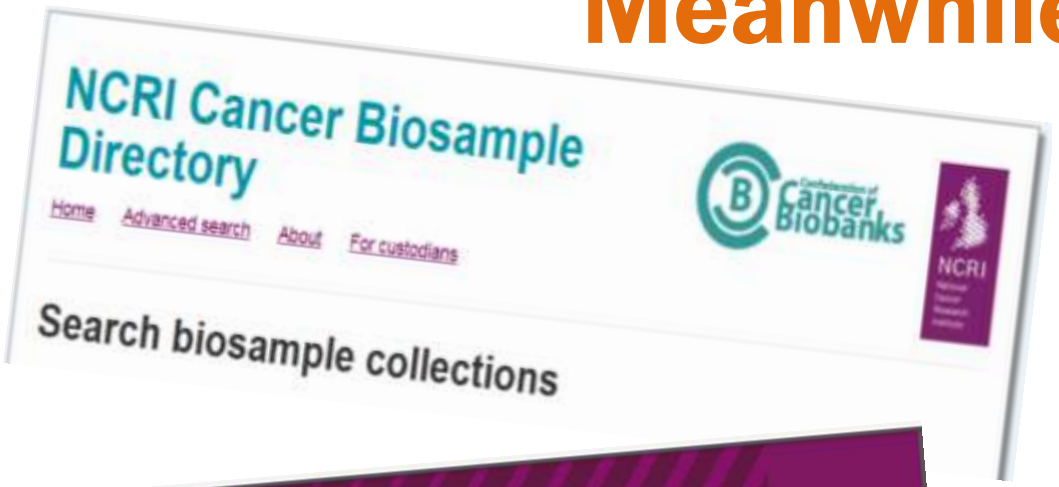
Meanwhile.....



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What human tissue resources are there in the UK?

- 140 holders of HTA licence to store human tissue for research (+ 142 “satellite” sites, + ???? under anatomy or post-mortem licence)
- 254 ethically approved Research Tissue Banks?
- 31 cohort studies collecting tissue?
- How much overlap between these?
- How many more?

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UKCRC Funders' Vision for Human Tissue Resources

"Funders aim to maximise the value of human tissue samples and resources while minimising duplication of effort.

This requires better characterisation of tissue samples, asking for generic consent, and increased linkage to accurate clinical data.

Sample collections must then be made more easily discoverable and accessible for use in high quality, ethical research."

http://www.ukcrc.org/research-infrastructure/experimental-medicine/funders-vision-for-human-tissue-resources/

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UKCRC Funders' Vision for Human Tissue Resources

- In order to achieve their vision funders will now require applicants to:
  - **justify the need** for new human tissue sample collections and consider opportunities to link sample collection to existing studies or trials collecting high quality clinical data;
  - **seek generic consent** or to justify why this would not be appropriate;
  - describe how their collection and storage of samples **complies with existing good practice**; and
  - make appropriate arrangements for access and register collections in a **publicly accessible directory**.

  - and require **existing awardees**, where collections have not been depleted, to:
    - have an access policy in place;
    - register collections in a publicly accessible directory; and
    - be able to provide existing sample metadata on request.

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- Call, led by MRC, to set up a national tissue directory and coordination centre
- Awarded to University College London/University of Nottingham (ADAC) consortium in December 2014

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- Provide strong leadership in realising the Funders' Vision, by increasing the quality, visibility and accessibility of the UK's world class specimen and cohort collections for academic and commercial researchers.

- Four concepts:
  - to identify the current limitation to optimal biobanking amongst a wide range of stakeholders and custodians of research samples;
  - to reach consensus on optimal solutions to those issues;
  - to implement the changes through three work streams, informatics, harmonisation and engagement;
  - to evaluate project outputs and identify future needs.

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What will we deliver?

- A robust and scalable web-based informatics platform with simple functionality, used to link and disseminate information on the work streams.
  - Success will depend on effectively engaging researchers, biosample collections, the public, regulators and policy makers, so as to develop an agreed, unified system for the UK
  - Biobanking groups will benefit by understanding and being actively involved in developing a pan-UK system, allowing reliable exchange of human biospecimens and associated clinical data
  - Researchers will gain from increased visibility of, and ease of access to, appropriate quality assured samples and data
  - Funders will avoid supporting unnecessary bioresources

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Informatics work stream

- Create a standardised representation of biobank data [concepts and terms] in a format that is compatible with clinical e-health records.
- Develop a website that delivers a step change in the ability for researchers to find suitable samples and demonstrate future capabilities by creating an enhanced conceptual demonstrator.
- Deliver a thorough peer reviewed assessment, including user evaluation of the system, and incorporating the views of the independent informatics advisory group and a horizon scanning exercise to identify the potential for future enhancements.

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Harmonisation work stream

- "Provide coordination and guidance to increase harmonisation of standards across the entire biosample lifecycle.
  - This should **take account of existing guidance** on standardisation and **provide coordination** as opposed to duplication of activity. The Centre should focus on **aligning guidance, highlighting best practice** to collections of human sample and **identifying areas where standards are required**
  - Making funders aware of any **lack of alignment** between the various sources of guidance."

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Harmonisation work stream

- Build on work of other groups such as CCB
  - Quality standard
  - Data standard
  - Self Assessment scheme
  - Audit programme
- Engage with other initiatives
  - ISO TC 276 Biotechnology
  - SPIDIA and CEN

- WG 1 Terms and Definitions
- WG2 **Biobanks and bioresources**
- WG3 Analytical methods
- WG4 Bioprocessing
- WG5 **Data processing including annotation, analysis, validation, comparability and integration**
- WG6 Metrology

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Engagement and communications

- Identify and engage stakeholder groups
- Promote collaboration
- Communicate through website, newsletters, e-media, meetings…….
- Annual biobanking meeting

- Biobanking board game

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Evaluation of effectiveness

- Funders
- Steering Committee
- Evaluation groups
- Google analytics, Constant Contacts….
- Feedback forms
- Surveys
- “Secret shoppers”

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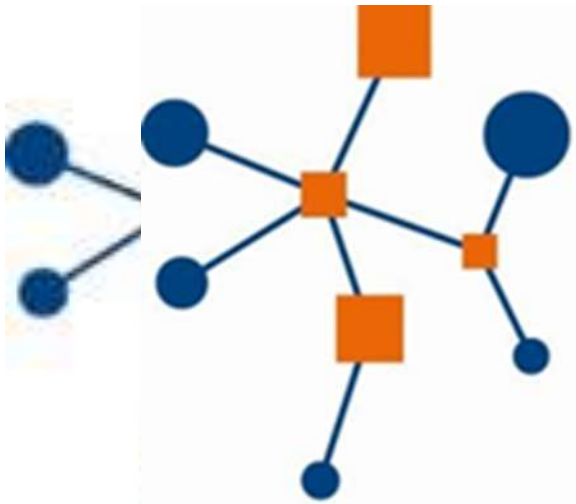

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Biobanking and
BioMolecular resources
Research Infrastructure
United Kingdom

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BBMRI-ERIC

- The objective of BBMRI-ERIC is to create a world leading research infrastructure for biomedical research in Europe. BBMRI-ERIC will increase efficacy and excellence of European biomedical research:
  - By facilitating access to quality defined human health/disease relevant biological resources, including associated data in an efficient and ethically and legally compliant manner
  - By reducing the fragmentation of the biomedical research landscape through:
    - Harmonisation of procedures,
    - Implementation of common standards and
    - Fostering high level collaboration
  - By capacity building in countries with less developed biobanking communities

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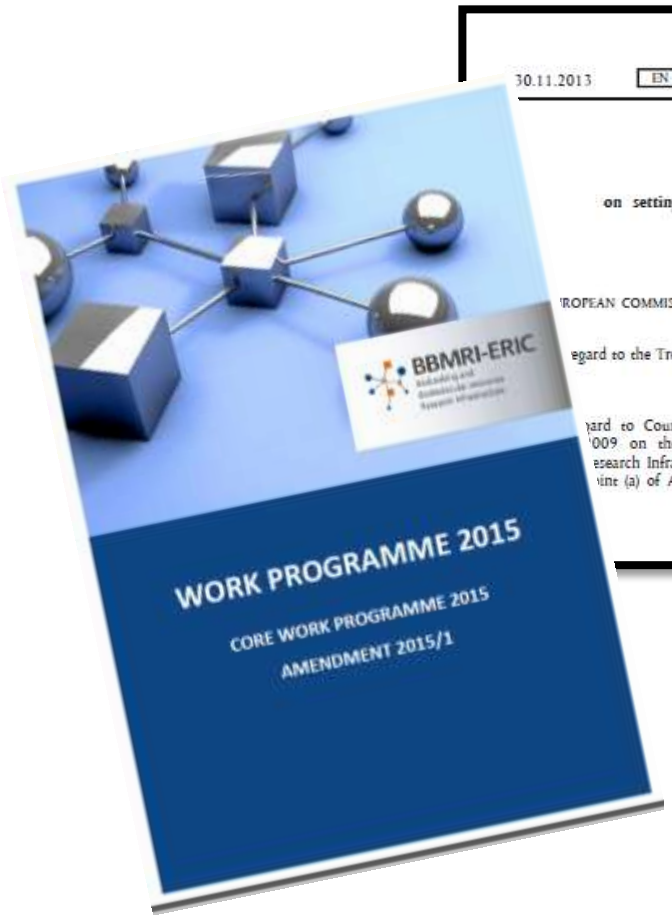
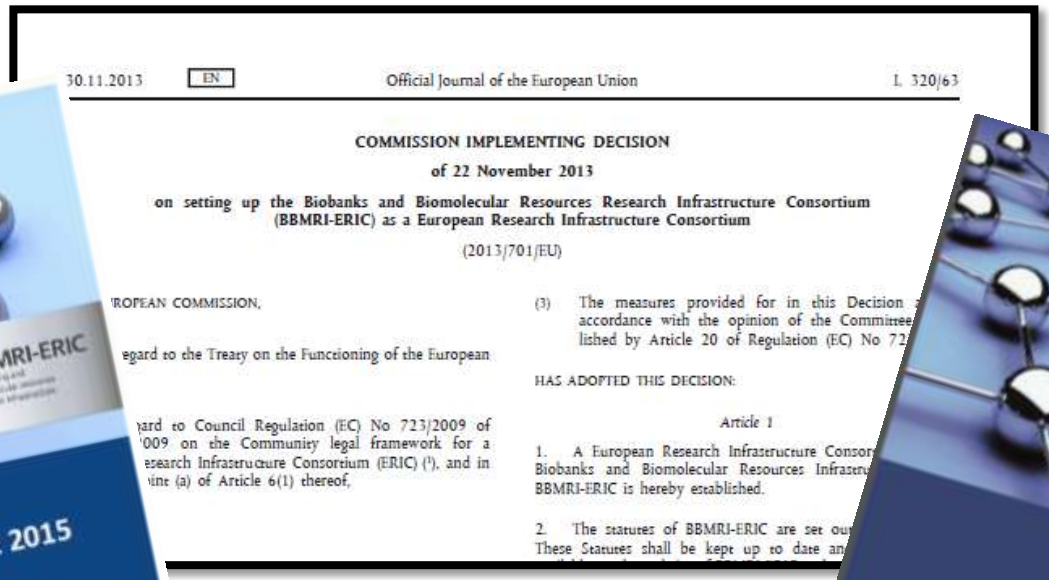
BBMRI-ERIC




30.11.2013 EN Official Journal of the European Union L 320/63

COMMISSION IMPLEMENTING DECISION

of 22 November 2013

on setting up the Biobanks and Biomolecular Resources Research Infrastructure Consortium (BBMRI-ERIC) as a European Research Infrastructure Consortium

(2013/701/EU)

ROPEAN COMMISSION,

egard to the Treaty on the Functioning of the European

ard to Council Regulation (EC) No 723/2009 of 009 on the Community legal framework for a esearch Infrastructure Consortium (ERIC) (1), and in int (a) of Article 6(1) thereof,

(3) The measures provided for in this Decision accordance with the opinion of the Committee lished by Article 20 of Regulation (EC) No 72

HAS ADOPTED THIS DECISION:

Article 1

1. A European Research Infrastructure Consor Biobanks and Biomolecular Resources Infrastru BBMRI-ERIC is hereby established.

2. The statutes of BBMRI-ERIC are set ou These Statutes shall be kept up to date an

http://bbmri-eric.eu/

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BBMRI-ERIC National Node

- '**National Node**' means an entity, not necessarily with legal capacity, designated by a Member State, that coordinates the national biobanks and biomolecular resources, and links its activities with the pan-European activities of BBMRI-ERIC. (Statutes, Article 1.6)

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UK and BBMRI-ERIC interactions

- MRC represents the UK on the BBMRI-ERIC Assembly of Members
- The National Node represents the UK on the BBMRI-ERIC Management Committee
- Nominated individuals represent the UK in BBMRI-ERIC Work Groups and Common Services
- Biobanks can join in the work of BBMRI-ERIC
- Biobanking projects can link to BBMRI-ERIC

BBMRI-ERIC Work Groups

- H2020
- European-Middle Eastern Engagement
- Clinical Biobanking
- China Engagement
- Sub-Saharan Africa Engagement
- BBMRI-ERIC Catalogue
- Financial workflow
- Rare diseases
- Journal proposal
- Archived tissue
- Infectious diseases
- Quality
- Education and training

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BBMRI-ERIC Common Services

- Ethical, Legal and Societal Issues (ELSI)
  - aims to facilitate and support cross-border exchanges of human biological resources and data attached for research uses, collaborations and sharing of knowledge, experiences and best practices.
  - among other things, it will provide an ethics check and help-desk format.
- IT
  - being set up – launch expected in October

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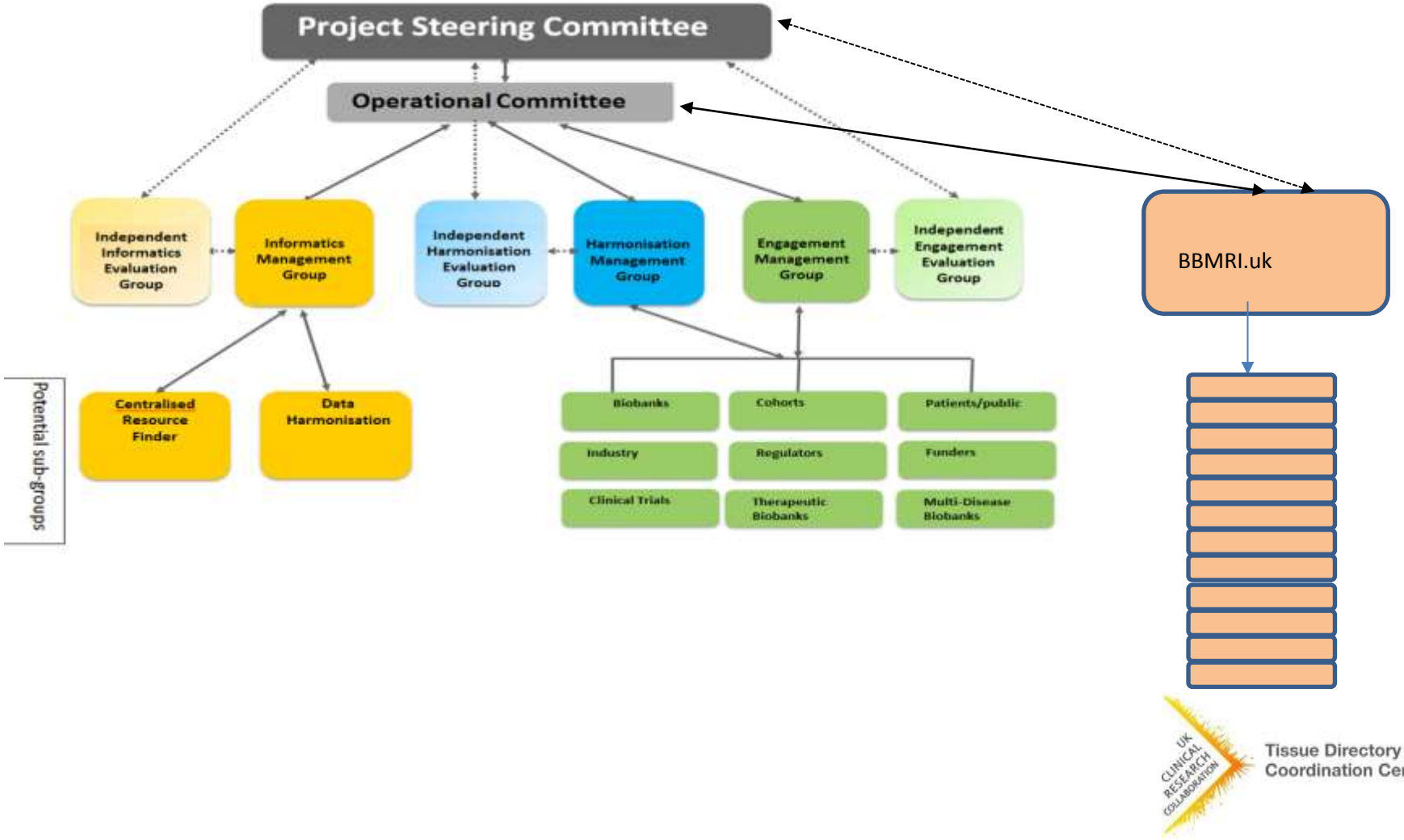
Project Steering Committee
Operational Committee
Independent Informatics Evaluation Group
Informatics Management Group
Independent Harmonisation Evaluation Group
Harmonisation Management Group
Engagement Management Group
Independent Engagement Evaluation Group
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Potential sub-groups
Centralised Resource Finder
Data Harmonisation
Biobanks
Cohorts
Patients/public
Industry
Regulators
Funders
Clinical Trials
Therapeutic Biobanks
Multi-Disease Biobanks
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BBMRI-ERIC
Partner Charter

Purpose and applicability

The BBMRI-ERIC Partner Charter should define the most important cornerstones for the participation of biobanks or biological resource centres (Partner) that are associated with BBMRI-ERIC to foster **scientific excellence**, guarantee **interoperability**, and **compliance with ethical and legal requirements**.

The Partner Charter is **binding** for any Partner of the BBMRI-ERIC and shall be **agreed between national BBMRI-ERIC nodes and the Partners**. Participation of a Partner in BBMRI-ERIC is non-exclusive and has no effect on any activity of a Partner outside of BBMRI-ERIC.

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What next?

- In this early phase, the Centre will focus on the UK, developing a national directory, implementing a harmonisation scheme and signing up partners
- The Centre's launch meeting (last March) was used to begin our stakeholder engagement
- Our website is available, the tissue directory portal is still under development but will be available to register collections by the end of the year
- In the meantime, **please register your interest on our website**

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www.biobankinguk.org

Contact me:

BBMRI.uk
Biobanking and BioMolecular resources Research Infrastructure United Kingdom

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