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# Ethics and Governance Issues relating to Biobanks in the UK

**Dr Catherine Elliott**

Head of Clinical Research Support and Ethics  
Medical Research Council

# Nature of Biobanks in the UK

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- Disease-specific banks
  - Cancer
  - Autism
  - MND
- Organ-specific banks
  - Brain banks
  - Fetal tissue
- Population samples
  - Birth cohorts
    - eg 1946, 1958, 1972, 2000
  - Whitehall cohort
  - UK BioBank

# Collection of tissues

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- Primary aim of project (UK Biobank)
- Secondary aim eg clinical trial
- 1ry and 2ry eg cohorts with research hypotheses

# Aims of Good Governance

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- Public confidence
  - Potential and actual participants
- Scientific confidence
  - Access resource
  - Quality data and samples
  - Interpretation of results
- Funder confidence
  - Appropriate use of resource

# Good governance

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- Ethics
- Sample and data security
- Access policies

# Good Governance - Ethics

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- Consent
  - Generic but informative
  - Commercial use
  - Types of research
  - Options within consent
- Confidentiality
  - Security
  - Feedback
  - Follow-up / recontact
- Legal / Regulatory Framework
  - Human Tissue / Data Protection Acts
  - NIGB ECC approval where necessary
  - REC approval

# Good Governance - Security

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- Data
  - IT systems
  - Identification / anonymisation
- Samples
  - Standard Operating Procedures
  - Back-up / Duplicates

# Good Governance - Access

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- Original consent
- Scientific merit
- Prioritisation
- IP rights
  
- Return of samples / data
- Acknowledgement



# UK Biobank

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- 500,000 participants across UK
  - 300,000 by April 2009
- Aged 40-69
- Data
  - Lifestyle and environment
  - Medical history – NHS record access
  - Physical measurements
- Biological samples
- £60 million funding over 10 years

# UK Biobank Ethics and Governance Framework

([www.ukbiobank.ac.uk/ethics/intro.php](http://www.ukbiobank.ac.uk/ethics/intro.php))

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- Confirms UK Biobank's role as steward of the resource and legal owner of the database and the sample collection.
- Describes the principles which govern access to the resource by researchers.
- Describes the broad benefit-sharing that will be required (including the obligatory publication of findings and accessible archiving of data and findings for future use).
- Describes the arrangements for management and accountability.

# UK Biobank Ethics and Governance Council

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- 10 members
- A **multi-disciplinary group** that draws together a wide range of expertise in law, ethics, biomedical science, social science, policy and consumer issue
- **Monitors** UK Biobank's conformance with the Ethics and Governance Framework and advises on revisions to the Framework.
- **Advises** UK Biobank on the interests of the participants and public in relation to the project.

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# Some ethics and governance issues

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- Changes to circumstances
  - Withdrawal:
    - 'no further contact / access / use'
  - Loss of capacity
  - Death

# Some ethics and governance issues

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- Access to samples / data
  - Confidentiality - anonymisation
  - Consent
- Feedback
  - Clinically relevant findings (proposed enhancements)
  - Findings of unknown relevance
  - Findings found to be relevant in future

# What does the Human Tissue Act do??

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- To obtain, store or use 'relevant material' or human body for certain 'scheduled purposes' is lawful provided 'appropriate consent' is in place

## *Need to understand:*

- Consent
- Scheduled purposes
- Relevant material

# Consent

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- Act sets out requirements for consent and HTA Code of Practice expands.
- Provision for tissue from living and deceased
- Children
- Adults who lack capacity

# Points about consent

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- Consent is a positive act
- Researchers are not required to obtain consent personally but need to be confident of procedures and review them regularly (HTA COP consent 13)
- Can be specific and / or general
- There are exceptions, including use of anonymised tissue from living person for REC approved project

# DNA analysis

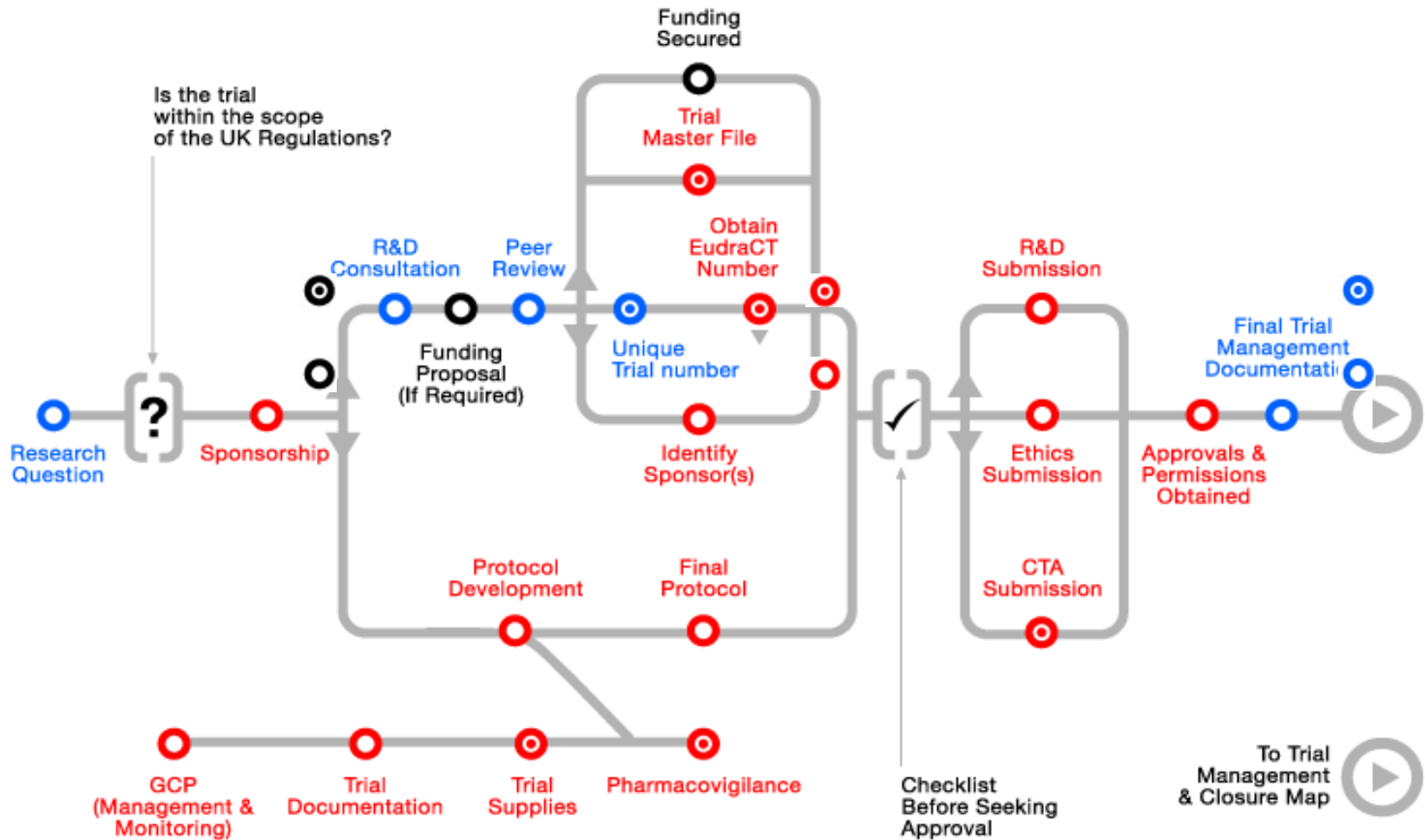
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- Section 45 (also applies in Scotland)
- Consent needed to have material with *intent* of analysing DNA (do not need separate consent if already given consent under Act)
- Exceptions:
  - Existing holding and anonymised for certain purposes (incl research)
  - Embryo outside human body
  - Over 100 years
  - Medical diagnosis / treatment of that person
  - Coroner / PF
  - Crime prevention / detection / prosecution / national security

# Access to samples

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- Consider potential users
- Access arrangements
- Security of funding
- REC and HTA approvals



# TAKING IT TO THE BioBANK

By CATHERINE HARRIS



Thank you!