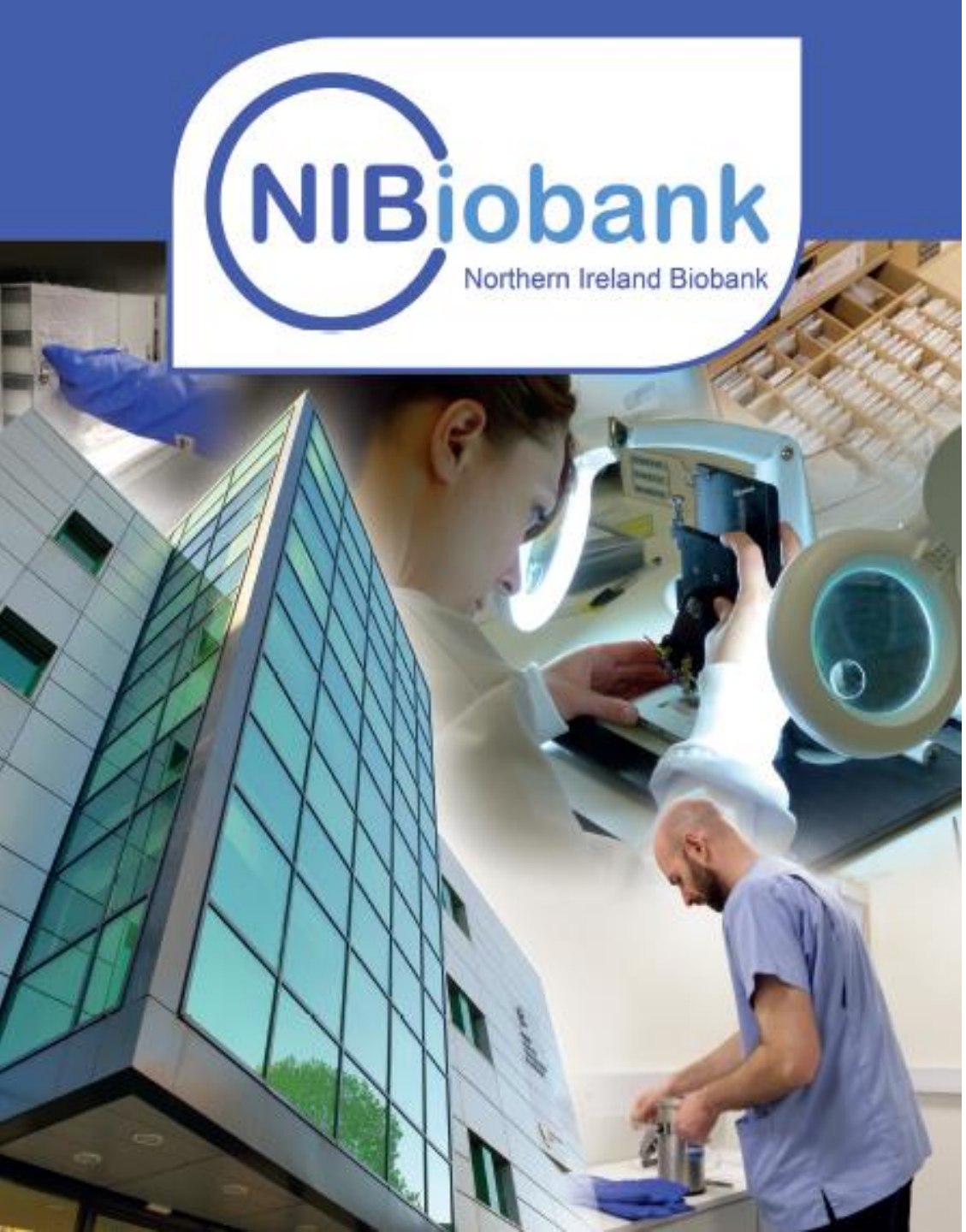

Setting up a biobank: regulatory and ethical considerations

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Northern Ireland Biobank

Governance

- Biobanks need to consider their governance framework
- This includes organisational structure, committees and documentation to enable proper functioning of the biobank
- A good biobank governance framework should help the biobank be transparent, accountable, efficient and fair
- Critical to good governance is engagement with public at all stages of biobank set up and running

Human Tissue Act (2004)

- The Human Tissue Act (2004) regulates the removal, storage, use and disposal of Relevant Material

- Any establishment in England, Wales and Northern Ireland removing and storing human tissue samples for research must have a Human Tissue Authority (HTA) licence, unless an exemption applies. The HTA licence permits the storage of the material.

- The HTA produce Standards they expect licensed establishments to adhere to. The standards fall into four broad categories: Consent; Governance and Quality systems; Traceability; and Premises, Facilities and Equipment.

- The HTA inspect establishments on a cyclical basis to make sure that establishments are meeting these standards.

Ethical considerations

- HRA approval is not required for the establishment of a biobank

- However, many organisations will apply on a voluntary basis for ethical approval

- Advantages of ethical approval:
  - Avoids need for individual project based ethical approval
  - Facilitates more timely review and approval of studies

- Conditions for ethical approval:
  - UKCRC Tissue Directory registration
  - Human Tissue Authority (HTA) License

Ethical considerations

- Broad, enduring consent versus dynamic consent?
- Will your biobank consent for the following?
  - Use of samples in animal models
  - Use of samples in commercial/industry studies
  - Use of samples in cell line models
  - Use of samples for Whole Genome Sequencing
- Tiered consent versus ‘all or nothing’
- Arrangements for collection of samples and access to samples
- Will you return incidental findings to donors?
- Age and language appropriate material

Data Protection and Privacy

- Biobanks have a duty to protect the confidentiality and privacy of donors

- Donors must be informed about:
  - What data will be accessed
  - Who will have access to personal data
  - How data will be shared
  - How their privacy will be protected

Of course it's anonymous! ... just make sure you lick the envelope, ok?

Data Protection and Privacy

Biobanks need to consider:

- Methods of de-identification
- Training of personnel wh
- Implementing data manage, limit and trace

GDPR

Material Transfer Agreement

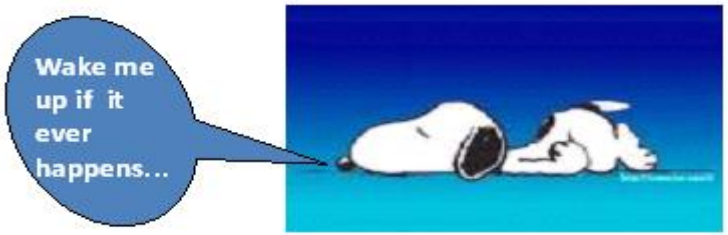
- A material transfer agreement (MTA) is a legally binding document that governs the conditions under which samples and data can be used

- These must be in line with the conditions of the original consent and ethical approval associated with the samples

- MTA should also address any rights to Intellectual Property generated from the use of the samples and data

Timeline of key events

- Formal request from ECMC/NICCTU for tumour banking — Feb 2007
- Formation of NI Tumour Bank Working Group — July 2007
- HSC R&D form NI Biobanking Advisory Group — Jun 2008
- NI Biobanking Advisory Group report published — Dec 2008
- CR-UK Centre Grant awarded to CCRCB — Apr 2009
- HSC R&D letter of award — July 2010
- Friends of Cancer Centre grant — July 2010
- Ethical approval granted — Mar 2011
- First sample collected — Nov 2011



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