

# Ethical review of biobanks – policy and procedure

# NRES Mission

- to protect the rights, safety, dignity and well-being of research participants
- to facilitate and promote ethical research that is of potential benefit to participants, science and society

# Overview

- NRES policy on ethical review of research tissue banks / biobanks
- Issues addressed in ethical review
- Application and review procedures
- Conditions of approval

## Definition

- Terminology varies but NRES has adopted “research tissue bank” (RTB) as a generic term

- NRES defines a RTB as:

*“A collection of human tissue or other human biological material, which is stored for potential research use beyond the life of a specific project with ethical approval or for which ethical approval is pending”*

- Ethical review scheme includes banks holding non-relevant material, e.g. DNA, plasma, serum
- May also include diagnostic archives with plans to support research

# Other terminology used

- Biobank
- Resource
- Repository
- Collection
- Registry
- Archive
- Library
- and others

## Ethical review is voluntary

- No formal requirements for ethical review of banks under either the Human Tissue Act or NHS research governance
- Applications for ethical review are voluntary but are encouraged and welcomed by NRES

# Why ethical review of tissue banks / biobanks?

- Many banks welcome ethical advice from RECs on their arrangements
- Ethical approval provides assurance to donors, funders, “collection centres” and regulatory bodies
- It facilitates research by enabling generic ethical approval for research projects using stored samples and data

## Complementary to licensing

- Our aim is that the ethical review of RTBs should be complementary to Human Tissue Authority licensing rather than duplicate it.

# Issues addressed in licensing

- Suitability of Designated Individual and other persons
- Premises
- Facilities
- Equipment
- Donor identification and tracking systems
- Security and risk management
- Consent (compliance with statutory requirements, records of consent)
- Arrangements for disposal of samples
- Quality systems
- Internal/external audit
- Staff training

# Main issues for ethical review

1. Prospective research purposes and uses of tissue/data
2. Arrangements for sample collection
3. Information sheets and consent forms – terms of generic consent
4. Feedback of clinically significant information
5. Policy for access by researchers and how decisions are made
6. Information governance
7. Donor involvement and feedback/publication of research findings

## Information sheets – points to consider

- Sample taking procedures and any risks
- Storage of tissue – who, where, why
- Types of research and tests (where known)
- Policy for access by researchers, any exclusions
- Potential to discover clinically significant information, policy for feedback
- Gifting and “ownership”
- Withdrawal of consent
- Information about research findings

# Applications

- Specific application form - select “research tissue bank” on filter page
- Applications through the Integrated Research Application System (IRAS) ([www.myresearchproject.org.uk](http://www.myresearchproject.org.uk))

# Review procedures

- Booking via NRES Central Allocation System with a “flagged REC” is recommended
- Normal SOPs for ethical review – 60 day timelines, one set of further questions only
- “Site-specific assessments” (SSA) by local RECs are not required
- Approval conditions issued as part of the ethical opinion; REC may vary the standard conditions issued by NRES

## Standard approval conditions (1)

- Must obtain HTA storage licence if required
- Notify any substantial amendments, e.g.
  - new classes of tissue or research purposes
  - further contact with donors
  - changes to consent arrangements
  - change in custodianship
- Duration of approval - 5 years, renewable

## Standard approval conditions (2) – licensing requirement

- No licensing requirement arises under the Human Tissue Act to store material for a scheduled purpose where the bank:
  - (a) is a NHS diagnostic archive
  - (b) is established in Scotland
  - (c) holds only non-relevant material

## Standard approval conditions (3) – generic approval for future projects

- Arrangements must be in place to ensure scientific critique of projects
- Research must be within terms of generic consent and donors must not be identifiable to the end user
- Supply agreements with end users
- Annual report to REC listing projects receiving tissue

# Pathology Archive RTB – Consent

Samples already in the pathology archive

1. Consent withheld
  - Samples cannot be used
  
2. Generic Consent
  - Anonymised samples can be used
    - Project specific approval
    - Research tissue bank generic approval
  
3. No indication either way
  - As for (2)

# Pathology Archive RTB – Consent

Samples prospectively added to the pathology archive

Is consent required for use of tissues for research?

- Legally, not necessarily if samples released in non-identifiable form with RTB ethics approval
- Ethically, the patient is now seen as a potential donor and consent should be sought

# Role of REC following ethical approval of RTB

- Give further ethical advice at any time if requested
- Review any substantial amendments
- Note annual reports, request further information or assurance if appropriate
- Review application for renewal after 5 years

# Researchers therefore have two routes to ethical approval.....

- Research studies may be ethically approved:  
either by making a project-specific application  
or by sourcing anonymised tissue from a RTB with generic approval
- Both forms of ethical approval will be valid for the purposes of the Human Tissue Act and NHS research governance

# Project-based applications should still be made where....

- A specific research project involves additional interventions or procedures involving participants, including collection of new samples/data
- Identifiable data is to be released with the banked samples
- The bank providing the samples/data has not sought ethical approval

# Summary

- NRES has introduced special arrangements for ethical review of RTBs on a voluntary basis
- Review of RTBs aims to add value to licensing without duplicating it, and to facilitate access to samples for valuable research
- The REC may give generic approval for future research subject to conditions without further review of individual projects
- Researchers can obtain ethical approval via an approved bank or by project-specific applications