Biobanks: What do regulators expect?

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Charlotte Allen, Quality and Performance Manager

Introduction

- Key legal and regulatory requirements for biobanks.
- Why seek ethical approval?
- What do Research Ethics Committees look for to ensure good governance?
- Why is regulation and transparency important to maintain public confidence?

UK Legislation

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- Research Tissue Banks can only store samples if they follow the required legislation in the UK.

- The Human Tissue Act (2004) applies in England, Wales and Northern Ireland,

- The HTA does not apply in Scotland.

  Each of the Scottish Health Boards has a research tissue bank, accredited by Healthcare Improvement Scotland.

Regulatory Requirements

- Tissue banks storing human tissue for use in as yet unspecified research must obtain a licence from the Human Tissue Authority (except in Scotland).
- There is no **requirement** for tissue banks to obtain ethical approval.
- Applications for ethical review are therefore made on a **voluntary** basis.
- Around 30-40 RTB applications are reviewed by NHS RECs each year.

If it's voluntary, why apply for ethical review?

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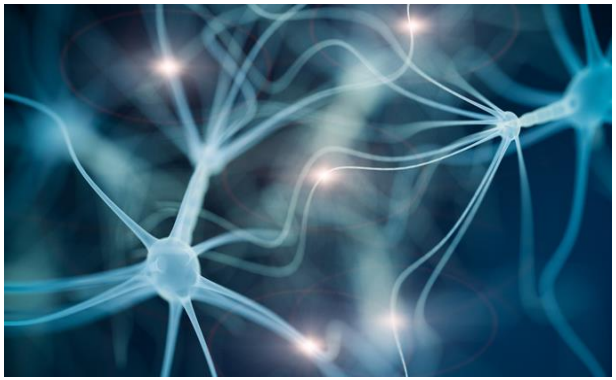
Applying for generic ethical approval for a bank can facilitate programmes of research without a need for individual project-based ethical approval (this saves having to submit a separate application for each project and submit for separate ethical review each time).



Why apply for ethical review?

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- Many banks welcome ethical advice from RECs. For example, regarding the quality of donor information and consent materials.
- Provides assurance to donors, funders, “collection centres” and regulatory bodies that the bank meets the highest ethical standards.
- The review complements the HTA licensing process rather than duplicating it.

What is generic ethical approval?

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- The Human Tissue Authority and the Research Ethics Service have agreed a position whereby RECs can give generic ethical approval for a research tissue bank's arrangements for collection, storage and release of tissue, providing the tissue in the bank is stored on HTA-licensed premises.

- Such research tissue banks need to be licensed because at least some of the tissue being stored is not for specific projects holding REC approval.

RTBs applying for generic ethical approval

- Samples and data must be anonymised before release.
- Supply agreement must be in place with the researcher – re storage, use and disposal of samples.
- The RTB needs to maintain a record of all projects for which samples have been released.
- Annual report to the REC.

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Research Tissue Banks – what are the ethical issues to consider?

Ethically Reviewing RTBs

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- Ethical review needs to be **proportionate** - balancing the need to protect the safety, rights and wellbeing of donors with the need to facilitate research of value to society as a whole.

Scope of the Ethical Review – what does the REC look at?

- Arrangements for collection of new tissue samples
- Consent arrangements from previous or new donors and from relatives of deceased donors (including arrangements for withdrawal of consent).
- Justifications given for any storage of tissue without consent
- Policy for access by researchers to tissue from the bank, the scientific critique of projects accessing the tissue and release conditions (Some bank's will not release material unless all projects using it have specific ethical approval. E.g. rare diseases)
- Plans for provision of the tissue donors with any feedback of clinically significant information in the future obtained in research using their samples
- Are there any arrangements for the continued collection of data to be stored with samples e.g. data on clinical outcomes following treatment or other follow ups over time with consent to do this at the outset?

Scope of the ethical review – What does the REC not look at?

- RECs are not required to address governance issues that will be covered in detail by the HTA as part of the licensing process.

- For example, the suitability of the Designated Individual and other persons named on the licence, premises, facilities and equipment for storage of samples, donor identification and tracking systems, records of consent, security and risk management, arrangements for the disposal of samples, quality systems, internal/external audit, staff training.

- Although there is an ethical dimension to some of these issues, it is primarily the responsibility of the HTA to set standards and ensure compliance

After ethical review - Post Approval Regulatory Requirements

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- The Annual Progress Report form for RTBs requests information about applications made to the bank for release of samples during the reporting period, as well as a lay summary of the purpose of each approved project.

- Renewals

Transparency

The HRA has a legal duty to promote research transparency and it is a condition of the ethical approval that all Research Tissue Banks are registered on the UK Clinical Research Collaboration (UKCRC) Tissue Directory:

https://directory.biobankinguk.org/Register/Biobank

Why register?

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- Without a centralised registry, there is the possibility of work being duplicated.

- The UKCRC Tissue Directory is a register of sample collections that covers multiple diseases and allows searching based on age, gender, disease classification, sample type and available datasets.

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Amendments

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The following changes should always be notified as substantial amendments:

1. Any significant change to the policy for use of the tissue in research, including changes to the types of research to be undertaken or supported by the Bank.

2. Any significant change to the types of biological material to be collected and stored, or the circumstances of collection.

3. Any significant change to informed consent arrangements, including new/modified information sheets and consent forms.

Amendments

4. A change to the conditions of generic approval.

5. Any other significant change to the governance of the RTB.

If the RTB did not previously apply for generic ethical approval for projects to which tissue is supplied, the RTB should submit a new application rather than a Notice of Amendment in order to request this.

REC Membership

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Would you enjoy promoting good ethical research by joining a Health Research Authority (HRA) Research Ethics Committee (REC)?

Further information about committee membership is available at:

www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/become-rec-member/

Further Information

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- Please sign up to our HRA Latest Newsletter to keep you up-to-date with developments in the HRA: https://www.hra.nhs.uk/about-us/hra-latest/

- Questions?