CONSENT AND THE HUMAN TISSUE AUTHORITY

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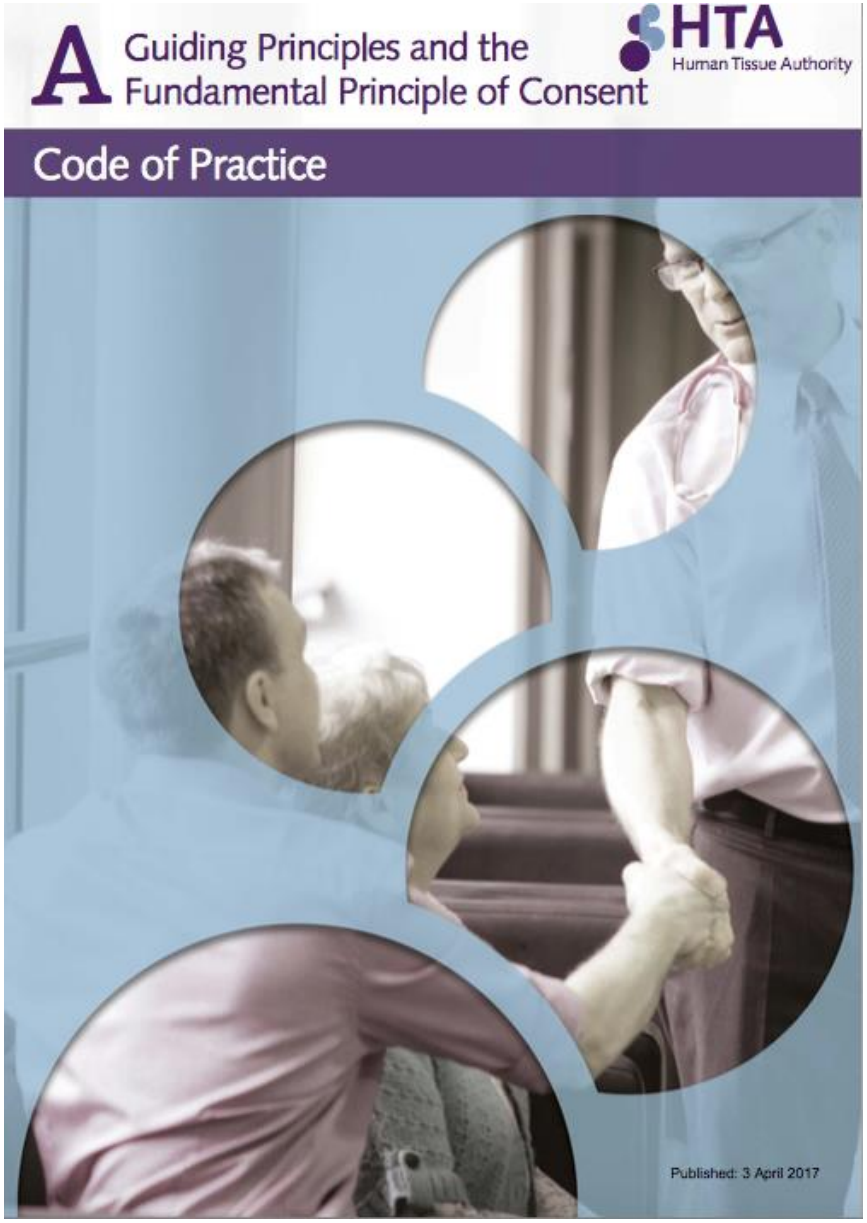
Background

Human Tissue Act 1961 – consent to retention of tissue could be presumed unless there was an objection from the donor or a surviving spouse or any surviving relative

Scandals involving human tissue in 1990s

- Organ retention scandal –1998. Children's hearts stored at Alder Hey hospital in Liverpool without the knowledge or consent of families

- Hospitals donated thymus glands removed from children during heart surgery to pharmaceutical companies in return for cash donations


A Guiding Principles and the Fundamental Principle of Consent
HTA
Human Tissue Authority
Code of Practice
Published: 3 April 2017

The HTA's Guiding Principles

1. Consent
2. Dignity
3. Quality
4. Honesty and openness

Consent – guiding principle

"The wishes of the donor have primacy when removing, storing and using human tissue."

- Human tissue should be used in accordance with the expressed wishes of donors
- Donors should be given the information they need to be able to make the decision that is right for them
- Those seeking consent should do so with sensitivity and an appreciation of the particular circumstances in each case

Appropriate and valid consent

"Appropriate" - governs who is able to give consent

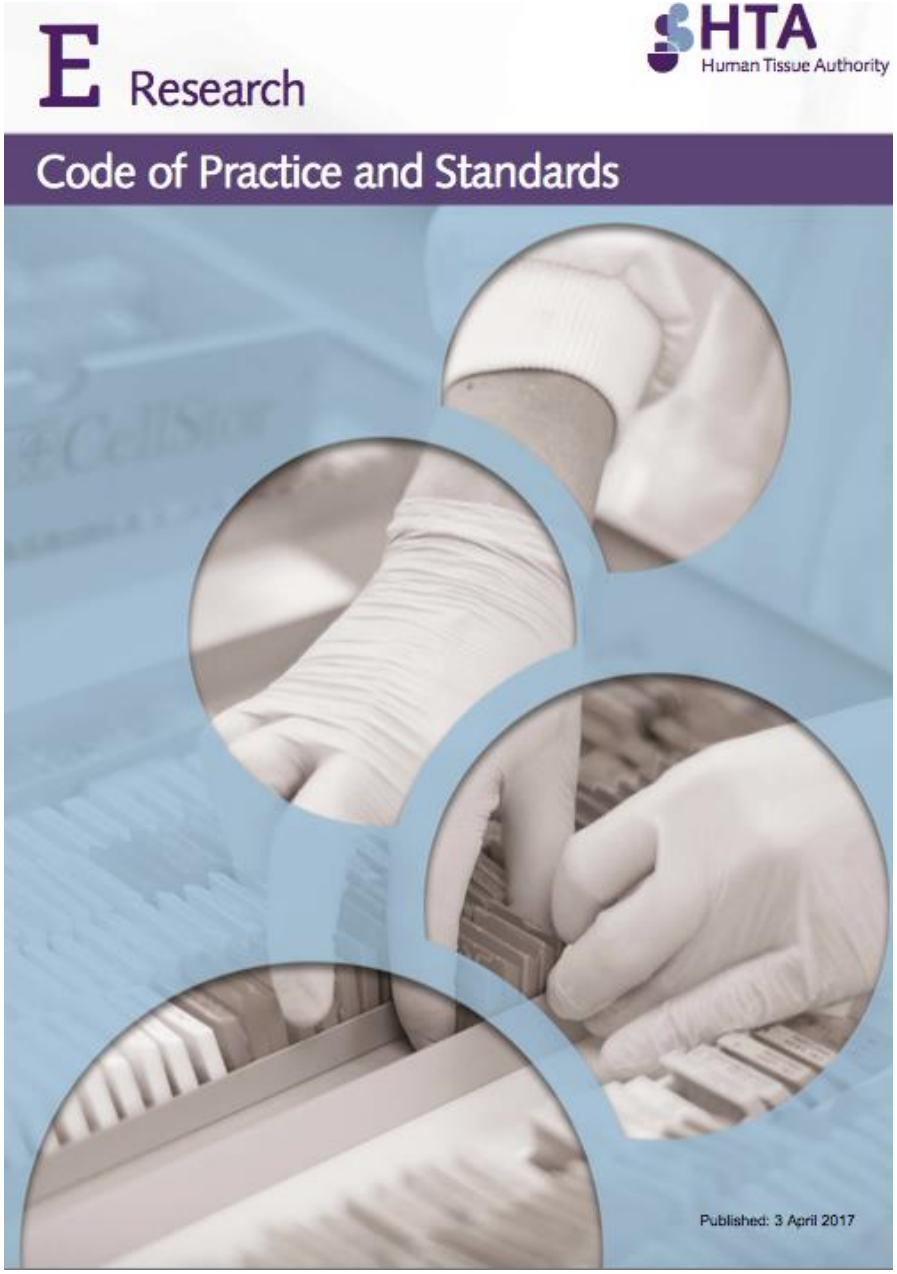
"Valid" – consent must be:

- Given voluntarily
- Appropriately informed
- Given by a person with capacity to agree to the activity in question

Consent may be specific or generic

Does not always need to be in writing

May be withdrawn


E Research
HTA
Human Tissue Authority
Code of Practice and Standards
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Code E - Research

Consent is needed for the "***removal, storage and use*** of human tissue for certain scheduled purposes, including research in connection with disorders or the functioning of the human body" – subject to certain exceptions.

Tissue vs data?

Tissue without data is generally much less valuable to researchers

Research tissue banks are often as much a store of data as of tissue

Human Tissue Act does not specifically cover data

DNA analysis is now cheaper and easier to do than when the HTAct was introduced and provides a huge amount of data on individuals

Research tissue donors need:

- To understand the nature and purpose of what is proposed
- To know of any material or significant risks inherent in the way the sample is obtained
- To know how the tissue will be used and any possible risks or implications of its use

Appropriate and clear information required

Particular areas of public concern – commercial sector involvement, genetic testing, use of human tissue in animals

Consent – other issues

- Withdrawing consent – donors must be free to do this but it will not affect results of any research that has already taken place

- Adults who lack capacity – can be involved in research but special provisions required to safeguard them

Consent is not always needed

- “Existing holdings” – pre 1st September 2006

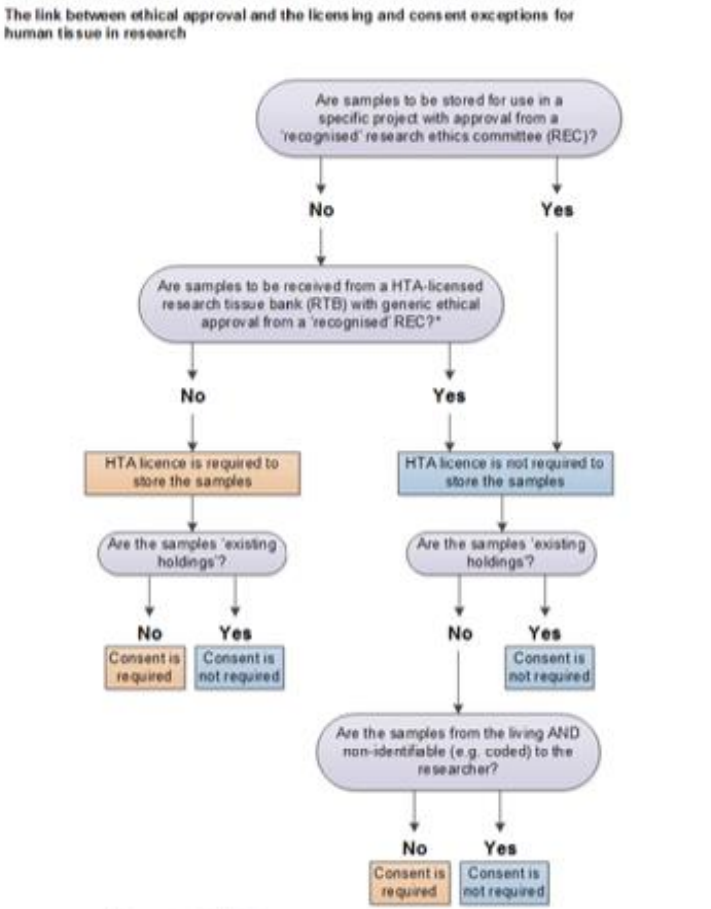
- Imported material

- Anonymised material where:

1. Tissue is from a living person
2. Researcher cannot identify the person from whom the tissue came
3. Research project has approval from a REC

Annex C

The link between ethical approval and the licensing and consent exceptions for human tissue in research



*Please note the following:

- Some RTBs require external researchers to obtain project-specific approval from a recognised research ethics committee.
- RTBs need to be covered by a HTA licence because at least some of the tissue being stored is not for specific projects holding approvals from recognised research ethics committees.