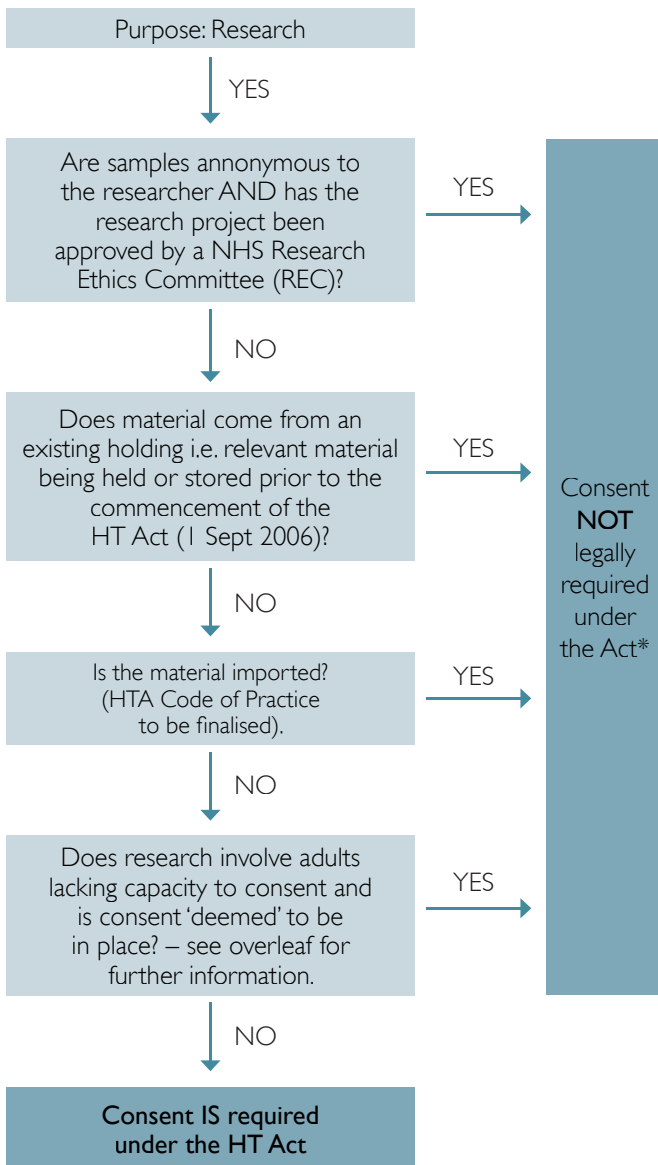


The Human Tissue Act 2004<sup>1</sup> (HT Act) sets out a legal framework for regulating the storage and use of human organs and tissue from the living, and the removal, storage and use of human organs, tissue and cells from the deceased, for specified health-related purposes including ‘research in connection with disorders or the functioning of the human body’. It received Royal Assent on 15 November 2004 and was fully implemented on 1 September 2006. The HT Act focuses on two issues: consent and licensing. The Human Tissue Authority (HTA) produced a Code of Practice on Consent<sup>2</sup>. **This page summarises the HT Act and HTA Code of Practice in relation to consent for research.**

**When is consent required for research under the HT Act?**

**TISSUES FROM THE LIVING**



\*Although consent is not legally required under the HT Act, it is good practice to obtain consent wherever practicable. For existing holdings, although not legally required, a decision should be taken as to whether consent should be sought<sup>2</sup>.

**TISSUES FROM THE DECEASED**

Consent **IS REQUIRED** for research involving both identifiable and anonymous samples of human tissue, including histology blocks and slides, unless the following exemptions apply: If material;

- comes from a person who died before 1 September 2006 and if 100 years have passed since their death,
- comes from an existing holding i.e. material being held or stored prior to the commencement of the HT Act (1 September 2006), or
- has been imported or comes from an imported body.

**DEFINITIONS**

**RELEVANT MATERIAL:** Material other than gametes, which consists of or includes human cells (does not include embryos). The HTA has released more information on relevant material on their website<sup>3</sup>.

**ANONYMOUS SAMPLES:** Tissue is anonymised such that the researcher is not in possession, and is not likely to come into possession, of information from which the individual can be identified.

This does not mean that samples must be permanently unlinked. Coding is a good way to meet these requirements. See MRC Ethics Series: Personal Information in Medical Research for information on coding<sup>4</sup>.

**EXISTING HOLDING:** Body of a deceased person or relevant material which has come from a human body held immediately prior to the commencement of section 1 of the Human Tissue Act 2004 for use for a scheduled purpose, i.e. prior to 1 September 2006.

**TIP:** Although legally consent is not required for ethically approved research using anonymous samples, the MRC in conjunction with NHS Research Ethics Committees, promotes where possible obtaining consent for storage and use of samples in research, and where applicable generic consent for storage and use in future studies.

## What type of consent is required for research under the HT Act?

If you have established that consent is required (from overleaf), the type of consent required under the HT Act is called 'appropriate consent', see below for details. Consent can be broad in both time and scope so does not need to be project-specific. This means generic consent can be obtained for storage and use of the material in future unspecified research projects, but please be aware a licence may be required to store this material (see MRC Research and Human Tissue Legislation Series: 'Licensing'<sup>5</sup>). The following information should help you identify appropriate consent.

### MATERIAL FROM LIVING PEOPLE

#### Living adults with capacity to consent

Consent should be obtained from the individual concerned.

#### Living adults who lack capacity to consent

The HT Act makes it lawful in certain circumstances to store, or use tissue (for a Scheduled Purpose such as research), where tissue is from an adult who lacks capacity to consent, and where consent can be 'deemed' to be in place. For research purposes, these circumstances are:

- For purposes of a clinical trial authorised and conducted under UK Medicines for Human Use (Clinical Trials) Regulations 2004<sup>6</sup>.
- When research is allowed under clauses 30-34 of the Mental Capacity Act 2005<sup>7</sup> (which comes into force in October 2007). Further guidance will be produced on the Mental Capacity Act.

In the case of adults lacking capacity to consent, consent should be obtained according to local legislation.

- Mental Capacity Act 2005 (England & Wales, comes into force 2007).
- Adults with Incapacity (Scotland) Act 2000<sup>8</sup>.

Guidance on consideration of competency is available from the Department of Health<sup>9</sup>.

#### Living children

Under the HT Act, a child is defined as being under 18 years old. If a child is considered competent, then consent should be sought from the child (it is good practice to involve person(s) with parental responsibility in this process)<sup>10</sup>.

As UK law is untested with regard to the legal age of consent to take part in research, the principle of "Gillick" (aka "Fraser") competence might be applied, whereby children who are felt to be competent to understand the research proposal and thus make decisions can give consent on their own behalf<sup>11</sup>. If the child is not competent or not willing to make a decision, consent should be obtained from a person with parental responsibility. See Department of Health guidance<sup>12</sup> and the HTA Code of Practice<sup>2</sup> for further information.

### MATERIAL FROM DECEASED PEOPLE

#### Deceased adults

1. Consent is appropriate from the individual if given whilst alive and competent.
2. If the individual did not make a decision to consent (or refuse) prior to death but did appoint a nominated representative, consent for research can be obtained from the nominated representative.
3. If the deceased individual did not appoint a nominated representative, appropriate consent can be sought from a person in a 'qualifying relationship' (also known as 'qualifying relative'), according to the following hierarchy (highest ranking first):
  - a) Spouse or partner (including civil or same sex partner)
  - b) Parent or child (in this context a child can be any age)
  - c) Brother or sister
  - d) Grandparent or grandchild
  - e) Niece or nephew
  - f) Stepfather or stepmother
  - g) Half-brother or half-sister
  - h) Friend of long-standing.

#### Deceased children

1. Consent is appropriate from the child if given whilst alive and considered competent.
2. If the child did not make a decision or was not competent, the appropriate consent should come from a person(s) with parental responsibility.
3. If there is no such person(s), consent should be sought from someone in a qualifying relationship according to the same hierarchy as above.

### DEFINITIONS

**QUALIFYING RELATIONSHIP:** type of relationship with an individual that qualifies them (known as qualifying relative) to give consent on that individual's behalf.

**NOMINATED REPRESENTATIVE:** A person appointed by an adult prior to their death to make decisions regarding consent after their death.

**GILICK COMPETENT:** A child is defined as being able to give consent if they are 'Gillick' competent, meaning they are under the age of 18 and able to make decisions regarding their own healthcare<sup>11</sup>. In Scotland, a child means a person who is under the age of 16 years; an adult means someone 16 years or older.

### What is an offence under the HT Act?

Offences include:

1. Removing, storing or using human tissue for Scheduled Purposes e.g. research, without appropriate consent.
2. Storing or using human tissue for a purpose not covered by consent.
3. Having bodily material with intent to analyse its DNA without qualifying consent, subject to certain **exceptions** (see p26-28 of Code<sup>2</sup> for list) which include:
  - Research involving existing holdings (see overleaf).
  - Research – where material is from a living person, is non-identifiable and the research is NHS REC approved.

### DNA Analysis

There are a number of differences in the provisions of the Human Tissue Act where research involves DNA analysis. Please see the MRC Research and Human Tissue Legislation Series: 'DNA Analysis'<sup>13</sup> for more information.

### Research in Scotland

There are some legal differences to consider in Scotland. Please see the MRC Research and Human Tissue Legislation Series: 'Summary of legal requirements for research with human tissue in Scotland'<sup>14</sup> for more information.

### References

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13. MRC Research and Human Tissue Legislation Series: 'DNA Analysis' [www.rsc.mrc.ac.uk](http://www.rsc.mrc.ac.uk)
14. MRC Research and Human Tissue Legislation Series: 'Summary of legal requirements for research with human tissue in Scotland' [www.rsc.mrc.ac.uk](http://www.rsc.mrc.ac.uk)