The consent process can help to foster an environment of trust and respect between researchers and participants. In terms of the HT Act, consent is legally required to store and use ‘relevant material’ from the living or deceased for the ‘scheduled purpose’ relating to research; there are exemptions covered below. There are other requirements with respect to DNA analysis and these are covered elsewhere. Further information is also available within our e-learning module Research and human tissue legislation.

The Human Tissue Act 2004 (HT Act) sets out a legal framework for regulating the storage and use of human tissue from the living and removal, storage and use of human tissue from the deceased, for purposes including ‘research in connection with disorders or the functioning of the human body’. It was fully implemented on 1 September 2006 in England, Wales and Northern Ireland; with Section 45 implemented UK wide (including Scotland). The HT Act has two main requirements: consent and licensing. In addition, the Human Tissue Authority (HTA) has produced a number of Codes of Practice. This page summarises the requirements of the HT Act and relevant HTA Codes of Practice in relation to consent for research.

**WHAT IS CONSENT REQUIRED FOR RESEARCH UNDER THE HT ACT?**

The consent process can help to foster an environment of trust and respect between researchers and participants. In terms of the HT Act, consent is legally required to store and use ‘relevant material’ from the living or deceased for the ‘scheduled purpose’ relating to research; there are exemptions covered below. There are other requirements with respect to DNA analysis and these are covered elsewhere. Further information is also available within our e-learning module Research and human tissue legislation.

**REMOVAL OF TISSUE**

Removal of tissue from the living is covered by common law, and always requires consent.

Under the HT Act consent is always required to remove tissue from the body of a deceased person and store or use it for research, even if the removal for this purpose has taken place during a Coroner’s post-mortem examination.

Guidance for hospital and mortuary staff on brain and spinal cord donations for research is available on the HTA website.

**WHAT IF SEEKING CONSENT ISN’T PRACTICAL?**

Consent is required to use and store tissues for research; unless:

1. The tissues are not classed as relevant material under the HT Act (see the HTA website for more details)
2. One of the legal exemptions apply (the HTA refer to these as the ‘consent exceptions’):
   - The relevant material is classed as an existing holding i.e. held or stored prior to 1st Sept 2006
   - The relevant material is imported (see HTA Code of Practice 8 - Import and export of human bodies, body parts and tissue).
   - The relevant material is:
     - From the living (at the time the sample was taken); AND
     - Anonymous to the researcher; AND
     - To be used in research with/pending project-specific ethical approval (from an NHS REC)
   - The relevant material is from a person who died more than 100 years ago.

Although there are legal exemptions from the need for consent under the HT Act (‘consent exceptions’), it is always best practice to obtain consent wherever this is practicable. For existing holdings it is good practice to consider the ethical issues involved in their potential use and balance this against the issues involved in obtaining consent. For imported tissues it is good practice to get assurance that samples have been obtained with valid consent. For further details please see the HTA’s Codes of Practice.

When analysing DNA for research, there are other requirements (please see our ‘DNA Analysis’ summary).
The HTA Code of Practice on Consent\(^9\) states that consent must be ‘appropriate’ in terms of who provides it, i.e. given by the person themselves or by someone on their behalf (see below) or, if they have died, someone close to them before they died. For consent to be ‘valid’, it must be given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question (and in practice, indicated). This applies equally to patients, healthy volunteers and/or colleagues (see guidance\(^10\)).

Consent can be specific to the project itself, or more generic to include storage and future use. If seeking generic consent, you need to decide how much information to provide to potential participants to help them understand the scope of future use and what this might mean for them. Likewise, think about how samples might be used in future and ask participants for this consent (e.g. you may need to extract DNA in future, if so ask for this consent up front). Many organisations (including the MRC and HTA) advocate obtaining generic consent whenever possible.

### MATERIAL FROM LIVING PEOPLE

#### Living adults with capacity to consent

Consent should be obtained from the person concerned. For a clinical trial of an investigational medicinal product (CTIMP) this is also a separate legal requirement.

#### Living adults who lack capacity to consent

There are legal frameworks that should be applied when adults lack capacity to consent for research:

- Where tissues are being used as part of a clinical trial of an investigational medicinal product (CTIMP), the UK Medicines for Human Use (Clinical Trials) Regulations 2004\(^11\) apply UK wide.
- For all other research involving tissue and adults (over 16) who lack capacity in England and Wales, the Mental Capacity Act 2005\(^12\) applies (separate legislation is expected to be introduced in Northern Ireland).

Further guidance is available from the Department of Health\(^13\), within the MRC’s - Medical research involving adults who cannot consent\(^14\) and the Adults lacking capacity to consent to research online tool kit\(^15\).

#### Living children

If a child is considered competent, then consent should be sought from the child. If a child is not competent, or not willing to make a decision, consent should be obtained from a person with parental responsibility. Even when a child is competent to consent, it is good practice to consult those with parental responsibility and involve them in the process of the child making the decision\(^16\).

- Where tissues are being used as part of a CTIMP a child (under 16) cannot legally provide consent for themselves. Consent should be sought from a person with parental responsibility.
- For all other research involving tissue in England, Wales and Northern Ireland, a child is anyone under the age of 18. Young people aged 16-18 are presumed to be competent to give consent and for under 16s the principle of ‘Gillick’ (or Fraser) competence might be applied. A child is considered ‘Gillick’ competent if they have sufficient understanding and intelligence to make decisions about their own healthcare (this is generally considered to apply for research situations).

#### 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 indicate their consent (nor specifically refused) prior to death, those close to them should be asked whether a ‘nominated representative’ was appointed to make these decisions.
3. If the deceased individual has not indicated their consent/refusal, nor appointed a ‘nominated representative’, then consent can be sought from a person in a ‘qualifying relationship’ according to the following hierarchy (highest ranking first):
   - Spouse or partner (incl civil or same sex partner)
   - Parent or child (in this context a child of any age)
   - Brother or sister
   - Grandparent or grandchild
   - Niece or nephew
   - Stepfather or stepmother
   - Half-brother or half-sister
   - Friend of long-standing.

#### Deceased children

1. Consent is appropriate from the child if given whilst alive (see Living children).
2. If the child did not make a decision whilst alive or was not considered competent, appropriate consent should come from a person with parental responsibility.
3. If there is no such person, consent can be sought from someone in a ‘qualifying relationship’ as above.

### Definitions

**Nominated Representative:**
A person appointed to represent someone after their death who is empowered to make decisions about consent on behalf of the deceased.

**Qualifying Relationship:**
Person(s) who can give consent for the deceased person if the deceased person has not indicated their consent nor appointed a nominated representative.

### RESEARCH IN SCOTLAND

There are some legal differences to consider in Scotland, although consent (or ‘authorisation’) is still a central tenet. To learn more please see the MRC Research and Human Tissue Legislation Series: ‘Summary of legal requirements for research with human tissue in Scotland’\(^3\).
WHAT IS AN OFFENCE UNDER THE HT ACT WITH REGARDS TO CONSENT FOR RESEARCH?

Unless an exemption applies, it is an offence to:
1. Store or use 'relevant material' for a 'scheduled purpose' without consent (it's also an offence to remove from the deceased, as noted on page 1).
2. Store or use 'relevant material' for a purpose not covered by the terms of consent.

For a full list of the exemptions which may apply, please see page 1.

Penalties for non-compliance can include imprisonment (up to a maximum of 3 years), a fine or both.

LICENSING

We've already noted that the HT Act has two key requirements: consent and licensing. To learn more about the licensing requirement (and specific offences) please see the MRC Research and Human Tissue Legislation Series: 'Licensing'3.

DNA ANALYSIS

There are other requirements for consent (and specific offences) with respect to DNA analysis. To learn more about the HT Act and DNA analysis, please see the MRC Research and Human Tissue Legislation Series: 'DNA Analysis'3.

References

2. Human Tissue Authority (HTA) Codes of Practice: https://www.hta.gov.uk/codes-practice
3. MRC Research and Human Tissue Legislation Series: available from the ‘Human Tissue’ link (from menu on left) at http://www.mrc.ac.uk/regulatorysupportcentre
4. MRC Research and human tissue legislation e-learning: available via the ‘Training & e-learning’ link at http://www.mrc.ac.uk/regulatorysupportcentre
8. MRC Ethics Series: Personal Information in Medical Research http://www.mrc.ac.uk/documents/pdf/personal-information-in-medical-research/
15. University of Leicester and University of Bristol’s Adults lacking capacity to consent to research online tool kit https://connect.le.ac.uk/alctoolkit