



Research and the Human Tissue Act 2004 Consent

Produced in
consultation with
the Human Tissue
Authority

**Terms are defined
on page 4**

The Human Tissue Act 2004¹ (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 1st September 2006 in England, Wales and Northern Ireland; with Section 45 implemented UK wide (including Scotland). The Human Tissue Authority (HTA) has also produced Codes of Practice and Standards². **This document summarises the requirements of the HT Act and relevant HTA Codes of Practice and Standards in relation to consent for research.**

When is consent required for research under the HT Act?

Consent is a fundamental principle of the HT Act. The consent process helps 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 a 'scheduled purpose' such as research; there are exemptions (see What if seeking consent isn't practical, page 2). There are other requirements with respect to DNA analysis which are covered in our DNA Analysis and Scotland summaries³. Further detail is also available in our e-learning module⁴.

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, including when 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 website⁵.

Project specific or generic/broad consent?

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 inform participants of this during the consent process (e.g. you may see the potential to do genetic analysis in future, or to collaborate with the commercial sector, if so you should discuss this with potential participants up front). Many organisations (including the MRC and HTA) advocate obtaining generic consent whenever possible.

Consent and DNA analysis

When analysing DNA for research, there are other requirements (please see our DNA Analysis summary³).

What if seeking consent isn't practical?

Consent **IS REQUIRED** to use and store tissues for **research; unless:**

The tissues are not classed as **relevant material** under the HT Act (see definitions on page 4, and the HTA website⁶ for more details).

OR One of the following legal exemptions applies (the HTA refer to these as the 'consent exceptions'⁷):

The relevant material is classed as an **existing holding** i.e. held prior to 1st September 2006

The relevant material is **imported**

The relevant material is:

- From the **living** (at the time the sample was taken); AND
- **Non-identifiable** (the samples are released in a form that is not identifiable to the researcher); AND
- To be used in research with/pending project-specific **NHS REC** ethical approval

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 good practice to obtain consent wherever it is practical to do so. For existing holdings, it is good practice to consider the ethical issues involved in their potential use, balancing this against the issues involved in obtaining new samples. For imported tissues it is good practice to get assurance that samples have been obtained with valid consent in the country of origin. For further details please see the HTA's Code of Practice on Research⁷.

Consent requirements for research under the HT Act and HTA Codes of Practice

The HTA Code of Practice on Consent⁸ outlines the HTA's guiding principles: consent; dignity; quality; honesty and openness. The Code states that consent must be 'appropriate' and 'valid.' '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, given by someone close to them before they died. 'Valid' in that consent must be given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question (and in practice this is indicated). This applies equally to patients, healthy volunteers and/or colleagues (see guidance⁹).

Material from living people

Living adults with capacity to consent

Consent should be obtained from the person concerned in line with the HT Act and any other relevant legislation.

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 2004¹⁰ apply UK wide.
- For all other research involving tissue and adults (over 16) who lack capacity in England and Wales, the Mental Capacity Act 2005¹¹ applies. In Northern Ireland the Mental Capacity Act (Northern Ireland) 2016¹² applies.

Further guidance is available from the Department of Health¹³ and in the MRC's Medical research involving adults who cannot consent¹⁴.

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 decision¹⁵.

- 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 samples 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).

Withdrawal of consent

Participants should be free to withdraw their consent and this should be made clear at the outset when consent is being sought. The practical implications of withdrawing consent should be discussed to help participants understand what is realistic in terms of withdrawal and to manage expectations.

Material from the deceased

Deceased adults

1. Consent is appropriate from the individual themselves, if given whilst alive and with capacity to consent.
2. If the individual did not indicate their consent (nor specifically refuse) 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):
 - a. Spouse or partner (incl civil or same sex partner)
 - b. Parent or child (in this context a child of 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 (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.

Due sensitivity should always be shown when approaching bereaved people to ask for consent (for further guidance please see Religion, belief and culture in our Disposal summary³).

What is an offence under the HT Act with regards to consent for research?

Unless an exemption applies (see What if seeking consent isn't practical, page 2), 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.

There are other offences relating to DNA analysis.

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

Licensing

The HT Act has two key requirements: consent and licensing. To learn more about the licensing requirement (and specific offences) please see our Licensing summary³.

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 our Scotland summary³.

Definitions

EXISTING HOLDING: Material from the living or deceased that was already held for a scheduled purpose(s) when the Human Tissue Act 2004 came into force; i.e. relevant or bodily material held prior to 1st September 2006 for research.

NHS REC: Ethical approval which qualifies for exemptions under the HT Act can only be given by:

- a) an NHS (or HSC in Northern Ireland) Research Ethics Committee listed on the Health Research Authority's website, or
- b) a REC recognised by the United Kingdom Ethics Committee Authority (UKECA) to review CTIMPs.

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

NON-IDENTIFIABLE SAMPLES: Samples which are not identifiable to the researcher. i.e. when the researcher is not in possession, and not likely to come into possession, of information from which an individual donor can be identified (nor do they seek to re-identify any individual donor). This does not mean that samples must be permanently unlinked.

QUALIFYING RELATIONSHIP: Person(s) who can give consent for the deceased person if the deceased person has not indicated their consent (nor specifically refused) and they have not appointed a nominated representative.

RELEVANT MATERIAL: Any tissue or sample that contains human cells (from the living or deceased). It **excludes:** gametes, embryos outside the body, nails and hair from the living, cells manufactured outside of the human body (e.g. cell lines once established) and any sample that has been processed to render it acellular. The HTA website⁶ has more information on relevant material.

SCHEDULED PURPOSES: Defined in the HT Act, these are purposes for which consent is required by the HT Act, one of which is research 'in connection with disorders, or the functioning, of the human body'.

References

1. Human Tissue Act 2004 <http://www.legislation.gov.uk/ukpga/2004/30/contents>
2. Human Tissue Authority (HTA) Codes of Practice and Standards <https://www.hta.gov.uk/hta-codes-practice-and-standards-0>
3. MRC Human Tissue Legislation summaries: available from mrc.ukri.org/regulatorysupportcentre
4. MRC Research and human tissue legislation e-learning: available from mrc.ukri.org/regulatorysupportcentre
5. HTA Guidance for hospital and mortuary staff on brain and spinal cord donations for research <https://www.hta.gov.uk/news/ensuring-smooth-brain-and-spinal-cord-donation>
6. HTA definition of relevant material <https://www.hta.gov.uk/policies/relevant-material-under-human-tissue-act-2004>
7. HTA Code E: Research <https://www.hta.gov.uk/sites/default/files/Code E.pdf>
8. HTA Code A: Guiding principles and the fundamental principle of consent <https://www.hta.gov.uk/sites/default/files/files/HTA Code A.pdf>
9. Guidance for staff asked to volunteer samples <https://www.mrc.ac.uk/documents/pdf/guidance-for-staff-asked-to-volunteer-samples/>
10. Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031) (or any amending or replacing Regulations) <http://www.legislation.gov.uk/uksi/2004/1031/contents/made>
11. Mental Capacity Act 2005 <http://www.legislation.gov.uk/ukpga/2005/9/contents>
12. Mental Capacity Act (Northern Ireland) 2016 <http://www.legislation.gov.uk/nia/2016/18/contents/enacted>
13. Department of Health Reference Guide to Consent for Examination or Treatment, Second Edition https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/138296/dh_103653__1_.pdf
14. MRC Ethics Guide: Medical research involving adults who cannot consent <https://www.mrc.ac.uk/documents/pdf/medical-research-involving-adults-who-cannot-consent/>
15. MRC Ethics Guide: Medical Research Involving Children <https://www.mrc.ac.uk/documents/pdf/medical-research-involving-children/>