

The Human Tissue Act 2004¹ (HT Act) is a framework for regulating the storage and use of human organs, tissues and cells from the living, and the removal, storage and use of organs, tissues and cells from the deceased, for certain scheduled purposes including ‘research in connection with disorders of the functioning of the human body’.

The HT Act makes consent the fundamental principle underpinning the lawful storage and use of human body parts, organs and tissue for specified scheduled purposes and creates a new **UK-wide offence** of DNA ‘theft’ or having bodily material with the intent to analyse its DNA without qualifying consent. The Human Tissue Authority² (HTA) produced a Code of Practice on Consent³, which includes a section on consent and the use of DNA.

This page summarises the HT Act and the HTA Code of Practice on Consent in relation to research involving DNA analysis.

What is an offence under Section 45 of the HT Act?

Having bodily material (see definition) with intent to analyse its DNA without qualifying consent (subject to certain exceptions).

The offence **applies UK-wide**.

When the offence does not apply:

Use for Excepted Purposes

Consent is not legally required if the results of the DNA analysis are to be used for the following ‘excepted’ purposes relating to research (the HTA Code of Practice includes additional excepted purposes³):

- Medical diagnosis or treatment of the person from whom the DNA came.
- The tissue is from a living person and used for:
 - clinical audit,
 - educational training relating to human health,
 - performance assessment,
 - public health monitoring, or
 - quality assurance.
- The tissue is from a living person, it is anonymised (see definition) and the research has been approved (or approval is pending) by an NHS Research Ethics Committee (REC).
- The research involves adults with incapacity and certain circumstances apply, e.g. for the purposes of a Clinical Trial under the UK Clinical Trial Regulations (see overleaf for more details).
- The tissue is an existing holding (held pre- 1 Sept 2006) and is used for research.

Excepted Material

The following material is excepted from the requirements of the Act and can be used for research without qualifying consent:

- All existing holdings that are held prior to 1 September 2006. Including any identifiable or anonymous material from the living or deceased;
- Any material manufactured outside the body is not considered ‘bodily material’ e.g. cell lines; or
- An embryo outside the human body (these are regulated by the Human Fertilisation and Embryology Act 1990, and so are classed as excepted material from the Human Tissue Act 2004).

Qualifying consent is legally required for research if the tissue is:

- From a living person and samples are identifiable; or
- From a living person and samples are anonymised (see Definitions) but NHS REC approval has not been obtained or is not pending; or
- From a deceased person and collected after 1 September 2006 (for both anonymous and identifiable samples).

DEFINITIONS

BODILY MATERIAL: Material that has come from a human body (living or deceased) and consists of or includes human cells. This includes hair, nails and gametes. Extracted DNA and RNA (where no whole cells remain) are not classed as bodily material.

ANONYMOUS SAMPLES: Ensuring if human tissue is removed, all necessary steps are taken to prevent identifying the person from whom the tissue has come by the person conducting the analysis.

This does not mean that samples must be permanently unlinked. Coding is a good way to meet these requirements.

What is qualifying consent?

Qualifying consent is consent that fulfils the requirements of the HT Act and therefore allows DNA analysis to be carried out without committing an offence. Schedule 4 of the HT Act 2004 sets out who can give qualifying consent. The requirements differ depending on whether the person is deceased or living, an adult or child (see overleaf).

The HTA Code of practice on Consent³ states that if consent has been obtained for an activity which is a scheduled purpose, it is not normally necessary to take consent again for DNA analysis in the course of carrying out this activity (i.e. research) but it is best practice to make clear to the donor or consenting person that their bodily material may be used for DNA analysis, if that is the intention. Consent does not have to be in writing for the purposes of DNA analysis. If it was taken verbally, this should be documented for evidence.

Licensing in England, Wales and Northern Ireland

Storage of relevant material for research requires a licence from the Human Tissue Authority (HTA) unless it is stored for a specific ethically approved project (or approval is pending), where the ethical approval has come from an NHS Research Ethics Committee. Relevant material is defined as material that consists of or contains cells. Therefore, the storage of DNA or RNA does not require a licence (storage of relevant material in Scotland is not licensable by HTA).

Who can give qualifying consent for DNA analysis?

BODILY MATERIAL FROM A LIVING PERSON

Living adults with capacity to consent

Consent for analysis of DNA should be obtained from this individual.

Living adults without capacity to consent

In the case of adults without capacity, consent should be obtained according to local legislation:

- Mental Capacity Act 2005⁴ (England & Wales, for research comes into force October 2007); or
- Adults with Incapacity (Scotland) Act 2000⁵.

Guidance on consideration of competency is available from the Department of Health⁶.

Living children

If no decision to consent or not consent is in place, or the child is not competent or not willing to make a decision, qualifying consent for analysis of DNA may be given by a 'person with parental responsibility' (or in Scotland, a 'person with parental responsibilities in relation to the child').

Please see the MRC Research and Human Tissue Legislation Series: Consent⁷ for more information on obtaining consent for research involving children.

BODILY MATERIAL FROM A DECEASED PERSON

Deceased adults

After death, qualifying consent for analysis of DNA may be given by anyone who stood in a qualifying relationship with the deceased adult immediately before their death.

The ranking method specified by HTA for other purposes³ does not apply for analysis of DNA. Any person in a qualifying relationship (any of those listed below) can give consent.

- a) Spouse or partner (includes civil/same sex)
- b) Parent or child (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

Qualifying consent for analysis of DNA may be given by a person with parental responsibility (or in Scotland, a person with parental responsibilities in relation to the child).

If none, a person in a qualifying relationship with the deceased child immediately before their death can give consent (see above list).

DEFINITIONS

RELEVANT MATERIAL: Material other than gametes, which consists of or includes human cells (does not include embryos). The HTA has produced information on relevant material on their website⁸.

QUALIFYING RELATIONSHIP: Type of relationship with an individual that qualifies them to give consent on that individual's behalf.

Mental capacity and DNA analysis

Regulations⁹ state that the following are 'excepted purposes' for which research involving DNA analysis from adults without capacity (or adults with incapacity in Scotland) can be undertaken without qualifying consent.

England, Wales and Northern Ireland:

- Purposes of a clinical trial authorised and carried out in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004¹⁰.
- Purposes of research (in connection with disorders, or the functioning of the human body) which has been ethically approved (by an NHS REC), and cannot reasonably be anonymised or carried out on persons with capacity to consent.

England and Wales only:

- Purposes of intrusive research under the Mental Capacity Act 2005 (sections 30-34)⁵.

Scotland:

- Purposes of a clinical trial authorised and carried out in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004¹⁰.
- Purposes of surgical, medical, nursing, dental or psychological research permitted under section 51 of the Adults with Incapacity (Scotland) Act 2000⁶.

HTA Guidance on non-consensual DNA analysis

The Human Tissue Authority have provided guidance¹¹ on when DNA analysis may be used, for obtaining scientific or medical information about the person whose body manufactured the DNA, even if their consent has not been obtained. This guidance also provides information about how establishments can apply to the HTA to carry out non-consensual analysis of DNA.

References

1. Human Tissue Act 2004, www.opsi.gov.uk/acts/acts2004/20040030.htm
2. Human Tissue Authority website www.hta.gov.uk
3. Human Tissue Authority Code of Practice: Consent http://www.hta.gov.uk/guidance/codes_of_practice.cfm
4. Mental Capacity Act 2005, <http://www.opsi.gov.uk/acts/acts2005/20050009.htm>
5. Adults with Incapacity (Scotland) Act 2000, www.opsi.gov.uk/legislation/scotland/acts2000/20000004.htm
6. Department of Health Reference Guide to Consent for Examination and Treatment, <http://www.dh.gov.uk/assetRoot/04/01/90/79/04019079.pdf>
7. MRC Research and Human Tissue Legislation Series: Consent www.rsc.mrc.ac.uk
8. Human Tissue Authority guidance on relevant material http://www.hta.gov.uk/guidance/licensing_guidance/definition_of_relevant_material.cfm
9. Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 <http://www.opsi.gov.uk/si/si2006/20061659.htm>
10. Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031) (or any amending or replacing Regulations) <http://www.opsi.gov.uk/si/si2004/20041031.htm>
11. HTA guidance on non-consensual DNA analysis http://www.hta.gov.uk/guidance/non-consensual_dna_analysis.cfm