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 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 on DNA analysis implemented UK wide (including Scotland). In addition, the Human Tissue Authority (HTA) has produced a number of Codes of Practice which provide guidance on good practice. This page summarises the HT Act and the HTA Code of Practice on Consent in relation to Section 45 (Non-consensual analysis of DNA). This guidance also applies to RNA analysis when used to provide information about DNA for research.

WHAT IS AN OFFENCE UNDER SECTION 45 OF THE HT ACT?

Consent is a fundamental principle of the HT Act. Under Section 45 it is an offence to hold ‘bodily material’ with the intent to analyse its DNA and use the results for research without ‘qualifying consent.’ There are some exceptions when obtaining consent is not practicable.

Unlike the rest of the HT Act, this offence applies across the whole of the UK – including Scotland.

WHAT IS QUALIFYING CONSENT?

The term ‘qualifying consent’ is only used within Section 45 of the HT Act. In practice, the act of obtaining qualifying consent is fundamentally the same as obtaining any other consent for research. The only difference between qualifying consent and consent in the rest of the HT Act lies in who can give it. The requirements differ depending on whether the person is deceased or living, an adult or child.

The HTA Code of practice on Consent states that if consent has been obtained for an activity which is a scheduled purpose (e.g. research) it is not normally necessary to take consent again for DNA analysis (for full details please see Who can give qualifying consent for DNA analysis overleaf*). However, if you intend to carry out DNA analysis in the future and this is known when seeking consent, then the HTA expects that this be made clear to donors during the consent process.

*If working with human tissue from the deceased, please note references to the ‘nominated representative’ on page 2.

WHEN THE OFFENCE DOES NOT APPLY (‘EXCEPTED PURPOSES’):

Qualifying consent is not legally required if the results of DNA analyses are to be used for an ‘excepted purpose’, which are fully detailed in Schedule 4 of the HT Act. These include using the results of DNA analysis for the following purposes relating to research:

- Medical diagnosis or treatment of the person whose body made the DNA.
- Where the ‘bodily material’ is from a living person and used for: clinical audit, education or training relating to human health, performance assessment, public health monitoring, or quality assurance.
- Where the ‘bodily material’ is an existing holding (held prior to the 1st September 2006) and is used for various purposes including research.
- Where the ‘bodily material’ is from a living person, it is anonymised and is to be used for research with/pending project-specific ethical approval from an NHS Research Ethics Committee (NHS REC).
- Where another legal framework applies e.g. for research involving adults who lack capacity to consent in very specific circumstances.

Consent is not legally required for ‘excepted material’ i.e. to use the results of DNA analysis of bodily material for research if it is:

- from the body of a person who died over 100 years ago;
- an ‘existing holding’ irrespective of whether these are identifiable or anonymous samples from the living or deceased.

Definitions

**Bodily Material:** Any tissue or sample that consists of human cells, this includes gametes, and hair and nails from the living or deceased. It excludes: Embryos outside the body; cells manufactured outside of the human body (e.g. established cell lines) and/or any extracted cellular components where no whole cells remain (e.g. extracted DNA and RNA are not classed as bodily material).

**Anonymous Samples:** Tissue is anonymised when the researcher is not in possession, and not likely to come into possession, of information from which an individual can be identified. This does not mean that samples must be permanently unlinked. Coding is a good way to meet these requirements and the MRC Ethics Series: Personal Information in Medical Research provides further guidance.

**Existing Holding:** Tissue held or stored prior to the enforcement of the HT Act, i.e. prior to 1 September 2006, for use for a ‘scheduled purpose’ such as research.

**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 website has more information on relevant material.
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 a separate legal requirement.

Living adults without capacity to consent

There are legal frameworks that should be applied when adults lack capacity to consent to DNA analysis for the purposes of 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 apply UK wide.

- For all other research involving tissue and adults (over 16) who lack capacity the following applies: in England and Wales the Mental Capacity Act 2005, in Scotland the Adults with Incapacity Scotland Act 2000, and in Northern Ireland separate legislation is expected to be introduced.

Living children

If a child is considered competent, then qualifying consent for DNA analysis 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.

- Where the DNA analysis is being carried out as part of a CTIMP a child (under 16) cannot legally provide consent for themselves, and consent should be sought from a person with parental responsibility.

- For all other research involving tissue, young people over the age of 16 can usually give consent for themselves. For further details please see our Consent and Scotland summaries.

Deceased adults

1. Qualifying consent from the individual if given whilst alive and competent.

2. If the individual did not indicate their consent (nor specifically refused) prior to death then qualifying consent for DNA analysis may be given by anyone who stood in a ‘qualifying relationship’ with the deceased adult immediately before their death.

   Those in a ‘qualifying relationship’ are listed top right. They can give consent regardless of the hierarchy specified in the HT Act for other purposes as this does not apply for analysis of DNA.

3. If the deceased has appointed a ‘nominated representative’ then their consent will only be valid for DNA analysis if that person was also in a ‘qualifying relationship’ with the deceased (as there is no provision for consent provided by a nominated representative under Section 45 of the HT Act).

Deceased children

1. Qualifying consent for DNA analysis is valid from a competent child if given whilst alive (see Living children).

2. If the child did not make a decision whilst alive or was not considered competent, qualifying 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.

What if seeking consent isn’t practical?

Consent IS REQUIRED to hold human tissue with the intent to use the results of DNA analysis for the purposes of research; Unless:

- The tissues are not classed as bodily material under the HT Act (see definition on page1)

OR an exception applies i.e. the results of DNA analyses are to be used for an ‘excepted purpose’ (full list detailed in Schedule 4 of the HT Act) or the DNA analysis will be carried out on ‘excepted material’.

These exceptions include:

Bodily material which 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)

Definitions

**Qualifying relationship:** Person(s) who can give consent for the deceased person if the deceased person has not indicated their consent.

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

In order to provide qualifying consent for DNA analysis this person must also be in a qualifying relationship with the deceased.
**HEALTH RELATED FINDINGS**

When research involves the analysis of DNA there is the potential to reveal significant results (e.g. a family genetic condition which may be relevant not only to the individual themselves but also to their immediate family, or future persons). For guidance on how to decide if and when to provide participants with health related feedback, please see the MRC/Wellcome Trust Framework on the feedback of health-related findings in research11.

**LICENSING**

There is a requirement to store 'relevant material’ for research under a licence from the Human Tissue Authority (HTA) in England, Wales and Northern Ireland but not in Scotland. There are exemptions (for more details please see our Licensing summary10). Relevant material is defined as any tissue or sample that contains human cells. Therefore, most ‘bodily material’ does need to be held under a licence (in England, Wales and Northern Ireland). DNA and/or RNA do not.

**GUIDANCE ON NON-CONSENSUAL DNA ANALYSIS**

The Human Tissue Authority have provided guidance12 on when the results of 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. This policy does not apply in Scotland where corresponding but different provisions apply. Scottish applications are made to the Court of Session.

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**References**

2. Human Tissue Authority (HTA) website https://www.hta.gov.uk
4. MRC Ethics Series: Personal Information in Medical Research http://www.mrc.ac.uk/documents/pdf/personal-information-in-medical-research/
5. HTA guidance on relevant material : https://www.hta.gov.uk/policies/relevant-material-under-human-tissue-act-2004
10. MRC Research and Human Tissue Legislation Series: available from the ‘Human Tissue’ link (from menu on left) at www.mrc.ac.uk/regulatorysupportcentre
12. HTA guidance on non-consensual DNA analysis https://www.hta.gov.uk/policies/non-consensual-dna-analysis