MRC Medical Research Council

Regulatory Support Centre

Research and the Human Tissue Act 2004 **DNA analysis**

Produced in consultation with the Human Tissue Authority

Terms are defined on page 4

The Human Tissue Act 2004[1] (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). The Human Tissue Authority[2] (HTA) has also produced a number of Codes of Practice and Standards. This document summarises the HT Act and HTA Code of Practice on Research[3] 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, 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 (these are discussed on page 2).

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, obtaining qualifying consent is fundamentally the same as obtaining any other consent for research. The only difference lies in who can give it. The requirements differ depending on whether the person is deceased or living, an adult or child.

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The HTA Code of practice on Research[3] states that if consent for research has previously been obtained and it is later decided to include DNA analysis in the research, as long as the consent does not rule-out DNA analysis, then the original consent will suffice as 'qualifying' consent for use in England, Wales and Northern Ireland. (For full details please see *Who can give qualifying consent for DNA analysis*). However, if you know when seeking consent that you intend to carry out DNA analysis in the future, then the HTA expects that this be made clear to donors during the consent process.

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, is non-identifiable to the researcher and is to be used for research with/pending project-specific NHS REC ethical approval.
- 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 samples are identifiable or non-identifiable, from the living or deceased.

Who can give qualifying consent for DNA analysis?

Bodily 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 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[4] 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[5], in Scotland the Adults with Incapacity Scotland Act 2000[6], and in Northern Ireland the Mental Capacity Act (Northern Ireland) 2016[7].

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[8].

- Where 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 samples, young people over the age of 16 can usually give consent for themselves. For further details please see our Consent and Scotland summaries[9].

Bodily material from the deceased

Deceased adults

1. Qualifying consent 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 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.
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).

Those in a 'qualifying relationship' are listed below. 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.

a) Spouse or partner (includes 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

The person giving consent should however be encouraged to discuss the decision with other family members.

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.

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 p4).

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 classed as an **existing holding**, i.e. held prior to 1st September 2006

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

Handling health-related findings

Any research involving human tissue has the potential to reveal significant health-related results. For example DNA analysis could reveal a family genetic condition, relevant not only to the individual themselves, but also to their immediate family, or future persons. Guidance on how to decide if and when to provide participants with health-related feedback can be found in the MRC/Wellcome Trust Framework on the feedback of health-related findings in research[10].

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 summary[9]). 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) but DNA and RNA do not.

Guidance on non-consensual DNA analysis

The HTA have provided guidance[11] 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.

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).

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

NON-IDENTIFIABLE SAMPLES: Samples which are not identifiable to the researcher, i.e. 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).

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[12] has more information on relevant material.

References

1. Human Tissue Act 2004 http://www.legislation.gov.uk/ukpga/2004/30/contents
2. Human Tissue Authority (HTA) website https://www.hta.gov.uk
3. HTA Code of Practice: Research https://www.hta.gov.uk/sites/default/files/Code%20E.pdf
4. 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
5. Mental Capacity Act 2005 http://www.legislation.gov.uk/ukpga/2005/9/contents
6. Adults with Incapacity (Scotland) Act 2000 http://www.legislation.gov.uk/asp/2000/4/contents
7. Mental Capacity Act (Northern Ireland) 2016 http://www.legislation.gov.uk/nia/2016/18/contents/enacted
8. MRC Ethics Guide: Medical Research Involving Children https://mrc.ukri.org/documents/pdf/medical-research-involving-children/
9. MRC Human Tissue Legislation summaries: available from mrc.ukri.org/regulatorysupportcentre
10. MRC/Wellcome Trust Framework on the feedback of health-related findings in research https://mrc.ukri.org/documents/pdf/mrc-wellcome-trust-framework-on-the-feedback-of-health-related-findings-in-researchpdf/
11. HTA guidance on non-consensual DNA analysis https://www.hta.gov.uk/policies/non-consensual-dna-analysis
12. HTA definition of relevant material https://www.hta.gov.uk/policies/relevant-material-under-human-tissue-act-2004