

SUMMARY OF LEGAL REQUIREMENTS FOR RESEARCH WITH HUMAN TISSUES IN SCOTLAND

Produced in consultation with the Human Tissue Authority and Scottish Government Health and Social Care Directorate

Two pieces of human tissue legislation apply in Scotland; both with the fundamental principle of obtaining consent or 'authorisation' to use samples in **research**:

1. **Human Tissue (Scotland) Act 2006**¹ – uses the term 'authorisation' (which equates to the principle of consent).
2. **Human Tissue Act 2004**² – applies in its entirety in England, Wales and Northern Ireland and uses the term consent. Only one section of the Human Tissue Act applies in Scotland (section 45, which regulates DNA analysis).

1. Human Tissue (Scotland) Act 2006

In terms of research, the Human Tissue (Scotland) Act 2006 sets out provisions for the removal, retention and use of 'organs, tissue and tissue samples' **from the deceased**, i.e. body parts or bodily fluids (including any derivative of skin) removed post mortem, and subsequently used for research. It does not regulate the use of tissue **from the living** for research. The Human Tissue (Scotland) Act 2006 states that authorisation is needed in order to remove and use post mortem tissue and tissue samples for research, unless they are Existing Holdings (see below).

TRANSPLANTATION

Authorisation for transplantation takes precedence over any other authorisation which may have been given for purposes covered by the Act (e.g. research).

Authorisation for research use of body parts can be given, either as an option in its own right or as an alternative if the body part proves unsuitable for transplantation.

TISSUE AND ORGANS NO LONGER REQUIRED FOR PROCURATOR FISCAL PURPOSES

If samples are being held by a Procurator Fiscal, the Fiscal will notify the hospital or university when samples are no longer required for their purposes.

Tissue blocks and slides then automatically become part of the deceased's medical record and can be used for research if specific authorisation has been given.

Whole organs can only be retained for research purposes with specific authorisation and NHS Research Ethics Committee (NHS REC) approval.³

HOSPITAL POST-MORTEMS

Hospital or consented post mortems can be carried out for a number of purposes which are set out in the Act.

Standard forms and leaflets can be used when seeking authorisation for hospital post-mortem examination and retention of tissue samples for research (including genetic research).⁴

If authorisation is given, tissue samples removed post-mortem become part of the deceased's medical record and can be used for research without further authorisation.

Retention/use of whole organs needs specific authorisation and includes options for research and/or genetic research.³

From 1 September 2006, it became an offence to retain or use tissue from a post mortem examination for research without authorisation (unless an exemption applies).

WHO CAN GIVE AUTHORISATION?

Adults (16 years of age or over)

Themselves before death; or after death a 'nominee' (see definition) or 'nearest relative' in order of priority:

- | | |
|-----------------------------|----------------------------|
| 1 Spouse or civil partner | 7 Grandchild |
| 2 Partner for over 6 months | 8 Uncle or aunt |
| 3 Child | 9 Cousin |
| 4 Parent | 10 Niece or nephew |
| 5 Brother or sister | 11 Friend of long standing |
| 6 Grandparent | |

A Welfare Attorney or Welfare Guardian cannot give authorisation on behalf of an incapacitated adult for activities post mortem unless they **are a 'nominee' or a 'nearest relative'** of the deceased.

Children

Child 12 years of age or over:

- Themselves before death if deemed competent; or if not deemed competent a person with parental rights and responsibilities.
- After death a 'nominee' or person with parental responsibility

Under 12 years:

- Person with parental rights and responsibilities only

WHEN 'AUTHORISATION' IS NOT LEGALLY REQUIRED - EXISTING HOLDINGS

All organs or tissue samples removed post mortem **prior to 1st Sept 2006** can continue to be used for research without authorisation (whole organs removed by a Procurator Fiscal also need NHS REC approval).

Definitions

Authorisation: The principle of 'authorisation' is an expression intended to convey that people have the right to express, during their lifetime, their wishes about what should happen to their bodies after death, in the expectation that those wishes will be respected.

Organs, tissue and tissue samples: Defined as anything removed from a human body post mortem including any derivative of skin to include nails and hair. It does not cover any tissue taken from the living.

Nominee: A person (aged 12 and over) can, before death, nominate a person or persons to represent them after their death. Nominees can authorise post mortem examination and the removal/retention of organs or tissues for research.

2. Human Tissue Act 2004 – Consent and the use of DNA

The Human Tissue Act 2004 (HT Act) applies in its entirety in England, Wales and Northern Ireland; with Section 45 on consent and DNA analysis implemented UK wide (including Scotland). Unlike the Human Tissue (Scotland) Act 2006, Section 45 of the HT Act applies to 'bodily material' **from the living or from the deceased**. **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?

Section 45 made it an offence to hold 'bodily material' with the intent to analyse its DNA and use the results for research without qualifying consent (there are exceptions when obtaining consent is not practicable).

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 lies in who can give it. The requirements differ depending on whether the person is deceased or living, an adult or child. Qualifying consent should be explicit for DNA analysis in Scotland.

WHO CAN GIVE QUALIFYING CONSENT?

In Scotland, as in the rest of the UK, consent should be obtained from the individual themselves if they are alive and competent. Scotland differs from the rest of the UK when:

Living adults lack capacity to consent:

Consent should be obtained in line with the appropriate legal framework (i.e. in accordance with the UK Medicines for Human Use (Clinical Trials) Regulations 2004 or Adults with Incapacity (Scotland) Act 2000 – where a Welfare Attorney / Welfare Guardian or nearest relative can consent).

Living children (under 16 years):

Consent should be sought from the child if competent. If they are not competent, or cannot decide, consent should be sought from a person with parental responsibility.

Deceased adults (16 years or over) who did not provide consent before death, or were not competent:

Consent should be sought from a person in a 'qualifying relationship'.

Deceased children (under 16 years) who did not provide consent before death, or were not competent:

Consent should be sought from a person with parental responsibility, or if not applicable, from someone in a 'qualifying relationship'.

Those in a 'qualifying relationship' are listed top right. They can give consent regardless of their position on the following list (as obtaining consent in line with any priority / hierarchy **does not apply** for DNA analysis).

However, the person giving consent should be encouraged to discuss the decision with the family.

QUALIFYING RELATIONSHIPS

- 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

If the deceased has a Welfare Attorney or Welfare Guardian then their consent for DNA analysis will only be valid if that person was also in a 'qualifying relationship' with the deceased.

There are legal exemptions to the need for qualifying consent. For more information, please see our DNA Analysis summary.⁵

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.' These include using the results of DNA analysis for the following purposes relating to research:

- Medical diagnosis or treatment.
- Where the bodily material is from a **living person** and used for: clinical audit, educational training relating to human health, performance assessment, public health monitoring or quality assurance.
- Where the bodily material is from a **living person** (i.e. 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**).

Where another legal framework applies (e.g. Adults with Incapacity (Scotland) Act 2000, for research involving adults who lack the capacity to consent themselves), you should comply with the requirements of these legal frameworks.

WHEN THE OFFENCE DOES NOT APPLY ('EXCEPTED MATERIAL'):

All existing holdings (i.e. 'bodily material' held prior to 1st September 2006) from the living or deceased. Anything which falls outside of the definition of 'bodily material' (please see definition overleaf).

3. Human Tissue Act 2004 – Licensing

LICENSING

The licensing requirement of the Human Tissue Act 2004 does not apply in Scotland (i.e. the Human Tissue Authority (HTA) does not license the storage of tissue for research in Scotland).

However, the HTA does have a remit in Scotland in other sectors (such as transplantation and Quality and Safety for Human Application regulations⁶). For further details please see our Licensing summary⁵.

NHS SCOTLAND'S ACCREDITATION SCHEME

On behalf of the Chief Scientist Office, Healthcare Improvement Scotland have developed a Scottish Accreditation Scheme for the collection and storage of tissue under the guardianship of NHS Scotland Research Tissue Banks / Biorepositories. The scheme covers four main areas: governance; access; the data/audit trail and consent. Four hub NHS Boards will be subject to full accreditation and will support their partner spokes to ensure they can also meet agreed standards. For further details please see CMO(2011)07⁷ and CMO letter issued 26 May 2015⁸.

Definitions

Bodily Material: Is 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 (or using a cipher) is a good way to meet these requirements.

References

1. Human Tissue (Scotland) Act 2006, <http://www.legislation.gov.uk/asp/2006/4/contents>
2. Human Tissue Act 2004, <http://www.legislation.gov.uk/ukpga/2004/30/contents>
3. Scottish Health Department letter: "Human Tissue (Scotland) Act 2006: A guide to its implications for NHS Scotland," issued on 20 July 2006 (Ref: NHS HDL (2006) 46), http://www.sehd.scot.nhs.uk/mels/HDL2006_46.pdf
4. The Scottish Government: Authorisation for a Hospital Post-Mortem Examination on an Adult, <http://www.gov.scot/Publications/2004/02/18927/33309>
5. MRC Research and Human Tissue Legislation Series: available from the 'Human Tissue Summaries' link (from menu on left) at www.mrc.ac.uk/regulatorysupportcentre
6. Human Tissue (Quality and Safety for Human Application) Regulations 2007 <http://www.legislation.gov.uk/uksi/2007/1523/made>
7. Chief Medical Officer letter: "Accreditation scheme for the collection and storage of NHS tissue in Scotland" issued on 15 June 2011 (Ref: CMO(2011)07), <http://www.sehd.scot.nhs.uk/cmo/CMO%282011%2907.pdf>
8. Chief Medical Officer letter: "Healthcare improvement Scotland accreditation of human tissue banks in Scotland" issued on 26 May 2015, <http://www.sehd.scot.nhs.uk/details.asp?PublicationID=562>
9. MRC Research and human tissue legislation e-learning: available from the 'e-learning' logo on www.mrc.ac.uk/regulatorysupportcentre