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).

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** – uses the term ‘authorisation’ (which equates to the principle of consent).

### 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
  2. Partner for over 6 months
  3. Child
  4. Parent
  5. Brother or sister
  6. Grandparent
  7. Grandchild
  8. Uncle or aunt
  9. Cousin
  10. Niece or nephew
  11. Friend of long standing

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

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
9. MRC Research and human tissue legislation e-learning: available from the ‘e-learning’ logo on www.mrc.ac.uk/regulatorysupportcentre

Research and Human Tissue Legislation Series
MRC Regulatory Support Centre, V2 June 2016. www.mrc.ac.uk/regulatorysupportcentre

Supersedes V1, October 2007