

Summary of legal requirements for research with human tissues in Scotland

Produced in consultation with the Human Tissue Authority and Scottish Executive Health Department

New human tissue legislation regulates the use of human tissues for research purposes, the fundamental principle of this legislation being the need for permission to use the samples for research, referred to as either authorisation or consent. This document summarises the situation in Scotland, outlining legally when authorisation/consent is, and is not, required for research purposes.

There are two pieces of human tissue legislation that apply in Scotland:

1. **Human Tissue (Scotland) Act 2006** – uses the term authorisation.
2. **Human Tissue Act 2004** – This is the Act that is mainly applicable to England, Wales and Northern Ireland, but one section regulating DNA analysis applies to Scotland as well – uses the term consent.

1. Human Tissue (Scotland) Act 2006

For research purposes this Act sets out provisions for the use of organs, tissues and samples (including skin, nails and hair) from the deceased, i.e. body parts or fluids that are removed post mortem, and are subsequently used for research. For research, it does not regulate the use of tissue from the living.

The Act states that authorisation is needed in order to remove and use post mortem tissue samples in research, unless they are Existing Holdings (see below).

Transplantation

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

Hospital post-mortems

Post mortem can be carried out for research purposes.

Authorisation forms and leaflets include a research option including a DNA analysis option for compatibility with the Human Tissue Act 2004 requirements (see overleaf).

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

Retention and use of whole organs for research needs separate authorisation.

Authorisations can be withdrawn.

It is an offence to retain or use a body part from a post mortem examination (which takes place after 1 September 2006) for research purposes without the appropriate authorisation.

Tissue and organs no longer required for Procurator Fiscal purposes

If tissue 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.

The samples then automatically become part of the deceased's medical record and can be used for research with appropriate authorisation (or for diagnostic purposes without authorisation).

After Fiscal notification, organs can only be retained for research purposes with authorisation if the research is approved by an NHS Research Ethics Committee.

Who can give authorisation?

Adults (16 years or over)

Themselves before death; a nominated person; or a 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 | |

Children

Child 12 years or over:

- Themselves before death if considered competent; or
- Nominated person; or
- Person with parental responsibility

Under 12 years:

- Person with parental responsibility only

When authorisation is not legally required – Existing Holdings

An organ or tissue sample removed post mortem prior to 1 September 2006 can continue to be used for research without authorisation.

Fiscal organs can be held for existing or new NHS REC-approved research.

All human material currently being used in research projects can continue in that project without the need for authorisation.

It is obviously good practice to obtain authorisation/consent for use of all tissue samples for research, where this is practical.

Reference: Will Scott, Scottish Executive, seminar at Wellcome Trust CRF, Edinburgh, 7 December 2006.

Continued overleaf

2. Human Tissue Act 2004

Most of the Human Tissue Act 2004 applies to England, Wales and Northern Ireland. One section relating to DNA analysis applies to the whole of the UK, including Scotland. This section creates a new offence of 'DNA theft' or having bodily material with the intent to analyse its DNA without qualifying consent. There are exceptions to this offence, which are outlined below.

What is bodily material?

Material that has come from the human body (living or deceased) and which consists of or includes human cells. This includes hair, nails and gametes.

The following material is excepted from the requirements of the Act and can legally 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 e.g. cell lines. (Embryos outside the body are regulated by the Human Fertilisation and Embryology Act 1990, and so are classed as excepted material from the Human Tissue Act 2004).

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 but no NHS REC approval; or

From a deceased person and collected after 1 September 2006 (for both anonymous and identifiable samples).

Consent for DNA analysis.

Consent should be explicit for DNA analysis in Scotland.

Consent does not have to be in writing. If it was taken verbally, this should be documented for evidence.

Anonymous Samples

Tissue is anonymised such that the researcher is not in possession, and is not likely to come into possession, of information from which the individual can be identified.

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

The Human Tissue Authority (HTA) does not regulate the storage of tissue samples for research purposes in Scotland. In England, Wales and Northern Ireland, the HTA have a licensing system.

When the offence does not apply

Consent is not legally required if the results of the DNA analysis are to be used for the following research-related purposes:

- Medical diagnosis or treatment.
- The material is from a living person and used for:
 - Clinical audit
 - Educational training relating to human health
 - Performance assessment
 - Public health monitoring
 - Quality assurance
- The tissue is from a living person, it is anonymised (does not mean irreversibly unlinked) and the research has been approved (or approval is pending) by an NHS Research Ethics Committee.
- 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.

Who can give consent?

Where consent is legally required this should be obtained from the individual themselves or from the following:

Adults who lack capacity to consent:

Obtain consent in accordance with Adults with Incapacity Act 2000.

May be 'deemed' to be in place, e.g. if for a Clinical Trial authorised and conducted under UK Regulations.

Deceased adult, not given consent before death:

Consent from a nominated representative, or one of the following:

Spouse; partner; child; brother; sister; grandparent; grandchild; niece; nephew; step parent; half sibling; friend of long standing.

Living child (under 16 years), cannot decide or is not competent:

Consent from a person with parental responsibility.

Deceased child (under 16 years), did not decide or was not competent:

Consent from a person with parental responsibility, or if not applicable, consent from a person on the list above.