A guide for the public to Code of Practice A: Guiding Principles and the Fundamental Principle of Consent

This guide is intended to be read alongside Code of Practice A: Guiding Principles and the Fundamental Principle of Consent.

About this guide

Our approach to regulation is based on four guiding principles:

- **Consent**: Emphasising that human tissue and organs will only be used in accordance with a person’s wishes.
- **Dignity**: Making sure that human tissue and organs are treated with respect and that a person’s privacy is always maintained.
- **Quality**: Guaranteeing that anyone working with human tissue and organs is doing so in a safe and well-managed way.
- **Honesty and openness**: Maintaining transparency and confidence in our regulation and between the public and our licensed establishments.

These principles not only inform our work, but also the work of anyone carrying out activities within our remit. For example, anyone storing or using human tissue for the purpose of research.

The guidance below sets out how each guiding principle is relevant to you. It explains what you can expect from organisations and individuals working under our remit.

Commonly used terms

**Tissue and organs**

**Organs**

Where we use the term organ, or organs, in this guidance, it refers specifically to a whole solid organ, or organs, including:

- Kidney
- Liver
- Heart
• Brain
• Eyes

The general definition of what constitutes an organ in this context is a body part which has a specific vital purpose.

Tissue
Where we use the term tissue, this refers to all other various human materials that are not whole solid organs.

Tissue and Organs
When we refer to “tissue and organs”, this is to make it clear there is a combination of both.

Consent

Your wishes are paramount to the removal, storage and use of your tissue.

This means:

• your body, tissues and organs will only be used in accordance with your wishes
• you will be given the information you want and need to be able to make the decision that is right for you
• anyone asking for your consent will do so with sensitivity and with an appreciation for your particular circumstances

We emphasise the importance of you giving informed consent for activities using your body or tissue. However, there are situations where you will be unable to give consent. For example, if you have died and your clinician has asked your family to give consent for a post mortem examination on your body. In this case, if your wishes are not known, then your nominated representative/s wishes will be given the same importance. If a representative has not been nominated, the decision on consent will be passed to relatives. If there are no relatives able to give appropriate consent, then it is not lawful to remove or use the body or tissues of the deceased.

The term ‘relatives’ includes a spouse or partner. Where there are no relatives, this includes close friends of a deceased person. Decisions regarding consent should be made according to the hierarchy of qualifying relationships.

Qualifying relationships

The Human Tissue Act 2004 includes a list of ‘qualifying’ relationships, which are ranked. When consent is sought for any process, such as a post mortem examination, the person nearest the top of the list should be asked first to give consent for removal, storage or use of relevant material. Their decision has priority over someone below them on the list. The list is as follows:
1. spouse or partner (including civil or same sex partner)
2. parent or child
3. brother or sister
4. grandparent or grandchild
5. niece or nephew
6. stepfather or stepmother
7. half-brother or half-sister
8. friend of long standing

For these purposes, a person is considered a partner if they live as partners in an enduring family relationship.

While the Human Tissue Act is clear on the hierarchy of relationships, there may be situations where relatives disagree on giving consent. There are procedures and advice on dealing with these conflicts in Code A: Guiding Principles and the fundamental principle of consent, paragraphs 30-39.

We recommend that any decision on consent is sensitively discussed with other relatives of the deceased person. This may include relatives not on this list, for example, an aunt or uncle.

**Dignity**

Your dignity, and the dignity of your relatives, will be respected at all times.

This means:

- you have a right to privacy
- all reasonable steps will be taken to protect your body, organs and tissues from harm
- if your tissues need to be disposed of, this will be done:
  - sensitively;
  - in a way that is appropriate to the type of tissue;
  - and in line with the wishes you have expressed in your lifetime
- organisations which import human tissue will make sure that the tissue comes from a country with ethical and legal safeguards for the donors

**Quality**

You can expect services to meet certain standards and to be cared for in a way that meets your needs.
This means:

- everyone working with your tissue/s or body will have the appropriate skills and training to provide high quality services
- everyone working with your tissue/s or body will follow good practice and professional guidance
- the site/s where your body and/or tissue/s are used or stored will be clean, secure and well maintained. This includes all equipment on site.
- your records and information will be accurate and kept in a way that means your body and tissue/s can be traced at all times
- your information will be held securely and confidentially

**Honesty and openness**

You can expect everyone working with your tissues or body to be honest and open about this work.

This means:

- your conversations with everyone using and/or storing your tissue/s and body will be open, honest, clear and objective.
- organisations will investigate fully all incidents to prevent similar incidents in future
- organisations will be open and transparent when responding to serious incidents
- any conversations you have about medical testing or treatment will be kept separate to conversations about donating your tissue/s or body
- organisations will give you clear and honest information about how they charge and are reimbursed

If you have any concerns about the services you have received, please contact the HTA on either 020 7269 1900 or by using our online form.