

Collection and use of human materials

1. Use of body parts and tissues from deceased persons

The use of body parts from deceased persons is governed by the [Human Tissues Act 2008](#) (the Act). This legislation must be complied with. It regulates the collection and use of tissue, primarily from dead human bodies and sets up a framework for informed consent around consent for human tissue collection and use. Under this Act, human tissue is defined as tissue collected from the body (living or otherwise); tissue which is, or includes, human cells. Human tissue is not a human embryo or human gamete. Cell lines derived from human tissue may be considered human tissue; however, the standard for non-therapeutic use of human tissue (NZS 8135:2009) should be referred to.

Under the Act, the primary consent or objection for the collection and use of human tissue will be that of the deceased, if formally recorded before he or she died, or of someone nominated by that person to make the decision on his or her behalf. If there is no nominee, consent or objection may be given collectively by the immediate family of the deceased, or by a specified members of the immediate family. Informed consent is required for collection of human tissue that is, or is collected from, a body; collection of non-health-care tissue for donor analysis or carries out donor analysis of non-health-care-tissue; use of the tissue for a secondary purpose after the donor's death, of human tissue collected from the living individual.

The Act has provision for standards for the non-therapeutic use of human tissue (i.e. research, education, audit, and anatomical examination) and standards or requirements for the import and export of human tissue. The Act outlines some exceptions to the general rule that informed consent is required to collect human tissue.

Cultural concerns should always be addressed before body parts and tissues are removed. For example, for Māori the brain has special spiritual significance. Failure to address these concerns may result in mental and emotional upset to relatives.

2. Use of body parts and tissues from living persons

It is important that the fully informed consent of the participant be obtained before any body parts or tissues are obtained from living participants. A person has the right to determine what is to be done with his or her body parts, particularly if there are commercial implications arising from their use.

If the course of the research changes in any way, or the use to which the human materials are to be applied changes, then normally the donor, or in the case of deceased persons the donor's relatives, should be informed in order to gain consent to the changes.

If consent for future unspecified use was obtained (see Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes), the human material may be used for research purposes provided approval from an ethics committee has been obtained.

The legal and cultural issues in relation to use of surplus parts and tissues (e.g. aborted fetuses, placentae, spare embryos) are complex. In respect of some parts and tissues, cultural concerns may need to be considered. For example, for Māori, the placenta has special spiritual significance. Researchers should ensure that the cultural concerns of participants are fully

considered and addressed before any research is commenced. These concerns may relate to use, or to storage and disposal.

There may be limited circumstances where it is ethically permissible to use human materials for purposes other than those for which they were originally collected without specific consent being obtained. Right 7(10) of the [Code of Health and Disability Services Consumers' Rights](#), provides that where body parts or tissue have been obtained in the course of a health care procedure they may be used for research without consent where it has been approved by an approved ethics committee.

Such limited circumstances must be ethically justifiable and must be approved by an approved ethics committee. Examples are where materials collected for one research use are proposed to be used for a different research project; or where left-over materials collected for clinical purposes are proposed to be used for research.

If a researcher considers that it is impossible, impractical or excessively costly to obtain consent, or that doing so would adversely affect the outcome of the research, application for use without specific consent must be made to an approved ethics committee. In these cases, material should be unlinked from all identifiers and thus made wholly anonymous before testing, unless there are valid reasons for not doing so.

In considering an application for use of human materials without specific consent the ethics committee must be satisfied that:

- (a) there is no harm to the person or interests of the donor or the donor's extended family; and
- (b) the research will be of significant potential public benefit; and
- (c) the research is not being conducted principally for commercial gain.

Ethics committees must be satisfied that it is not practicable to get consent, or that the potential public benefit in allowing the research to proceed outweighs the very strong need to protect an individual's right to consent.

The World Health Organisation has recommended additional safeguards for unlinked anonymous testing for human immunodeficiency virus (HIV, the causative virus of AIDS) using left-over blood collected for clinical purposes (see **1.8 Resource Documents**). For further ethical guidelines on the collection, storage, use and disposal of human materials see the [Human Tissue Act 2008](#) and the NZ Standard for Non-therapeutic Use of Human Tissue.

3. Collection of human tissue for future unspecified use

At the time of consent for a clinical procedure, donors have the right to consent to the use of their tissue in any future unspecified research. Consent shall meet the requirements of the [Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes](#).

Consent to the future unspecified use of a person's tissue samples must be distinct from consent to collect the sample and distinct from consent to use the sample in specified research. Consent may be given for unidentified and de-linked use; however, the donor must be made aware that they will not be able to withdraw their consent for the use of samples in the future.

4. Use of cells from established embryonic stem cell lines for research

Research involving established human embryonic stem cell lines and genetic modification of cells must be reviewed by the Environmental Protection Authority (EPA), in addition to other approvals required, before cells are imported to New Zealand. Ethical review of research involving established human embryonic stem cell lines must be undertaken by an HDEC.

Human embryonic stem cell lines must originate with embryos which have been created for the purpose of fertility treatment and are no longer required for that purpose. Evidence of free and informed consent to the use of the embryo for research purposes must be provided and evidence that provision of human stem cells was in accordance with the laws and regulations of the country of origin must be provided when importing.

For more information, refer to *Guidelines for using Cells from Established Human Embryonic Stem Cell Lines for Research*, Ministry of Health 2006.