

The collection and use of tissue and body parts and informed consent

Certain health care procedures require body parts or bodily substances to be removed or obtained. This may be from a living or a deceased patient. Those parts or substances may then need to be disposed of or preserved. It is important for doctors to make sure that patients (or their representative/guardian/family) are properly informed about their rights in relation to such procedures, and are careful to ensure that informed consent is properly obtained.

Removal of body parts and bodily substances from a patient when they are alive

Under right 7(9) of the code of health and disability services consumers rights, patients have the right to decide what happens to their body parts or bodily substances removed or obtained in the course of a health care procedure.

A decision about the disposal or removal of body parts or bodily substances can be of significant personal and cultural importance to a patient. It is essential then that the informed consent of the patient is obtained prior to any procedure.

MCNZ provides detailed guidance on informed consent in its statement; ***"Informed consent: helping patients make informed decisions about their care"***.

After a body part or bodily substance has been removed or obtained, right 7(10) of the code provides that it may not be stored, preserved or used otherwise than:

- With the informed consent of the patient; or
- For the purposes of research that has received the approval of an ethics committee; or
- For the purposes of 1 or more of the following activities:
 - A professionally recognised quality assurance programme;
 - An external audit of services;
 - An external evaluation of services.

Removal of human tissue from a deceased patient

In general, the human tissue act 2008 does not cover consent for the collection and use of tissue from living people. However, it does close a gap in current regulation by requiring consent to the analysis of human tissue (including DNA analysis) taken from living people outside of a health care procedure.

When collecting or using human tissue from a deceased patient, the human tissue act 2008 applies. As with collecting or using human tissue from a patient who is alive, with limited exceptions the act requires informed consent to be obtained (and sets out who may object to such a procedure).



The collection and use of tissue and body parts and informed consent

It also requires decision-makers and the person collecting or using human tissue to take the immediate family's cultural and spiritual needs, values and beliefs into account.

There are a number of circumstances provided in the act in which tissue may be collected or used after a patient has died. It is important to be aware that there is not one set of rules as to who can give consent (or raise an objection) and how that should be obtained. Where consent may be obtained from individuals other than the donor, there is a "hierarchy of consent" to be followed. In other words, you need to work your way progressively through the hierarchy until instructions are obtained, one way or the other.

For example, in relation to the collection or use of tissue for general purposes as defined by the act, the act lists four persons who may give consent (or raise an objection). The primary consent or objection is that of the deceased, if formally recorded before he or she died. (note: having donor recorded on the persons driver's license is not sufficient).

If there is no consent given or objection raised by that individual, then consent can be sought from the below persons in the following order:

1. **that individual's nominee(s);**
2. **a member of the individuals family;**
3. **a close relative of that individual.**

In other circumstances, the entitlement to give consent may be limited to the deceased only, or perhaps two of the above persons. (usefully, there are a number of schedules to the act which contain flowchart diagrams of the hierarchies of consent).

It is an offence to collect and use human tissue without informed consent, with a possible penalty of 1 year imprisonment or a \$50,000 fine.

Even where informed consent is obtained, consideration should be given as to whether collection should proceed. Possible reasons why collection should not proceed may include if an individual's organs and tissue are unsuitable for donation, or where the immediate family is aware that the deceased person had changed their mind since recording their consent.

In short, when dealing with tissue and body parts of a patient, it is essential to consider the purpose for which the tissue or body part is being collected or used, whether and how informed consent needs to be obtained, and the needs, values and beliefs of the patient and their family.

Contact Us

NZMII are here to help!

[nzmii.co.nz](https://www.nzmii.co.nz)
0800 102 220
general@nzmii.co.nz



[@nzmedicalindemnityinsurance](https://www.instagram.com/nzmedicalindemnityinsurance)