



Australian Government
National Health and Medical Research Council



Ethical guidelines for cell, tissue and organ donation and transplantation in Australia

Executive Summary

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Overview

The *Ethical Guidelines for Cell, Tissue and Organ Donation and Transplantation in Australia* (the Guidelines) provide a framework to support ethical practice and inform decision-making by all those involved in Australia's donation and transplantation system. They are intended for use by:

- health professionals and others involved in the donation, transplantation, manufacture, allocation, distribution, and custodianship of human cells, tissues and organs
- potential donors and recipients of transplanted cells, tissues and organs, and their families, carers, and communities
- public and private institutions, such as hospitals, donation services, eye banks, umbilical cord blood banks, tissue banks, tissue manufacturers, and donor or transplant recipient registries
- governments and regulatory bodies.

The ethical principles in the Guidelines are aligned with community expectations that altruistic donations of human cells, tissues and organs are treated respectfully, shared equitably, and used effectively for the benefit of all. They are consistent with established ethical and legal norms governing healthcare practice in Australia, and with respect for human rights and the rights of all individuals as patients receiving healthcare.

The guidelines are designed for use in a range of ways according to the needs and preferences of individuals. Some may choose to read the entire text, whereas others may prefer to read specific chapters to deepen their understanding of specific aspects of ethical practice in donation and transplantation or specific issues.

These guidelines do not exhaust the ethical discussion of donation and transplantation. A multitude of situations may arise for which specific guidance in the Guidelines may be limited, or to which its application may be uncertain. Other guidelines, codes of practice, and legislation cited in these Guidelines should also be used to help clarify the obligations of health professionals and organisations in particular contexts.

Summary of content

Chapter 1 provides an overview of the guidelines and their intended use. **Chapter 2** describes the current system for cell, tissue and organ donation and transplantation in Australia and specific types of activities in donation and transplantation. **Chapter 3** outlines the core ethical principles and values that underpin policy and practice in donation and transplantation in Australia, which are outlined below, and provides a brief overview of relevant legislation. It also outlines an approach to ethical decision-making.

Chapter 4 explores ethical considerations in obtaining valid consent for donation and transplantation from adults and in decision-making about deceased donation, whereas **Chapter 5** addresses special ethical considerations of decision-making involving children or adults without decision-making capacity.

In **Chapter 6**, ethical considerations with regards to evaluation and management of risks and benefits in the context of donation and transplantation are examined. **Chapter 7** provides information about key considerations with regards to respect for privacy and confidentiality.

Ethical concerns relating to justice or equity in donation and transplantation are addressed in **Chapter 8**. In **Chapter 9**, the concept of self-sufficiency in organ and

tissue donation and transplantation, as well as ethical considerations with regards to import or export of cells, tissues and organs and international travel for transplantation are explored. **Chapter 10** considers ethical concerns relating to commodification or sale of human cells, tissues, and organs, including trafficking in organs and tissues for transplantation.

In **Chapters 11 and 12**, several ethical issues that may arise in the context of living and deceased donation are explored, including ethical considerations relating to some new and emerging practices in donation and transplantation.

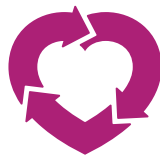
Ethical values and principles guiding cell, tissue and organ donation and transplantation in Australia

The following core principles aim to support decision-making by all those involved in donation and transplantation activities in Australia, particularly health professionals and policy makers. More than one principle may need to be considered in a specific situation.

- **Principle 1** Decision-making about donation and transplantation should seek out and take account of expressed preferences of donors, recipients, their families and communities, and facilitate self-determination.
- **Principle 2** Decision-making about donation and transplantation should promote cultural safety, demonstrating cultural humility, critical reflection, and awareness of power dynamics.
- **Principle 3** Decision-making about donation and transplantation should be free from bias or discrimination based on clinically irrelevant factors such as disability, cultural identity, or social or economic circumstances.
- **Principle 4** In donation and transplantation activities, potential conflicts of interest should be avoided and, where unavoidable, should be appropriately managed.
- **Principle 5** Donation and transplantation activities and associated decision-making should be transparent and open to scrutiny.
- **Principle 6** Donation and transplantation activities and associated decision-making should protect the privacy of individuals and their families and the confidentiality of information related to donation and transplantation activities.
- **Principle 7** Donation and transplantation activities should provide benefit and minimise burdens and risk of harm: where burdens or risks are unavoidable, they should be proportionate to the benefits that are anticipated.
- **Principle 8** Donation and transplantation activities should promote equity in the distribution of and access to donation and transplantation of organs and tissues.
- **Principle 9** Donation and transplantation activities should foster solidarity, efficiency, and sustainability, and support progress towards self-sufficiency with regional and international collaboration where necessary.
- **Principle 10** Human organs, tissues and cells should not be treated as ordinary commodities that can be sold or exchanged for profit: any profits arising from the removal, processing, distribution, storage, transfer or use of donated cells, tissues or organs should be used to enhance quality, safety, sustainability, and equity in healthcare for all.
- **Principle 11** Decision-making about donation and transplantation should be free from coercion, exploitation or financial incentives; this should not preclude coverage of costs associated with donation or transplantation.



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