Ethical guidelines for organ transplantation from deceased donors

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## Glossary

<table>
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<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td><strong>Assent</strong></td>
<td>Affirmative agreement to participate. Mere failure to object is not deemed assent.</td>
</tr>
<tr>
<td><strong>Consensus Statement</strong></td>
<td>Transplantation Society of Australia and New Zealand (TSANZ) Organ transplantation from deceased donors: Consensus statement on eligibility criteria and allocation protocols. The Consensus Statement will be referred to in this document with the caveat that it will be superseded by implementation of the Clinical Protocols.</td>
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<tr>
<td><strong>Deceased donor</strong></td>
<td>A person who donates organs and/or tissues after death for the purpose of transplantation into another person. A human being declared, by established medical criteria, to be dead and from whom cells, tissues or organs were recovered for the purpose of transplantation. The two pathways to deceased donation are Donation after Brain Death and Donation after Circulatory Death.</td>
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<tr>
<td><strong>Donation after brain death</strong></td>
<td>Organ donation after death has been determined on the basis of permanent cessation of brain function.</td>
</tr>
<tr>
<td><strong>Donation after circulatory death</strong></td>
<td>Organ donation after death has been determined on the basis of the permanent cessation of circulation of blood in the body of the person.</td>
</tr>
<tr>
<td><strong>Electronic Donor Record</strong></td>
<td>The Electronic Donor Record is a clinical information system designed to capture donor referral data, medico-social history and family consent information for potential and actual donors; enable in real time the offer, allocation and distribution of organs and tissue across Australia for potential and actual organ and tissue recipients; and facilitate transplantation to improve and maintain the health of organ and tissue transplant recipients. The Electronic Donor Record has been in use in all Australian states and territories except Queensland since 31 March 2014, and in Queensland since 1 July 2014.</td>
</tr>
<tr>
<td><strong>Eligibility criteria</strong></td>
<td>Criteria by which the multidisciplinary team assess individuals to determine whether they are suitable for transplantation.</td>
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<tr>
<td><strong>Higher risk criteria organs</strong></td>
<td>Donor organs that have been assessed as presenting a higher risk to the health of recipients than standard criteria organs, based on donor and organ characteristics.</td>
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<tr>
<td><strong>Ischaemic time</strong></td>
<td>The time between loss of blood supply to the donor organ and its transplantation into a recipient.</td>
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<tr>
<td><strong>Organ</strong></td>
<td>Differentiated and vital part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with an important level of autonomy (e.g. kidney, heart, lung, liver, pancreas, vascularised composite tissue allografts).</td>
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<tr>
<td><strong>Recipient</strong></td>
<td>A person who receives organs and/or tissues from another person (the donor).</td>
</tr>
<tr>
<td><strong>Standard risk criteria organs</strong></td>
<td>Donor organs that have been assessed as providing the best overall outcomes for recipients based on donor and organ characteristics.</td>
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<tr>
<td><strong>Tissue</strong></td>
<td>All constituent parts of the human body formed by cells (e.g. cornea, heart valves, bone, skin.</td>
</tr>
<tr>
<td><strong>Vascularised composite tissue allograft</strong></td>
<td>Part of the body that comprises multiple tissues such as muscle, bone, nerve and skin, as a functional unit (e.g. a hand or face).</td>
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Introduction

Organ transplantation is a highly effective treatment for advanced organ failure. Australia’s organ transplantation success rates are some of the highest in the world, with a 5-year survival rate of 80% for most organs.¹ In 2013, 1,122 Australians received an organ transplant. This is the highest number of transplant recipients since national records began.² Deceased organ donation is only possible if a person dies in a hospital under certain circumstances, usually in hospital intensive care units or emergency departments.

The need for organs from deceased donors outweighs their availability. At any time, there are around 1,500 Australians awaiting a transplant,³ a number of whom die before receiving a transplant as their disease progresses beyond the point at which transplantation is possible. Given the relative shortage of donor organs, it is inevitable that, whatever criteria are used to make decisions about organ transplantation, there will be many people who would benefit from an organ transplant but will not be able to receive one. It is essential, therefore, that organ allocation and transplantation decisions and policies are ethically robust and transparent, and that ethical principles and values guide decision-making when determining eligibility for transplantation and the suitability and allocation of donor organs. Decision-making regarding the allocation and transplantation of donated organs seeks to balance the needs of individuals who would benefit from a transplant with the need to exercise responsible stewardship of this scarce and valuable resource.

For the last 20 years the Transplantation Society of Australia and New Zealand [TSANZ] has maintained eligibility criteria for organ transplantation and protocols for the allocation of organs. In 2011, funding provided by the Organ and Tissue Authority (OTA), enhanced the capacity of TSANZ to develop Version 1.1 of Organ transplantation from deceased donors: Consensus statement on eligibility criteria and allocation protocols (the Consensus Statement)⁴ which provides:

• nationally uniform eligibility criteria to ensure that the process of listing potential recipients for organ transplantation is equitable and transparent; and
• nationally uniform allocation protocols to ensure consistency in organ allocation across Australia.

Following a joint request from TSANZ and the OTA, the National Health and Medical Research Council (NHMRC) established an expert advisory group to develop Ethical guidelines for organ transplantation from deceased donors (the Ethical Guidelines) (see Appendix A). The Ethical Guidelines will inform the next version of the organ-specific clinical protocols (Clinical Protocols) for organ transplantation from deceased donors to be developed by TSANZ. The Consensus Statement will be superseded by the Ethical Guidelines and the Clinical Protocols. In this document, the Consensus Statement will be referred to with the caveat that it will be superseded by implementation of the Clinical Protocols.

Role of the Ethical Guidelines

The Ethical Guidelines provide an overarching framework to inform decision-making for the allocation and transplantation of organs from deceased donors. The ethical principles in this document are in line with community expectations that human rights and the right to access to health care are respected and protected. These Ethical Guidelines are consistent with the principles outlined in international documents such as:

• World Health Organization (WHO) Guiding principles on human cell, tissue and organ transplantation,⁵ endorsed by the Commonwealth of Australia; and
• The declaration of Istanbul on organ trafficking and transplant tourism,⁶ endorsed by NHMRC and TSANZ.

Other documents also provide guidance on transplantation practice, such as:

• clinical guidelines, in particular the Consensus Statement, which supports specific decision-making based on clinical criteria and predicted patient outcomes; and
• implementation guidelines, which describe detailed procedures and protocols at the local level (e.g. concerning tissue typing to allow matching of donor organs with potential recipients).
**Scope of the Ethical Guidelines**

These Ethical Guidelines inform ethical practice in:

- assessing the eligibility of an individual for transplantation;
- assessing the suitability of donor organs for transplantation; and
- allocating solid organs and vascularised tissue composite allografts (such as the hand or face) from deceased donors.

The Ethical Guidelines do not apply to:

- the process of organ donation;
- transplantation of organs from living donors;
- transplantation of human tissue other than solid organs and vascularised tissue composite allografts;
- transplantation of gametes, ovarian or testicular tissue, or embryos for reproductive purposes; or
- medical practice more generally.

All activities referred to in these Ethical Guidelines must be carried out in compliance with existing law, legislation and regulatory frameworks (see Appendix B). The activities must also comply with relevant professional and accreditation standards and the maintenance of appropriate quality management systems.

**Structure of the Ethical Guidelines**

The Ethical Guidelines provide information on a number of levels.

- **Chapter 1** provides background information on the current system in Australia for determining an individual’s eligibility for transplantation, assessing suitability of organs for transplantation, allocating organs, and monitoring organ donation and transplantation activity.

- **Chapter 2** highlights ethical principles and values and their application in organ transplantation from deceased donors.

- **Chapter 3** provides practical guidance on discussing transplantation (Section 3.1) and ethical decision-making specific to:
  - determining eligibility for transplantation, assessing organ suitability and allocating organs (Section 3.2); and
  - innovative transplantation practices (Section 3.3).

Case studies are included throughout the document to highlight the complex ethical issues and decision-making that occurs when considering organ allocation and transplantation. The case studies also demonstrate the way in which the ethical principles and guidance can assist decision-making. In some instances, the case studies lead to a resolution of these issues.

The appendices provide information on the development of the Ethical Guidelines, and list further relevant resources and information. The glossary lists how specific terms are used in these Ethical Guidelines.
1 Current system for organ transplantation in Australia

The clinical criteria developed by TSANZ are used to determine the individuals who are eligible for transplantation, whether donated organs are suitable for transplantation and how these organs are allocated.³

1.1 Who is eligible for transplantation?

The scarcity of donor organs means that clear and transparent clinical criteria for determining eligibility for transplantation are required to ensure a just and equitable system for the delivery of this treatment to the Australian community.

The Consensus Statement outlines specific inclusion and exclusion criteria for eligibility for transplantation of each organ, as well as general conditions that apply across the organ types.³ The Consensus Statement is reviewed regularly by TSANZ, along with data on outcomes, and the criteria updated to ensure currency with evolving clinical practice and research.

The process of determining eligibility for transplantation involves:

• referral by a specialist physician of an individual, generally with end-stage organ disease, to a transplant unit; and

• assessment against eligibility criteria by a multidisciplinary team at the transplant unit — this takes into consideration medical history and other relevant factors, such as an ability to adhere to medical therapy, which affect transplantation outcomes.

Waiting times for transplantation are usually 6 months to 4 years⁴, but can be longer, and depend on the availability of an organ suitable to the individual and the urgency of the potential recipient’s need for transplantation.

While they are waiting for a transplant, potential recipients receive support from a multidisciplinary team who keep them, and their family, informed of developments and timelines.

The transplant team regularly reviews potential recipients to ensure that they remain suitable for transplantation. Individuals may be assessed as no longer eligible for a transplant if their condition changes, either because their organ function improves to a point that organ transplantation no longer offers a benefit or because their condition deteriorates to the point where they no longer meet the eligibility criteria.

1.2 Are all organs suitable for transplantation?

At the time of donation, organs are assessed for their suitability for transplantation. Organs can be assessed as:

• suitable for transplantation based on standard risk criteria; and

• suitable for transplantation based on higher risk criteria.

**Standard risk criteria organs**

Standard risk criteria for the assessment of organs are based on donor and organ characteristics that have been shown to provide the best overall outcomes for the recipient, and data collected to inform improvements in transplantation practice. These criteria are set out in the Consensus Statement and include:

• the donor’s medical history, including history of chronic disease and the manner in which he or she died (e.g. as a result of brain death or circulatory death);

• the risk of transmission of malignancy, viruses such as HIV, hepatitis B, hepatitis C, and other infectious agents; and

• factors that relate to the viability of the donor organ, such as ischaemic time and how the organ is preserved before transplantation.
**Higher risk criteria organs**

Some organs become available that, if transplanted, may provide a benefit to the recipient, but may present a higher risk to their health compared to organs assessed as suitable for transplantation based on standard risk criteria. These organs are referred to as ‘higher risk criteria organs’.

Donor organs are assessed as higher risk criteria organs based on the characteristics of the donor (e.g. medical conditions, infectious diseases) or the donor organ (e.g. longer ischaemic time) that can be associated with poorer outcomes after transplantation in some recipients. These higher risk criteria organs are considered for transplantation with the primary aim of increasing the number of people able to benefit from a transplant and making optimal use of a scarce resource. The transplantation of these organs is being undertaken with increasing success rates internationally and in Australia. Decision-making regarding the allocation and transplantation of these organs is difficult due to the complexity of the risk assessment involved which will differ for each individual.

In some circumstances, these organs are used to allow people who do not meet standard eligibility criteria for transplantation to receive a transplant. Sometimes these individuals are referred to as being on an ‘alternate listing’. However, this term is misleading and these guidelines refer to the identification of potential recipients for higher risk criteria organs.

### 1.3 How are organs allocated?

The allocation of organs is a complex and time-critical process, influenced by a range of factors including medical need, urgency, donor/recipient matching and logistical factors. Australia has strict clinical protocols about the allocation of organs for transplantation. These are outlined in the Consensus Statement.3

The organ allocation process differs according to the organ type (the kidney allocation process differs from the allocation process for other organs), and the state or territory where the donor and/or the recipient is located. As the ischaemic time is critical to post-transplantation outcomes, most donated organs are allocated within their home state or territory.

When a kidney becomes available for transplantation, it is allocated by the National Organ Matching Service (NOMS), which is administered by the Australian Red Cross Blood Service. When organs other than kidneys become available, the necessary information is transmitted directly to transplant units in that state or territory through the Electronic Donor Record. The allocation of these organs involves a team at the transplant unit making a clinical judgement as to which person awaiting a transplant is best matched to receive that particular organ, at that particular time.

If no suitable recipient is identified by that transplant unit, the organ is then offered to transplant units in other states and territories and New Zealand in accordance with a strict rotation system that is designed to promote equity.

**Urgent situations**

Individuals who have a very high risk of death if they are not transplanted in the immediate future may be prioritised for the offer of an organ. This applies to each organ type except pancreas and lung. Examples are individuals with acute liver failure intubated in the intensive care unit, individuals with kidney failure for whom dialysis is no longer an option, or individuals with severe heart failure who are unsuitable for mechanical support or develop life-threatening complications while on support.3 If a person’s clinical need is assessed as urgent, this means that they will be offered the next available compatible donor organ arising anywhere in Australia and New Zealand.

Decisions relating to an individual’s eligibility for urgent status must be subject to clinical peer review and oversight.
**Higher risk criteria organs**

When a higher risk criteria organ becomes available, different considerations apply with regard to identification of suitable recipients. The risks and benefits of waiting for a standard risk criteria organ are assessed against those associated with acceptance of a higher risk criteria organ. A decision is based on an individual’s assessment of the risks and benefits as they relate to their individual circumstances.

### 1.4 How is the process monitored?

Data related to organ donation and transplantation activity is essential in identifying opportunities to improve the care of donors and monitor the quality of transplanted organs and transplant recipient outcomes. The Australia and New Zealand Organ Donation (ANZOD) Registry, in conjunction with the Australia and New Zealand Dialysis and Transplant Registry (ANZDATA), the Australia and New Zealand Liver Transplant Registry (ANZLTR), the Australian and New Zealand Cardiothoracic Organ Transplant Registry (ANZCOTR) and the National Pancreas Transplant Registry (NPTR), records and reports on organ donation and transplantation within Australia and New Zealand (see Appendix B). Through this process, information is publicly available on:

- the number of organs donated by deceased donors, including comparison with international donation rates;
- organ donation pathways (e.g. whether donation occurred after brain death or circulatory death, whether donation proceeded and, if not, reasons why);
- the number of people awaiting transplantation for each organ type;
- the number of organs transplanted, including reasons why donated organs were not transplanted; and
- outcomes of organ transplantation.
2 Foundations

2.1 Human rights, ethical principles and values

Respect for human rights is relevant to the development and implementation of health policies, laws and practices, including those that relate to the allocation of health resources.

The right to a standard of living adequate for the health and well-being of a person and their family has been broadly protected in international law since the inception of the United Nations (UN). It is recognised in The universal declaration of human rights and has been articulated in numerous international instruments protecting the right to health of vulnerable populations. This general protection was further interpreted by the UN Committee on Economic, Social and Cultural Rights in declaring that people have a right to access quality health care and that states have basic duties, within the availability of resources, to provide their citizens’ with access to adequate and affordable health care.

As is the case with human rights, fundamental ethical principles and values may be used as the basis for the development and assessment of health care systems, policies and practices. These principles and values include respect, autonomy, justice, equity, solidarity, altruism, reciprocity, transparency, effectiveness and efficiency. While all of these principles and values are important, they will not always be equally important in any given situation. Judgments will always be needed as to what weight should be attached to each value and how the obligations arising from each value should be satisfied.

These principles and values may be defined as follows.

- **Respect** — The right for all individuals to be treated with dignity, including respecting their autonomy (i.e. the right to self-determination based on an individual’s particular set of values, preferences, and beliefs).

- **Justice** — Justice is concerned with equality and fairness and is one of the core principles upon which society and its institutions (including health care systems) are based. Forms of justice relevant to the provision of health care include:
  - **Distributive justice**: ‘fair, equitable, and appropriate distribution in society determined by justified norms that structure the terms of social cooperation’;
  - **Social justice**: the exercise of justice within a society, including recognition of causes of social inequality and the moral necessity to address them; and
  - **Procedural justice**: fairness in the processes that allocate resources and resolve disputes, which provides a means for making health resource decisions even where there is disagreement about which principles should govern priority setting and what constitutes justice in health care.

- **Equity** — The fair distribution of benefits and burdens. For allocation of (scarce) resources to be fair, the process must be public and transparent; decisions must rest on reasons, principles and evidence that all stakeholders agree are relevant; there must be clear processes for revision and appeal; and there must be mechanisms in place to ensure each of these three conditions.

- **Solidarity** — The concept of ‘standing together’ as a group, community or nation, which reflects a collective commitment to share ‘costs’ (financial, social, emotion or otherwise) to assist others.

- **Altruism** — Acts that are not based on any form of understanding that something will be returned.

- **Reciprocity** — A relationship between parties characterised by corresponding mutual action in return for contributions given. In the context of healthcare, this generally refers to broad reciprocal socio-political obligations rather than to specific obligations owed to individuals (such as monetary payment or access to a particular organ at a particular time) directly in ‘return’ for their decisions or actions.

- **Transparency** — The open disclosure of clear and accurate information about activities and decision-making processes.
• Effectiveness and efficiency — The notion of effectiveness requires that waste is reduced, practices that clearly don’t work are avoided, and proven measures that are likely to succeed are implemented. Effectiveness, or utility, is linked to the concept of efficiency, which requires that limited resources be used in the most productive manner possible.

2.2 Application of ethical principles and values to organ transplantation

The nature of organ allocation and transplantation raises a number of particular ethical issues and dilemmas, primarily because donated organs are a scarce resource that has the potential to dramatically improve the health and life of recipients. This scarcity of organs requires clear eligibility and allocation criteria to ensure a fair and equitable system for access to this limited resource.

There are many ways to justify allocating an organ to one individual over someone else, rather than just one ‘right’ way, and differing perspectives exist on what is fair and equitable. The donor and her/his family, the recipient and the community in general may all have differing views about what is equitable. The decision-making process in organ transplantation should therefore ensure the balanced consideration of all relevant ethical principles, should be transparent and should be developed in collaboration with all major stakeholders. In this regard, it is important to note that ethical questions cannot be completely separated from social, economic, cultural and political questions and that there may be practical constraints on the achievement of an ethical principle, particularly in an area of scarce resources.

The principles and values outlined below aim to support decision-making so that, regardless of the situation, health professionals have an ethical framework to guide clinical consideration and judgment. This in turn should help to ensure that their decision-making is rigorous, consistent, transparent and supported by the community. More than one principle may need to be considered in a specific situation.

2.2.1 Donation of organs is an act of altruism and solidarity that provides significant benefits to those in medical need.

Transplantation practices should be motivated by the needs of the recipient and the need to ensure the appropriate use of scarce health resources.

The availability of transplantation as a treatment to members of the Australian community is wholly dependent on the preparedness of individuals and their family to consent to altruistic donation.

Reciprocity in organ transplantation means that as the Australian community benefits from the altruistic donation of organs, then there is a reciprocal obligation to ensure equitable access to donated organs, and that processes for the allocation of donated organs are efficient, fair and transparent.

Organs used for transplantation must be obtained without exploitation or coercion of, or payment to family of a deceased donor. While reasonable compensation of expenses is ethically acceptable, providing payment that acts as an incentive is unacceptable. It is unethical for people, or the family of deceased persons, to purchase, offer to purchase or sell organs for transplantation.4

2.2.2 Processes and policies for determining a person’s eligibility for transplantation, and for allocating donated organs must be just, equitable and respectful of the inherent dignity and of the equal and inalienable rights of all persons.

Within the threshold of effective outcomes, there should be equity in opportunity for organ transplantation.

Decision-making about allocation must include explicit evaluation of the risk and benefits to the potential recipient as well as the need to ensure the appropriate use of scarce health resources. There must be no arbitrary discrimination against potential recipients on the basis of:

• race, religious belief, gender, marital status, sexuality, social or other status, disability or age;
• need for a transplant arising from the medical consequences of past lifestyle;
• capacity to pay;
• location of residence (e.g. remote, rural, regional or metropolitan); or
• refusal to participate in research.

The choices of potential recipients should be respected. These include those based on the following.
• Views about the acceptability of organ donation and transplantation — The refusal to accept an organ for transplantation must not lead to any form of discrimination.
• Beliefs about the acceptability of specific medical procedures or treatments required for transplantation — The right of a potential recipient to accept or reject some procedures or treatments required for transplantation should be respected. However, where such choices are likely to have an adverse effect on the success of the transplantation, then it is appropriate that this is taken into account in the decision-making regarding the offer of an organ for transplantation.

Respect should be given to the expertise and opinion of health professionals as they make decisions relating to organ transplantation, involving complex issues, often in urgent situations.

2.2.3 Decision-making about transplantation must recognise and respect the autonomy of the recipient.

As for all medical procedures, valid consent must be given before transplantation can proceed. If the individual does not have capacity to give consent, a representative should be involved in ongoing discussions and decision-making. For consent to be valid:
• the decision to consent to the procedure must be made without undue pressure from health professionals, family and friends;
• sufficient information about the procedure must be made available, including the benefits and risks and what will happen if the procedure does not go ahead — health professionals should not withhold information just because it may be upsetting;
• the consent must be specific, and is valid only in relation to the procedure for which information has been given; and
• the person giving consent must be considered by the treating clinician to have the capacity to provide valid consent.

2.2.4 The allocation and transplantation of organs must be undertaken in a manner that protects recipients from harm.

Organ transplantation should only be undertaken when it is believed that it provides a benefit to the recipient.

Decisions regarding the use of organs that are associated with an increased risk to the recipient should take into account the condition of the organ as well as the general health and medical need of the recipient, and the likelihood of a successful transplantation outcome.

While awaiting transplantation, an individual’s psychological and physical wellbeing should be supported as far as possible. With the individual’s consent, this may include medical interventions or treatments and the use of medical devices (e.g. dialysis, ventricular assist devices).

2.2.5 The process of allocating and transplanting organs should acknowledge both the needs and wellbeing of the recipient and the necessity to achieve the best outcome for the community as a whole.

Predictions about the likelihood of benefit arising from a transplant are often difficult and uncertain, with some factors being subjective in nature. Such predictions and the uncertainty around them should be conveyed to the potential recipient as part of the process of seeking consent.

Decisions should take into account the views of the individual about expected outcomes, and should not deviate from established clinical criteria. Factors that should be considered include:
• the needs of the individual and the potential benefit to the individual as well as the need to ensure the appropriate use of scarce health resources;
• pre-transplant quality of life, expected extended length and quality of life and duration of benefit; and
• medically relevant criteria related to the recipient and the organ to be transplanted.

2.2.6 The organisation and implementation of transplantation activities, as well as their clinical results, must be transparent and open to scrutiny, while ensuring that the personal anonymity and privacy of donors and recipients are always protected.

Criteria used for decision-making must be transparent and made publicly available. Detailed records must be maintained so that the long-term outcomes of organ donation and transplantation can be assessed in order to document benefit and harm. The objectives of the system are to maximise the availability of data for research, monitoring and professional oversight and to identify risks — and facilitate their correction — in order to minimise harm to donors or recipients. Processes must be in place for audit and peer review of clinical decisions.

Conflicts of interest
Health professionals involved in the care of a potential recipient should not participate in decision-making about the care of individuals who may become donors or in the determination of their death. Current practice is that decisions about the eligibility of an individual to receive an organ are made by the transplant team, rather than the individual’s physician.

Privacy
Health professionals and institutions must respect the privacy of donors and recipients, and their families, and confidentiality of all records and must have a privacy policy that ensures compliance with relevant legislation and guidelines.
Health professionals have a responsibility to counsel and advise recipients and their families about the potential consequences of releasing information about the procedure (e.g. via social media).
Recipients have a responsibility to respect the privacy of the donor and his or her family and to not release information that will potentially identify the donor.


3 Ethical practice

The ethical principles and values outlined in Section 2 must inform:

• discussions about transplantation;
• determining eligibility for organ transplantation; and
• assessing donor organ suitability and allocating organs.

This section highlights particular issues to be considered in these situations. Constraints on the implementation of an ethical principle are also discussed, recognising that these may change over time.

3.1 Discussing transplantation

Discussions about transplantation should commence well before an organ becomes available and be ongoing throughout treatment. Potential recipients need to be made aware that their consent to transplantation will take place through an ongoing series of discussions, which may ultimately lead to the individual deciding to accept a transplant of an organ.

The nature of organ transplantation is unpredictable and often involves the need to make complex and urgent decisions by both the potential recipient and the health professionals involved. Critical decision points include those that occur when eligibility is being discussed and at the time when an organ becomes available.

Information about the suitability of donor organs that may become available needs to be provided to the potential recipient early in the process so that they are well-prepared to make a decision about whether to accept the offer of a particular organ in the limited time available when an organ offer is made.

When an organ is offered, more specific information about the particular organ and the risks and benefits of transplantation may need to be provided, such as the characteristics of the donor organ and the potential recipient’s clinical circumstances.

As part of ongoing discussions about transplantation between potential recipients and members of the multidisciplinary team, the following information should be made available.

• When deciding whether to accept the offer of an organ, there is a need to balance the risks and benefits to the recipient. Recipients may need to consider multiple risk factors and the benefits of continuing with medical therapy rather than proceeding to transplantation.

• The information that will be provided to the potential recipient about the risks and benefits associated with transplantation of a particular organ is based on population statistics. Inevitably, therefore, there will be uncertainty about how the epidemiological data applies to the individual. All procedures also carry some element of risk and it may be difficult to quantify risks and benefits at the individual level.

• There may be potential for the recipient to be offered and accept an organ that carries a higher risk to his or her health than an organ that meets the standard risk criteria.

• The timing of deceased organ donation is unpredictable and there will be little time for reflection as rapid decision-making is needed when an organ becomes available. It is therefore important to consider a range of scenarios well in advance of an offer being made.

Decision-making by potential recipients

The process of decision-making should be conducted in consultation with the potential recipient or their representative and the potential recipient’s partner, family and/or carer. Relevant information should be provided in a manner that is likely to be understood by the potential recipient and others involved, and appropriate to their needs and particular situation. Individuals have the right to determine the amount of information they require to make decisions.
Consideration must be given to a potential recipient’s ability to understand the information and to provide valid consent.

While it must be assumed that all adults have capacity to make decisions about their own health care and can provide valid consent, it is always important to make certain that potential transplant recipients have the capacity to make their own health care decisions, that their decision-making is supported and that the decisions they make are free and voluntary. Sometimes, it may be difficult to determine an individual’s capacity to provide valid consent. In these situations, health professionals with the skills to assess this capacity must be included in the multidisciplinary team involved in the care of the individual.

**Adults with impaired decision-making capacity**

If an adult is considered to lack capacity to give valid consent, a representative, such as a ‘person responsible’ or a guardian, should be involved in the decision-making process. The person’s representative should be involved in substituted, facilitated or supported decision-making depending on whether incapacity is permanent, temporary, partial or intermittent (e.g. due to the effects of the progression of the disease).

It should not be assumed that adults who are intellectually impaired or have mental illness are incapable of giving consent. Individuals who have the ability to understand and retain information and to weigh that information to arrive at a decision may have capacity to give consent. However, if it is established that an individual does not have this capacity, a representative should be involved in early discussions about eligibility and decision-making about proceeding with the transplant.

All Australian states and territories have enacted guardianship legislation that deals with consent to the treatment of adults who lack capacity to consent on their own behalf (see Appendix B). This legislation promotes the autonomy of the represented person and/or safeguards the person’s best interests.

**Children**

It is critically important that a child who is being considered for organ transplantation is helped to understand the transplantation process as thoroughly as possible, consistent with age and maturity. As children mature, they will have a greater capacity for understanding and a clearer appreciation of the significance of their own decisions. Therefore, although legally still minors, older children should be encouraged to take an active part in decision-making (see Adolescents below).

The parent/s or guardian must provide valid consent for transplantation for children. Specific legislation regarding the capacity of children to consent to medical procedures exists in some jurisdictions (see Appendix B).

**Adolescents**

It is recognised that the capacity of adolescents to make decisions about treatments does not follow chronological age and that the capacity among adolescents aged 16 years and younger varies with individuals. If a person in this age group “achieves a sufficient understanding and intelligence to enable full understanding of what is proposed”, then they may be considered capable of giving informed consent, (described as “Gillick competence” which has been approved by the Australian High Court). But even where young people are judged to lack sufficient maturity to make decisions regarding transplantation, they should still be actively involved in decision-making, be supported to understand the situation they are in and what is being proposed, and, where possible, assent to transplantation.

In the adolescent age group, the capacity to provide consent should be determined on an individual basis. Responsibility for determining this capacity rests with the multidisciplinary team involved in the care of the individual.

**Individuals who do not speak English**

If the potential recipient does not speak English, accredited interpreters should be available to the individual and members of the multidisciplinary team throughout the transplantation process, both to enable consent and to optimise care.
3.2 Ethical decision-making in the context of transplantation

3.2.1 Eligibility for transplantation

The values and principles outlined in Section 2 should be used by the multidisciplinary team to guide the assessment of an individual’s eligibility for transplantation.

Decisions regarding eligibility for organ transplantation must exclude arbitrary discrimination on medically irrelevant grounds and ensure that medically relevant factors are carefully assessed. As outlined in Section 2.2.2, there must be no discrimination against potential recipients on the basis of:

• race, religious belief, gender, marital status, sexuality, social or other status, disability or age;
• need for a transplant arising from the medical consequences of past lifestyle;
• capacity to pay;
• location of residence (e.g. remote, rural, regional or metropolitan); or
• refusal to participate in research.

However, it is ethically acceptable for the following factors to be taken into account when considering eligibility for transplantation:

• relative severity of illness and disability and urgency of the need for transplant (e.g. imminent death);
• general health including factors that will directly affect the likelihood of a poor outcome, such as degree of frailty and relevant medical conditions; and
• reasonable likelihood that the recipient will be able to adhere to the necessary ongoing treatment and health advice after transplantation.

Individuals assessed for eligibility for transplantation have the right to know whether or not they are considered suitable, and, if they are evaluated as being ineligible for transplantation, the basis for this determination.

Case study 1
A young woman with bipolar disorder has been referred for assessment for a kidney transplant. Mental health conditions are among the medical conditions assessed by the multidisciplinary team in determining eligibility.

• Considerations include whether the woman’s bipolar disorder is being adequately managed, whether she has the capacity to give informed consent, her ability to adhere to ongoing treatment and health advice after transplantation, and the social support available to her.
• In this case, the decision by the multidisciplinary team should be informed by advice from a psychiatrist and/or a social worker.

Case study 2
A 32-year-old woman has a mental age of a young child and lives with her parents, who are her carers and guardians. The woman has end-stage kidney disease, which is being managed through home dialysis and medication given to her by her parents. The parents have requested that the woman be considered for transplantation.

• As the parents are the woman’s guardians, they would be involved in decision-making and provision of consent.
• A primary consideration is whether the woman will have the ability to adhere to ongoing treatment following transplantation either by herself or with the assistance of her parents.
• In this case, the parents have experience and demonstrated ability in administering medications and adhering to treatment regimens. The woman is considered eligible for a transplant.
Case study 3
A 42-year-old man is currently being assessed for a heart transplant. He has a history of amphetamine use and repeatedly claims to have stopped using amphetamines over 12 months ago. However, laboratory tests confirm recent amphetamine use. Apart from his heart condition he has no other medical conditions. His heart condition is now rapidly deteriorating and an urgent decision needs to be made.

• Active substance abuse excludes people from being considered as eligible for heart transplantation. 3
• While he is in urgent need of a transplant, his current amphetamine use, confirmed by blood testing, means that he is more likely to have a poorer outcome following transplant, the likelihood of organ transplantation success is reduced and he is less likely to be able to adhere to the necessary ongoing treatment and health advice after transplantation.
• Given his confirmed amphetamine use, this man is not currently eligible for a transplant despite the urgency of his need.

Individuals who do not meet usual eligibility criteria for transplantation
It is ethically justifiable in some cases to expand the opportunity for recipients to receive an organ by assessing them as eligible for transplantation of a higher risk criteria organ where this still provides them with a benefit to their health and where they understand the risks and benefits involved. The requirements for decision-making in these cases are similar to the general requirements for organ transplantation, however, decisions need to be based on an understanding of the higher risks involved. The individual needs to balance the risks and benefits as they relate to their individual circumstances. For some individuals, delaying transplantation may present a greater risk than accepting a higher risk criteria organ, while for others the risks associated with accepting such an organ may be too great.

Retransplantation
Ethical decision-making for eligibility for organ retransplantation should be based on the same criteria as for the initial transplant. However, the post-transplant history and previous compliance with treatment are relevant considerations. The outcome of this decision-making may mean that a person may be offered a second transplant ahead of another individual who has yet to receive a transplant.

Combined organ transplantation
There are times when patients require combined organ transplants, e.g. heart-lung, heart-kidney or heart-liver. While in such cases ethical decision-making for eligibility is the same as for single organ transplantation, the evaluation of these patients is more complex because it requires detailed assessment and agreement by both organ transplant teams that the patient meets all eligibility criteria. While the transplantation of two organs into one patient may raise issues of equity – as two people could benefit from transplantation instead of one – the medical need of the potential recipient must be respected in the same way as those requiring single organ transplants.

Process of review
There must always be a process for an impartial review of decisions relating to eligibility for transplantation where a second opinion is sought. The process should be independent and conducted in a timely and transparent manner. Medical records and the results of tests and other investigations relevant to the patient’s situation should be made available to facilitate a second opinion. The review should assess the processes followed in reaching the decision as well as the clinical basis for the decision.
Given the specialised nature of organ transplantation, the review will often be conducted by another transplant unit in another state or territory. Consequently, in some cases, a positive review outcome may mean relocation of the person and associated assistance with accommodation and transport costs (see Appendix B).
Case study 4
A woman is deemed ineligible for kidney transplantation by the multidisciplinary transplant team. She wishes to contest the decision and requests a review.

- The woman has the right for her case to be reviewed either by different people or a different transplant unit.
- A second-tier review committee at state level may be involved to review the decision.
- An independent advocate may also be involved to ensure that the best interests of the woman are protected.

3.2.2 Organ allocation

The values and principles outlined in Section 2 should be used by the multidisciplinary team to guide decisions about organ allocation.

The allocation of organs must be done in a way that makes the best use of a scarce resource. The process of allocation should be equitable, externally justified, transparent and explained to recipients and their families. Allocation of organs should proceed on the basis of best matching of organs and urgency of the need of potential recipients.

Consideration should also be given to maximising the benefits of each available organ. For example, high quality livers may be suitable for splitting and able to provide the benefit of transplantation to two recipients (usually an adult and a child).

Decisions regarding allocation of organs for transplantation should exclude arbitrary discrimination based on factors that are medically irrelevant (see Section 2.2.2). Medically relevant factors must be carefully assessed and arbitrary denial of the offer of an organ by transplant clinicians must not occur.

Allocation of organs is a complex process that depends on a range of factors besides general health, medical need and capacity to benefit. There are unpredictable elements in the process that relate to the timing of an organ becoming available and the matching of organs to recipients. Potential recipients may wait varying periods of time. This waiting time may be unrelated to their medical need, but dependent upon a matched organ becoming available. This information should be conveyed to potential recipients and their families as outlined in Section 3.1.

It is legitimate that the following criteria be taken into account when considering potential recipients for a particular organ:

- urgency of a transplant given the likely deterioration of health without transplantation, especially if the survival of the potential recipient is immediately threatened;
- length of time awaiting a transplant, taken from the time that illness progressed to a point that a transplant would be of immediate benefit;
- general health including medical factors that will affect the likelihood of success, such as the closeness of tissue-matching and matching of organ quality with the potential recipient’s medical status;
- the prospects of transplantation producing a better outcome than medical therapy alone; and
- the likelihood that the potential recipient will be able to adhere to the necessary ongoing treatment and health advice after transplantation.\textsuperscript{1,2,13}

For transplantation involving vascularised composite tissue allografts, such as face and hand transplantation, aesthetics may be a valid consideration. For example:

- it may be appropriate to match skin colour of donor and recipient; and
- light-skinned donor tissues are often preferred to enable detection of early skin rejection in transplants.

By its nature, the allocation process is very difficult to follow with absolute equity. Multiple factors are involved and this can make clinical decisions about allocation very difficult. Every attempt should be made to provide the best judgement upholding the principles outlined above. A process of audit and peer review of clinical decisions must therefore be in place.
Case study 5
A man has been offered a liver transplantation. However, at the time of considering the offer, he states that he is not willing to consent to a blood transfusion.
• While individual beliefs and values should be respected, in the case of organ transplantation, the right to self-determination needs to be balanced against the right of the transplant team to decide not to proceed with on medical grounds.
• The man should be counselled by the transplant team about the necessary medications and treatments including the need for blood transfusion, that are required for the transplant to be successful and the reasons why this is the case.
• If the man will not consent to the full range of treatments required for transplantation, then the transplant team can make a decision on medical grounds not to proceed with the transplant.

Case study 6
A liver has become available for allocation and the best-matched recipient is a woman who requires a transplant because of alcoholic liver disease. The woman currently lives with her elderly parents.
• The fact that the woman requires a liver transplantation due to alcoholic liver disease is not a relevant factor in determining allocation of organs. Discrimination against potential recipients on the basis of the cause of the illness is unethical.
• Decision-making about the allocation of the liver should take into account the woman’s social situation and the likelihood of her continuing to abstain from alcohol following the transplant and adhering to post-transplant treatment. These factors are clinically relevant to the success of the transplant.
• It is very difficult to predict with absolute certainty the way individuals will cope with post-transplant therapy, abstinence and other lifestyle changes.
• Throughout the transplantation process, the multidisciplinary team should engage the woman and her parents in discussions about the importance of adhering to ongoing treatment and lifestyle advice following transplant.

Case study 7
A donor heart is suitable for two individuals awaiting transplantation. One potential recipient is a 20-year-old man whose first transplant is failing after 10 years. He is now in urgent need of a transplant. The other is a 35-year-old man awaiting a first transplant, whose clinical condition is stable.
• The fact that one individual has already had a transplant, must not influence the decision about which individual to transplant.
• This decision must be made on clinically relevant factors, which can include the reasons as to why the transplant is failing and the time interval since the first transplant.
• In this case the decision is made to retransplant the younger man.

Consent for transplantation
When the offer of an organ is made, the potential recipient or their representative should be provided with appropriate information about the risks and benefits of the organ, without breaching the confidentiality of the donor.
Discussion should take into consideration the individual’s current quality of life, likelihood of survival without immediate transplant and the risks and benefits associated with transplantation of the particular organ being offered, as far as these can be predicted.
Consent must be given by a potential recipient or their representative before transplantation can proceed (see Section 3.1).

**Case study 8**

A man with Down syndrome and associated congenital heart disease is in need of a lung transplant. There is concern about the man’s ability to provide consent for transplantation.

- It should not be assumed that this man is incapable of giving consent.
- However, as it is difficult to determine his capacity to give consent, the multidisciplinary team involved with his care must include people with the skills to assess this capacity.
- If it is established that the man does not have the capacity to give consent, a representative must be involved throughout all stages of the process, including early discussions about eligibility and subsequent decision-making about proceeding with the transplant.
- This representative would then provide valid consent for the transplantation.

**Case study 9**

A 15-year-old girl has been assessed as eligible for a kidney transplant. An offer of a kidney is made and her parents are keen for her to have the procedure and give their consent. However, the girl refuses to have the transplant surgery. The girl has expressed an understanding of the nature of the procedure, and the need for ongoing medical therapy following transplant.

- Discussions should ensure that the girl has full information about the consequences of not proceeding with the transplant, including the long-term risk and benefits of her current treatment.
- As the girl has demonstrated an understanding of the risk and benefits of the surgery as well as not proceeding with the transplant, she should be considered capable of giving consent and her autonomy regarding her decision should be respected.
- The multidisciplinary transplant team has an obligation to ensure that the decision about transplantation is revisited at a later point in time as the girl matures, as this may affect her initial decision not to proceed.
- It may be necessary to involve an independent advocate to assist in resolving any conflicts between the wishes of the girl and those of her parents.

**Use of higher risk criteria organs**

Decisions about the suitability of organs for transplantation should be based on established criteria, with the aim of achieving the best overall outcomes for the recipient and the appropriate use of scarce health resources.

If the organ being offered carries a higher risk to the health of the recipient than standard risk criteria organs, this should be made clear and the medical factors and risk of potential harm highlighted as part of discussions about consent.

In situations where a decision has been made to use organs that have a higher risk to the health of recipients, the potential recipient’s increased likelihood of survival and the need to ensure the appropriate use of scarce health resources should be balanced against the medical factors and risk of harm involved.
Case study 10
A higher risk donor kidney is available that is matched to two individuals awaiting transplant. The potential recipients are a 25-year-old woman and a 72-year-old man. The man has been on dialysis longer than the woman.

- Decisions regarding the allocation of the kidney should take into account the need to balance the expected survival of the kidney and that of the potential recipients, as well as the risks and benefits of them remaining on dialysis rather than accepting the higher risk kidney.
- On balance, given the health status of the woman, the risks associated with transplantation of a higher-risk kidney exceed those of waiting for a standard criteria organ. These include the risk of failure after transplant and the likelihood of requiring retransplantation sooner. The woman is currently coping on dialysis and may accept the risk of waiting for a standard risk criteria kidney to become available.
- As the man has been on dialysis longer than the woman, the risks to his health are higher if he receives the higher risk criteria kidney and the prognosis is not as good. However, he has a poorer prognosis on dialysis than the woman. While both potential recipients would benefit more from a standard risk criteria organ, the man’s likelihood of death while awaiting transplant is greater.
- Members of the multidisciplinary team should have prepared the man for this scenario at the time he was considered eligible for transplantation, as the decision to accept this higher risk criteria organ will need to be made as a matter of urgency once the offer is made.

Deceased directed donation
The donation of deceased donor organs in Australia is an unconditional altruistic act. Deceased donor organs are allocated to the most suitable people, as outlined above. It is not ethically appropriate for a donor, through previously expressed wishes, or the family of a deceased person to impose conditions on organ donation, or to specify potential recipients.

In very specific situations where there were already arrangements in place for directed living donation and the potential donor dies before this can take place, it may be ethical for the directed donation to occur after the donor’s death.

Case study 11
A man has been accepted as a living donor so that he can donate part of his liver to his daughter. However, before the living donation is able to occur, the man dies through unforeseen circumstances. The man is a registered organ donor and his family agrees that his organs should be donated after death. They have requested that part of his liver be donated to the daughter, as was the intention before his death.

- As the man had already been accepted as a living donor and as his untimely death was the only reason that this did not occur, the process of donating part of the man’s liver after death to the daughter can be honoured.
- The other donated organs must be allocated to the most suitable recipients in accordance with established procedures.
**Case study 12**

A young man in an Intensive care unit meets the criteria for donation after brain death. His family agree for his organs to be donated but only to people of the same religious faith as the family. If this is not possible, then they will not agree to the organ donation going ahead.

- It is not ethically acceptable for conditions to be placed on the donation of organs as it undermines the altruistic nature of organ donation.
- In this case, if the family will only agree to the conditional donation of organs, then the organ donation cannot proceed.

**Issues of access**

Every Australian who requires an organ transplant must be provided with an equal opportunity to receive one. In practice, however there are some issues that constrain the ability of transplantation units to provide absolute equality of access in the allocation process. These include:

- costs — in some situations an otherwise suitable organ is not able to be transplanted due to the costs of transporting the organ and/or relocating the recipient;

- people living in rural and remote areas — access for those who live in rural or remote areas is related either to their willingness and ability to relocate closer to the transplant unit and/or the provision of adequate logistic assistance with accommodation and transport; and

- people in correctional institutions — difficulties occur where correctional services are not able to transport recipients within the necessary timeframes or ensure provision of post-transplant care.

**International patients**

In view of the existing gap between donor organ need and availability, only in exceptional circumstances should people who are not Australian citizens or permanent residents be assessed for possible transplantation.

Under the Medicare arrangements, Reciprocal Health Care Agreements exist with some countries that allow for essential medical treatment to take place in Australia, without cost to the recipient.\(^1^4\)

Transplantation may be necessary if an international visitor develops acute organ failure, where the only therapy is transplantation, and they are too unwell to return to their home country. In this situation it would need to be established that the visitor would return to an environment that permits appropriate ongoing post-transplant surveillance and treatment.
3.3 Ethical decision-making in innovative transplantation practice and research

Ongoing awareness of developments in medical technologies is integral to understanding and utilising the best options available to the Australian community. There are scientific developments and research on the horizon that will challenge current accepted clinical and ethical practice in donation and transplantation. The Australian community needs to be prepared to deal with the ethical issues that may arise in relation to any evolving technology and techniques in organ transplantation and the transition from research and innovation to established practice.

The disparity between the availability of donor organs and the number of individuals in need of transplantation highlights the importance of continually refining and developing new transplantation methods, processes and techniques that may allow for the better utilisation of organs, or that better prepare individuals for transplantation. While many innovations may not have been fully assessed for safety and/or efficacy before they are used in clinical practice, it is important to note that innovative practice occurs on a spectrum. At one end of the spectrum small changes may be made around the edges of established practice over many years. Such changes may pose little risk to patient safety. At the other end of the spectrum are new and possibly revolutionary procedures that may ultimately transform the organ transplantation landscape. Such practices are part of clinical research, undertaken in line with an ethically approved protocol.

Whether an individual’s treatment is innovative clinical practice or is clinical research will often depend on the extent to which the procedure is departing from established practice. For instance, increasing donor age limits is an example of an innovative practice that would usually be a matter for the responsible health professional’s judgement, guided by clinical protocols. Even so, the implementation of a new innovative practice would require notification to the hospital where the practice is taking place and the collection of data for monitoring and reporting purposes, to determine whether it can become part of standard clinical care.

The following points are intended to guide ethical decision-making and practice when considering innovative techniques.

- Innovative transplantation practices should be informed, where possible, by international experience.
- Processes for reviewing innovations in transplantation practice should be in place (such as keeping data on outcomes at a national level) and must be notified to the hospital.
- The potential for improved quality of life following innovative procedures must be balanced against the short-term risk of complications or rejection and the longer-term risks to the recipient.
- While it is expected that innovations in practice may challenge established constructs, this innovation must not threaten the viability of established practice.
- Where a proposed intervention is innovative and/or experimental, this must be made clear to the potential recipient as part of the process of informed consent, along with the risks and benefits that accompany the procedure.
- As newly developed practices and procedures are associated with limited understanding of the long-term physical and psychological outcomes, continuing monitoring of the recipient following an experimental or innovative procedure is of particular importance.

There are times when the boundary between innovation in clinical practice and research is not clear. If there is any doubt about whether the innovation constitutes research, then it should be referred to a Human Research Ethics Committee for advice.

Developments in the field of organ transplantation such as machine reperfusion of organs (or ex-vivo perfusion) have the potential to transform and increase the opportunities for patients needing a transplant. Repairs and regeneration of organs will have a substantial impact on the number of suitable organ donors. Both mechanical and biological (stem cell) organ replacement therapies may also change the profile of people needing an organ transplant.
Appendices

A Terms of reference and membership of the Expert Advisory Group

Terms of reference

The Expert Advisory Group will be established to advise on the development of the Ethical guidelines for eligibility criteria and allocation protocols for organ transplantation from deceased donors.

In developing its advice the Expert Advisory Group will:

• Consider ethical issues relating to eligibility criteria for entry onto organ transplant waiting lists; donor suitability criteria for organ allocation for transplantation; and the organ allocation protocols for determining transplant recipients. At a minimum this will include issues identified in development of the 2011 TSANZ Consensus Statement Version 1.2 including:
  — use of likelihood of survival as an eligibility criterion for entry on transplant waiting lists;
  — the process of alternate listing for matching extended criteria donors with extended criteria transplant recipients;
  — access to transplantation for rural and regional patients;
  — ethical principles to guide criteria for retransplantation;
  — ethical principles to guide the balance of criteria relating to utility and equity for entry onto transplant waiting lists and allocation protocols for determining transplant recipients;
  — ethical principles to guide criteria for access to transplantation by international patients;
  — ethical principles to guide consideration of an appeals mechanism relating to clinical decisions about entry onto transplant waiting lists;
• consult with key stakeholders and consider feedback from consultations;
• develop final advice in the form of draft ethical guidelines for consideration by the Australian Health Ethics Committee;
• make any consequential recommendations to AHEC in relation to the currency of the current NHMRC Ethical Guidelines:
  — Organ and tissue donation after death, for transplantation - Guidelines for ethical practice for health professionals (2007);
  — Making a decision about organ and tissue donation after death (2007).
## Membership

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<th>Member</th>
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<tr>
<td>Professor Ian Olver (Chair)</td>
<td>Chair, Australian Health Ethics Committee</td>
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<tr>
<td>Ms Diana Aspinall</td>
<td>Member with community/consumer expertise with a background in transplantation, donation and/or health ethics</td>
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<tr>
<td>Professor Steve Chadban</td>
<td>Member with expertise in kidney transplantation, nominated by the Transplantation Society of Australia and New Zealand</td>
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<td>Professor Jeremy Chapman</td>
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<tr>
<td>Professor Jonathan Fawcett</td>
<td>Member with expertise in liver transplantation, nominated by the Transplantation Society of Australia and New Zealand</td>
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<tr>
<td>Professor Kirsten Howard</td>
<td>Member with expertise in community preferences for health care interventions</td>
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<tr>
<td>A/Professor Ian Kerridge</td>
<td>Member from Australian Health Ethics Committee with expertise in medico-legal and/or health ethics</td>
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<tr>
<td>Professor Peter Macdonald</td>
<td>Member with expertise in heart transplantation, nominated by the Transplantation Society of Australia and New Zealand</td>
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<tr>
<td>Professor Geoffrey McCaughan</td>
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<tr>
<td>Ms Eva Mehakovic</td>
<td>Member with expertise in deceased donation policy, nominated by the Organ and Tissue Authority</td>
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<tr>
<td>Dr Stewart Moodie</td>
<td>Member with medical expertise in deceased donation, nominated by the Australian and New Zealand Intensive Care Society</td>
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<td>Mr David O’Leary</td>
<td>Member with community/consumer expertise with a background in transplantation, donation and/or health ethics</td>
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<td>Dr Helen Opdam</td>
<td>Member with medical expertise in deceased donation, nominated by the Australian and New Zealand Intensive Care Society</td>
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<td>Mr Paul Robertson</td>
<td>Member with clinical expertise in deceased donation, nominated by Australian Transplant Coordinators Association</td>
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<tr>
<td>Professor Loane Skene</td>
<td>Member from Australian Health Ethics Committee with expertise in medico-legal and/or health ethics</td>
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<tr>
<td>Professor Greg Snell</td>
<td>Member with expertise in lung transplantation, nominated by the Transplantation Society of Australia and New Zealand</td>
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<tr>
<td>Dr Helen Watchirs</td>
<td>Member with community/consumer expertise with a background in transplantation, donation and/or health ethics</td>
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Further sources of information

Legislation and regulatory frameworks
The legislation listed below can be viewed online on the Australian Legal Information Institute website — www.austlii.edu.au.

Guardianship
Australian guardianship law is the key regulatory mechanism for protecting the health of adults with disabilities and the elderly. Australia has eight different guardianship regimes, which vary widely in their forms of regulation.

- ACT Guardianship and Management of Property Act 1991
- NSW Guardianship Act 1987
- NT Adult Guardianship Act 1988
- QLD Guardianship and Administration Act 2000
- SA Guardianship and Administration Act 1993
- TAS Guardianship and Administration Act 1995
- VIC Guardianship and Administration Act 1986
- WA Guardianship and Administration Act 1990

Capacity of children to consent
Specific legislation regarding the capacity of children to consent to medical procedures exists in New South Wales and South Australia.

- NSW Minors (Property and Contracts) Act 1970
- SA Consent to Medical Treatment and Palliative Care Act 1995

Organ and Tissue Authority

Communication

Cultural awareness

Interpreters
- Telephone Interpreting Service: Free interpreting services for non-English speaking Australian citizens and permanent residents communicating with general practitioners and medical specialists in private practice and their reception staff.
  131 450
• Doctors Priority Line: A free telephone interpreting service for general practitioners and specialists providing services that are claimable under Medicare, delivered in private practices and provided to non-English speakers who are Australian citizens or permanent residents. The Doctors Priority Line is available 24 hours a day, seven days a week.


Monitoring of organ donation and transplantation activity
• Australia and New Zealand Dialysis and Transplant Registry (ANZDATA) — www.anzdata.org.au/v1/index.html
• Australia and New Zealand Liver Transplant Registry — www.anztr.org/
• Australian and New Zealand Cardiothoracic Organ Transplant Registry — www.anzcotr.org.au/

Assistance with travel and accommodation
All Australian states and territories operate a Patient Assisted Travel Scheme. These schemes provide a subsidy to assist with travel, escort and accommodation expenses incurred when people who live in rural and remote areas travel over 100 kilometres to access specialised health care not available within a specified distance from their place of residence.

• Queensland Patient Travel Subsidy Scheme — www.health.qld.gov.au/ptss/
• South Australian Patient Assistance Transport Scheme — www.countryhealthsa.sa.gov.au/Services/PatientAssistanceTransportSchemePATS.aspx
• Tasmanian Patient Travel Assistance Scheme — www.dhhs.tas.gov.au/hospital/ptas
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<th>Acronyms and abbreviations</th>
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<tr>
<td>ANZCOTR</td>
<td>Australian and New Zealand Cardiothoracic Organ Transplant Registry</td>
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<td>ANZDATA</td>
<td>Australia and New Zealand Dialysis and Transplant Registry</td>
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<td>ANZLTR</td>
<td>Australia and New Zealand Liver Transplant Registry</td>
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<td>ANZOD</td>
<td>Australia and New Zealand Organ Donation Registry</td>
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<td>NHMRC</td>
<td>National Health and Medical Research Council</td>
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<td>NPTR</td>
<td>National Pancreas Transplant Registry</td>
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<td>OTA</td>
<td>Organ and Tissue Authority</td>
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References


