

# Position statement

Protecting the human rights of adults with decision-making disabilities

## Decisions about medical research

**The *Guardianship and Administration Act 1990* (the Act) Part 9E provides the authorisation and safeguards for consent to be given for a person with a decision-making disability to participate in approved medical research. This research must have been approved by a Human Research Ethics Committee that complies with the National Statement on Ethical Conduct in Human Research issued under the *National Health and Medical Research Council Act 1992* (Commonwealth).**

The intent of the provision in the Act is to ensure that people with a decision-making disability have access to emerging and novel treatments when it is assessed as in their best interests, or is not adverse to their best interests.

The Act specifies those people authorised to make a research decision for a person with a decision-making disability. It is not always necessary to apply to the State Administrative Tribunal to have a guardian appointed to make a research decision if someone else specified in the Act meets the criteria to make the decision. However, a guardianship order may be sought when there are disagreements or when ethically contentious medical research is proposed.

The Office of the Public Advocate has developed the following information to ensure health professionals, service providers, family and friends are aware of the process to follow when medical research is being considered for a person with a decision-making disability. There are also general guidelines to use when considering whether or not an application for a guardianship order is required.

## Medical Research

In the Act the term medical research means research conducted with or about individuals, or their data or tissue, in the field of medicine or health; and includes an activity undertaken for the purpose of that research. A person being considered for, or provided with, treatments in approved medical research is called the research candidate.

Section 3AA of the Act defines activities that are considered to be medical research but other activities may be prescribed by regulations. Medical research includes, but is not limited to:

- the administration of pharmaceuticals or placebos
- the use of equipment or a device
- health care that has not yet gained the support of a substantial number of practitioners in that field of health care



- carrying out a comparative assessment between established and novel health care therapies
- taking samples from an individual, including taking a blood sample; or a sample of tissue or fluid from the body, including the mouth, throat, nasal cavity, eyes or ears
- any non-intrusive examination including a visual examination of the mouth, throat, nasal cavity, eyes or ears; or the measuring of an individual's height, weight or vision
- observing an individual
- undertaking a survey, interview or focus group
- collecting, using or disclosing information, including personal information
- considering or evaluating samples or information taken under an activity listed above.

Medical research does not include research about individuals, or their data or tissue that only analyses such data and does not result in the disclosure or publication of personal information.

## Treatment

In the Act, for the purpose of;

- Part 9B – Advance health directives
- Part 9E – Medical research

the term 'treatment' is defined as any medical, surgical or dental treatment or other health care, including a life-sustaining measure or palliative care, and medical research.

**Medical research is not included in the definition of treatment when it is applied to other parts of the Act.**

## Treatment decision

A treatment decision is a decision to consent or refuse consent to the commencement or continuation of any treatment of the person. In Part 9B – advance health directives – the definition of treatment decision is expanded to include participation in medical research.

## Substitute decision-making

The Act ensures that there are provisions for treatment and research decisions to be made for people who are not capable of making reasoned decisions for themselves because of conditions such as dementia, an intellectual disability, psychiatric illness or an acquired brain injury.

The Act provides options for people to choose how decisions about treatment and/or their participation in medical research will be made, if they ever lose capacity to make decisions for themselves. People can do this by making an advance health directive or by appointing an enduring guardian.

The Act also allows for substitute decision-makers to be appointed by the State Administrative Tribunal where a person has lost capacity. A person appointed by the State Administrative Tribunal to make personal, lifestyle, treatment and medical research decisions is known as a guardian.

Persons for whom a guardian is appointed lose the right to make decisions about those areas of their life for which the Tribunal gives the guardian authority. To protect a person's decision-making rights wherever possible, a guardian will be appointed only if it is considered necessary to safeguard the best interests of the person whose decision-making capacity is impaired and if other less restrictive options are not available or appropriate.

## **Advance health directive**

This is a legal document that a person 18 years of age or older, with full legal capacity can complete. It allows the person to provide or withhold consent for specific health care, medical, surgical or dental treatments or procedures, including life-sustaining measures and palliative care, and participation in medical research.

This document is then used if the person is unable to make a treatment and/or medical research decision at the time it is required due to loss of capacity.

Section 110ZR (4) requires that a research decision-maker must not consent to medical research on a person if the research is inconsistent with any advance health directive in respect to the person.

Similarly, section 110ZS (2) requires that a researcher must not conduct medical research on a person if the researcher is aware, or ought reasonably to be aware, the research is inconsistent with any advance health directive in respect to the person.

## **Enduring power of guardianship**

This is a legal document that a person 18 years of age or older, with full legal capacity can complete. It enables the person to appoint a person of their choice to make personal, lifestyle, treatment, and medical research decisions on their behalf if they become unable to make these decisions for themselves.

## **Guardianship**

The State Administrative Tribunal may appoint a guardian for a person if it is satisfied that the person:

- is 18 years of age or older
- is either:
  - incapable of looking after their own health and safety;
  - unable to make reasonable judgements about personal matters; or
  - in need of oversight, care or control in the interests of their own health and safety or for the protection of others; and
- is in need of a guardian.

## **Research decision-maker**

A research decision-maker is a person who has the authority to consent on behalf of a person with a decision-making disability to participate in medical research. Section 110ZP of the Act specifies when a person can be a research decision-maker: see the section below "Process for obtaining a research decision" for further details.

The research decision-maker, on advice from a medical practitioner as outlined below, provides consent or refuses consent to the research. Section 110ZR (4) requires that a research decision-maker must not consent to medical research on a person if the research is inconsistent with any advance health directive in respect to the person.

Section 110ZR of the Act specifies what must be considered before approval is given for a person to be a research candidate. Preconditions are that:

- the research is approved by a Human Research Ethics Committee; and
- the research candidate is unable to make reasonable judgements about their participation in the research; and
- an independent medical practitioner has determined that the research candidate is not likely to regain the ability to make reasonable judgements and consent to their participation within the timeframe approved by the Human Research Ethics Committee. Section 110ZV of the Act specifies what the independent medical practitioner must take into account in forming this determination.

Before consent can be provided by the research decision-maker, the research decision-maker must receive the determination of an independent medical practitioner that:

- the medical research is in the best interests of the person or not adverse to their interest; and
- the research candidate's participation will only involve observing that person or carrying out another non-invasive examination, treatment or procedure; or
- if the point above does not apply, and if there is an existing treatment available to the candidate, the medical research does not involve any known substantial risks to the person; or
- if the above points do not apply, the medical research will not involve substantial risks to the research candidate greater than if that person did not participate in the research.

Section 110ZU of the Act specifies what the independent medical practitioner must take into account in forming a determination that the medical research is in the best interests of the research candidate.

The independent medical practitioner must inform the research decision-maker or researcher of their determination and the reasons for it in writing before the research starts. If that is not possible, the determination can be provided orally and then in writing after the research candidate commences participation in the research.

## **Urgent medical research without consent**

Section 110ZS of the Act enables a researcher, in certain limited circumstances, to conduct medical research in relation to a research candidate who needs urgent treatment as defined in Section 110ZH to save the person's life, prevent serious damage to the person's health or to prevent the person from suffering significant pain or distress. This research must have been approved by a Human Research Ethics Committee.

Certain criteria must be met in order for the medical research to be conducted in the absence of a decision by a research decision-maker. A research candidate must:

- require urgent treatment
- be unable to make reasonable judgements as to their participation in the research, and
- not be subject to an existing research decision regarding the research.

It must also not be practicable for the researcher to obtain a decision from a research decision-maker, and unlikely that the researcher will be able to obtain a decision within the time frame approved by the Human Research Ethics Committee.

Approved medical research can only be provided if an independent medical practitioner has determined that:

- the research candidate is not likely to be able to make reasonable judgements about participation in the research, and
- it is in the research candidate's best interests or not adverse to their interests. Section 110ZU of the Act specifies what the independent medical practitioner must take into account in forming this determination.

The researcher must also receive from the independent medical practitioner a determination that:

- the research candidate's participation will only involve observing that person or carrying out another non-invasive examination, treatment or procedure; or
- if the above point does not apply, the medical research will not involve any known substantial risks to the person; or
- if the above two points do not apply and there is an existing treatment available to the research candidate, the medical research will not involve any known substantial risk to that person greater than the risks associated with the treatment; or
- if all the above points do not apply, the medical research will not involve substantial risk to the research candidate greater than if that person did not participate in the research.

The independent medical practitioner must inform the research decision-maker or researcher of their determination and the reasons for it in writing before the research starts. If that is not possible, the determination can be provided orally and then in writing after the research candidate commences participation in the research.

Section 110ZS (2) requires that a researcher must not conduct medical research on a person if the researcher is aware, or ought reasonably to be aware, the research is inconsistent with any advance health directive in respect to the person.

Section 110ZS (3) requires that when a researcher conducts medical research on a person in accordance with an urgent research decision the lead researcher associated with the medical research must take reasonable steps to obtain approval from the research decision-maker for the candidate.

## **Process for obtaining a research decision**

Sections 110ZP and 110ZQ of the Act specify the procedure to be followed by a researcher to identify a research decision-maker when seeking to engage a research candidate with a decision-making disability.

If the proposed research candidate is unable to make reasonable judgements about their participation in the medical research the researcher must determine who has authority as the research decision-maker. The way in which the research decision-maker is identified is outlined below under the heading “Hierarchy of medical research decision-makers”.

Service providers such as allied health professionals and paid support workers have no authority under the Act to make a research decision and are encouraged to provide the treating health professional or researcher with the name and contact details of any legally appointed substitute decision-maker.

## **Hierarchy of medical research decision-makers**

Under the Act, if a person has completed an advance health directive which covers the circumstances and treatment required, health professionals and researchers must follow the treatment and/or research decision in the advance health directive.

A researcher must not conduct medical research on a person if the researcher is aware, or ought reasonably to be aware, the research is inconsistent with any advance health directive in respect to the person.

In very limited circumstances the advance health directive may be considered invalid and the health professional may not follow the directive but instead, must consult the first person listed in the legislation who can make a treatment and/or a research decision.

Under Section 55A (1) (1A) of the Act the guardian of a person cannot make a research decision unless the guardianship order gives them the authority to do so. Plenary guardians have this authority but limited guardians require specific authority to make research decisions.

Under Section 110I (1) (1A) of the Act the enduring guardian of a person cannot make a research decision unless the person has authorised all functions or provided specific authority to make research decisions.

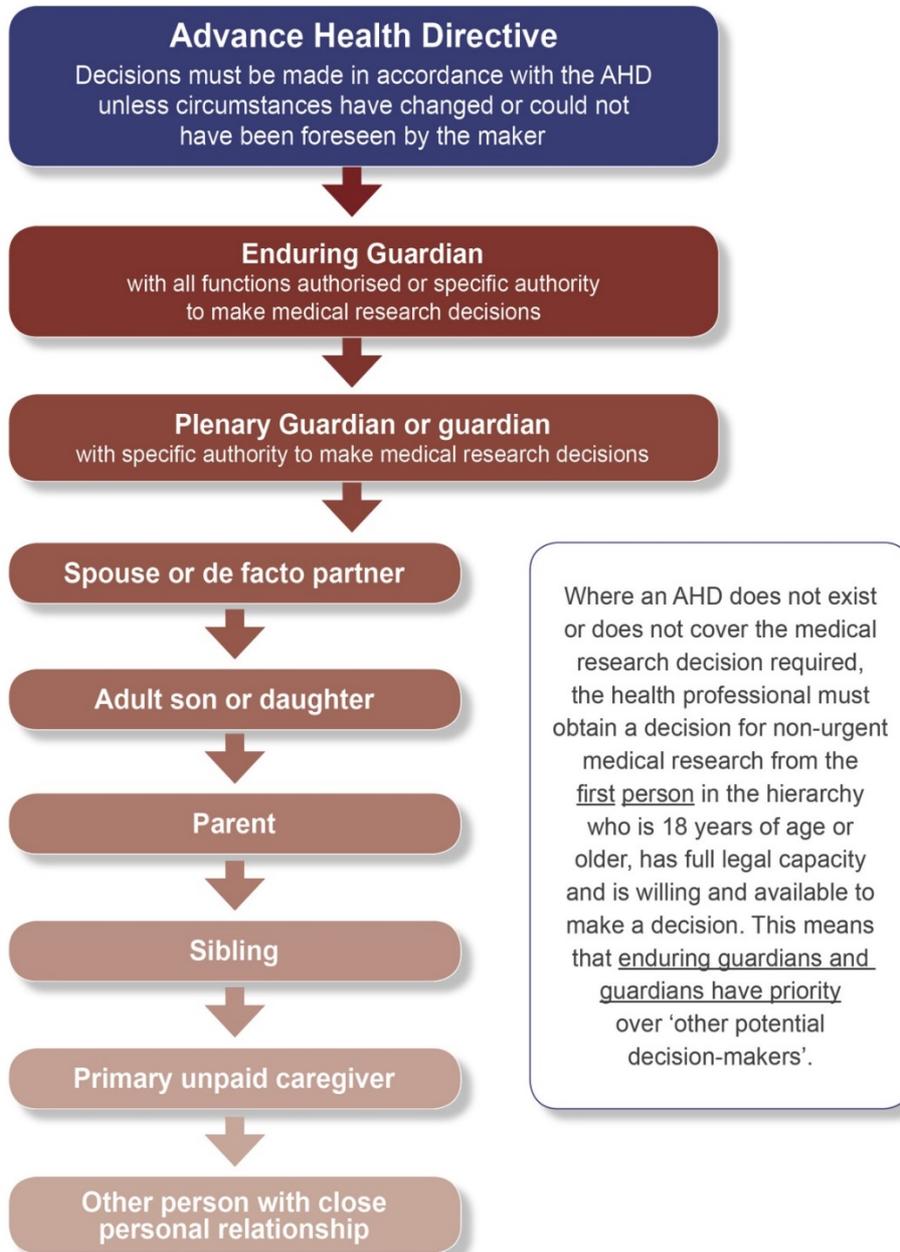
If the guardian or enduring guardian does not have authority to make research decisions, then the researcher must determine the research decision-maker by considering the hierarchy of medical research decision makers.

Sections 110ZP and 110ZQ of the Act lists the persons who may act as research decision-makers for a research candidate and it can be summarised as a hierarchy. When obtaining a research decision, the researcher must go to the first person in the hierarchy, who is 18 years of age or older, has full legal capacity, and is reasonably available and is willing to make the decision.

If any of these conditions are not met, for example if the potential research decision-maker does not have capacity or is not reasonably available, the health professional can go to the next person in the hierarchy.

## Hierarchy of medical research decision-makers\*

To be read in conjunction with Sections 110ZP and 110ZQ of the *Guardianship and Administration Act 1990*, as noted earlier. Note, in the flowchart below, an advance health directive may be in the prescribed form or a common law directive.



### \*Explanatory notes:

A health professional must consult the order above (spouse/de facto partner, adult child, parent, sibling) in seeking a research decision

De facto partner: "It does not matter whether (a) the persons are different sexes or the same sex; or (b) either of the persons is legally married to someone else or in another de facto relationship." *The Acts Amendment (Lesbian and Gay Law Reform) Act 2002*.

A researcher does not have to seek a research decision from the eldest person within any category as there is no distinction in relation to age, therefore all adult children of a person have equal priority.

A person is to be regarded as maintaining a 'close personal relationship' with the person needing the research decision if the relationship is maintained through frequent personal contact and a personal interest in the welfare of the person.

## Capacity of a person to make a research decision

The responsibility for making sure that a person being provided with medical research understands the nature and consequences of the research treatment proposed, and for obtaining a research decision from the correct person, lies with the researcher.

If the researcher does not believe the patient has the capacity to make the research decision then it is their responsibility to seek the research decision from the appropriate person.

## Sterilisation and electroconvulsive therapy is prohibited

Section 110ZT of the Act prohibits a research decision-maker from consenting to a procedure for the sterilisation of the research candidate or for electroconvulsive therapy to be performed on the research candidate. Penalties apply for a breach of this provision. The 'procedure for sterilisation' takes the meaning given to it under Division 3 of Part 5 of the Act.

## Application for a guardianship order

It is the view of the Public Advocate that an application for a guardianship order should be made to the State Administrative Tribunal when:

- there is conflict about the adult's capacity to make a decision in relation to the proposed medical research, so the treating health professional requires clarification about capacity
- there is conflict between interested parties about who should be making a research decision
- there is no enduring guardian appointed and there is no one within the description of persons listed in sections 110ZP and 110ZQ to make a research decision
- the person authorised in the Act to make a research decision is unwilling or unable to perform this role or cannot be contacted in a reasonable timeframe
- the person for whom the medical research is proposed objects to the medical research
- notwithstanding the priority list in the hierarchy of research decision-makers, there are disagreements about what medical research will be in the best interests of the person.

## For further information contact

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