Decisions about medical research

The *Guardianship and Administration Act 1990* (the Act) Part 9E provides a process and safeguards for consent to be given for a person who is not capable of making reasoned decisions for themselves to participate in medical research when it is assessed as in their best interests or not adverse to their interests.

When a person lacks capacity to consent to participation in medical research a substitute decision-maker is required. The Act provides a process to identify a research decision-maker and it also specifies what information the decision-maker must consider before making a decision to consent or not consent to participation in the research.

When there are disagreements about whether-or-not a person should be recruited into medical research, an application may be made to the State Administrative Tribunal for the appointment of a guardian with specific authority for research-decision making.

The Office of the Public Advocate has developed the following information to support health professionals, service providers, family and friends to be aware of the process to follow when medical research is being considered for a person who does not have the capacity to make reasoned decisions for themselves. The Act refers to this person as the research candidate.

The Department of Health (WA) has produced a guidance document for medical researchers that can be accessed at rgs.health.wa.gov.au/pages/document-templates.aspx.

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.

Section 3AA of the Act defines activities that are considered to be medical research but other activities may be prescribed by regulation. 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 and 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

In the Act, 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 makes provision 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, while they are still capable, 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. This is done 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 State Administrative 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.

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 research candidate who is unable to make reasonable decisions for themselves to participate in medical research. Section 110ZP and Section 110ZQ of the Act specify when a person can be a research decision-maker. The section below titled ‘Hierarchy of medical research decision-makers’ provides more information about how a research decision-maker is identified.

Decisions about medical research

Section 110ZR of the Act specifies what information the research decision-maker must consider in determining whether to consent or refuse consent for a research candidate to participate in medical-research.

An important step in the decision-making process is determining if the proposed research candidate has an advance health directive. Section 110ZR(4) of the Act requires that a research decision-maker must not consent to medical research on a person if the research and/or treatment 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 and/or treatment is inconsistent with any advance health directive in respect to the person.

The circumstances in which the research decision-maker may make a research decision are when:

- the research is approved by a Human Research Ethics Committee; and
- the lead researcher is a registered health practitioner[1]; 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.

The research decision-maker for a research candidate must not consent to a candidate's participation in medical research unless they have received a determination from an independent medical practitioner about the risks and benefits to the research candidate from participation. Having regard to the information provided by the independent medical practitioner, the research decision-maker must determine that:

- the medical research is in the best interests of the person or not adverse to their interests; and
- the research candidate's participation will:
  a. only involve observing that person or carrying out another non-invasive examination, treatment or procedure; or
  b. if (a) does not apply, the medical research will not involve any known substantial risks to the person; or
  c. if (a) and (b) 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
  d. 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.

Section 110ZU of the Act specifies what the independent medical practitioner must take into account when assessing 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.

Section 110ZR(6) of the Act enables the research decision-maker to change their decision and withdraw the research candidate from the medical 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

[1] 'registered health practitioner', has the meaning given to it in section 5 of the Health Practitioner Regulation National Law (Western Australia) (HPRN)
https://www.legislation.wa.gov.au/legislation/statutes.nsf/law_a146782.html

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 and the lead researcher must be a registered health practitioner.

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 that decision from the research decision-maker 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:

a) the research candidate's participation will only involve observing that person or carrying out another non-invasive examination, treatment or procedure; or
b) if (a) does not apply, the medical research will not involve any known substantial risks to the person; or
c) if (a) and (b) 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
d) 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.

Hierarchy of medical research decision-makers

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 to be the research decision-maker. If a person has completed an advance health directive which covers the circumstances and treatment to be delivered through the proposed medical research, health professionals, researchers and medical decision-makers must follow the directive in it.

Sections 110ZP and 110ZQ of the Act specify the procedure to be followed by a researcher to identify a research decision-maker. The list of persons in Sections 110ZJP and 110ZQ of the Act can be summarised as a hierarchy (Figure 1). To obtain a medical 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, is reasonably available and is willing to make the decision. If all of these conditions are not met, for example if the person does not have capacity or is not available, the health professional can go to the next person in the hierarchy.

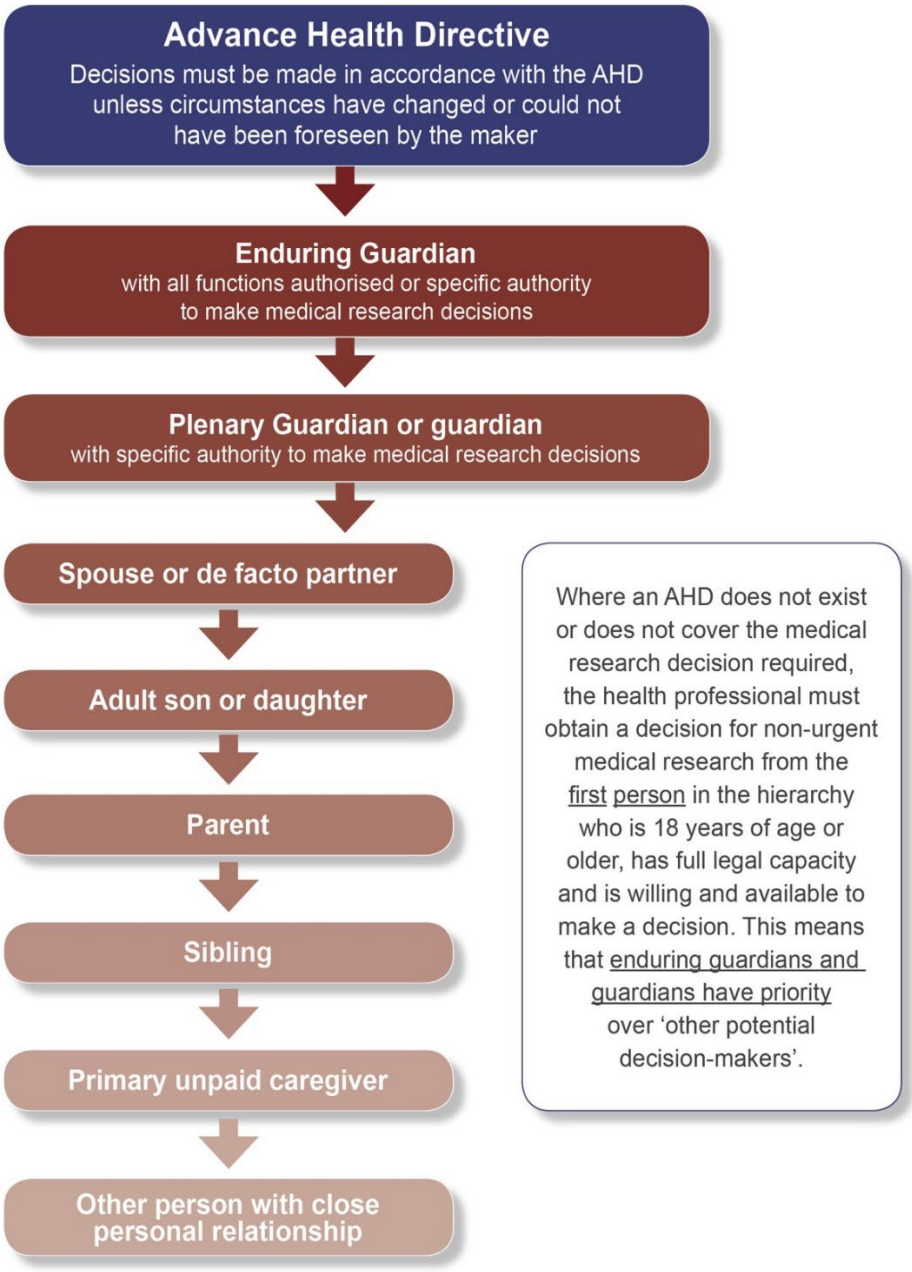
In situations where an enduring guardian or guardian has been appointed, the researcher must consider what authority has been given to them. If they have plenary authority, where all functions are authorised, then the enduring guardian or guardian may act as the research decision-maker. If the enduring guardian or the guardian have limited authority, the researcher will need to determine if that limited authority includes decisions about participation in medical research. If it does not, then the enduring guardian or the guardian may not act as the research decision-maker.

If the enduring guardian or guardian are not authorised to make decisions about participation in medical research, then the researcher must determine the research decision-maker by going to the next person on the hierarchy until someone is found who is willing and able to make a decision for the research candidate.

It is important to note that service providers such as allied health professionals and paid support workers have no authority under the Act to make a research decision. However they may be able to provide the treating health professional or researcher with the name and contact details of any legally appointed substitute decision-maker.

Figure 1: 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 are 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.

The Public Advocate publishes position statements on:

- Decisions about treatment
- Restrictive Practices (Restraint)
- The role of the Public Advocate as guardian of last resort with authority to make accommodation decisions
- The role of the Public Advocate as guardian of last resort with authority to make treatment decisions
- The role of the Public Advocate as guardian of last resort with authority to make contact decisions
- The role of the Public Advocate as guardian of last resort with authority to make treatment decisions: palliative care
- **Decisions about medical research**
- The role of the Public Advocate as guardian of last resort with authority to make decisions about restrictive practices

For further information contact

Office of the Public Advocate
PO Box 6293, EAST PERTH WA 6892
Telephone: 1300 858 455
Email: opa@justice.wa.gov.au
Web: www.publicadvocate.wa.gov.au

December 2023