

# Guide to the legislation relating to the provision of consent for a person with impaired capacity to provide informed consent for the provision of treatment (and which legislation may apply to such person's participation in human research)

## Western Australia

This guide provides an outline of the relevant legal requirements in the State of Western Australia regarding the provision of consent for the provision of treatment to a person who lacks the capacity to provide informed consent. These principles *might* apply in relation to the participation of an adult with impaired capacity to provide informed consent in a human research project to the extent that the human research involves or constitutes the giving of treatment.

**Disclaimer:** The information provided in this guide is an overview of the relevant legal requirements and is of a general nature only. The guide does not provide legal advice in relation to any specific human research project or clinical trial. You should obtain legal or other professional advice appropriate to your circumstances before acting or relying on any matter referred to in this guide.

### Relevant legislation

There is no Western Australian legislation that *specifically* refers to or directly deals with the provision of consent for an adult who lacks the capacity to provide informed consent to participate in a human research project, including a clinical trial.

However, other legislation may be relevant to considerations of whether an adult with impaired capacity to provide informed consent can participate or be enrolled in human research activities, including the following:

- *Guardianship and Administration Act 1990 (WA) (GAAWA)*

### What are the relevant provisions?

The GAAWA prescribes requirements regarding who may make a *treatment decision* for an adult who 'is unable to make reasonable judgments in respect of any *treatment* proposed to be provided to them'. The relevant procedures for the making of such a decision are set out in Part 9D of the GAAWA.

A *treatment decision* is a 'decision to consent or refuse consent to the commencement or continuation of any *treatment* of the person'. *Treatment* is defined as medical or surgical treatment, including a life sustaining measure and palliative care, dental treatment, or other health care.

To the extent that a human research project involves or constitutes *treatment*, the requirements of the GAAWA **might** apply to it. In practice, there may be few human research projects which could be characterised as involving the provision of *treatment*.

### **What are the specific requirements for the making of a ‘*treatment decision*’?**

The GAAWA provides that the order of priority of persons who may make a *treatment decision* in relation to an impaired capacity adult is the following:

- If the person has made an advance health directive containing a *treatment decision* in respect of the *treatment*, whether or not the *treatment* is provided to the person must be decided in accordance with the advance health directive.
- An enduring guardian (appointed under the GAAWA) who is authorised to make a *treatment decision* in respect of the *treatment*, is reasonably available and is willing to make a *treatment decision* in respect of the *treatment*.
- A guardian (appointed under the GAAWA) who is authorised to make a *treatment decision* in respect of the *treatment*, is reasonably available and is willing to make a *treatment decision* in respect of the *treatment*.
- A *person responsible* for the person. The *person responsible* for the person is the first in order of the below listed persons who is of full legal capacity, is reasonably available and is willing to make a *treatment decision* in respect of the *treatment*:
  - The person’s spouse or de facto partner if that person has reached 18 years of age and is living with the person.
  - The person’s nearest relative who maintains a close personal relationship with the person, being the first in order of priority of the following relatives who has reached 18 years of age:
    - The spouse or de facto partner
    - A child
    - A parent
    - A sibling.
  - A person who has reached 18 years of age and is the primary provider of care and support (including emotional support) to the impaired capacity person but is not paid for providing that care and support.
  - Any other person who has reached 18 years of age and maintains a close personal relationship with the impaired capacity person. A person maintains a close personal relationship with the impaired capacity person only if the person has frequent contact of a personal (as opposed to a business or professional) nature with the impaired capacity person and takes a genuine interest in the impaired capacity person’s welfare.

When making a *treatment decision* for the impaired capacity person, the *person responsible* for the impaired capacity person must act according to the person’s opinion of the best interests of the impaired capacity person.

### **Can *treatment* be carried out on an impaired capacity person without consent in emergency circumstances?**

A health professional may provide *urgent treatment* to a person in the absence of a *treatment decision* if the *treatment* is urgently needed by the person to save the person’s life, to prevent serious damage to their health or to prevent them from suffering or continuing to suffer significant pain or distress. In addition, the following conditions must be satisfied:

- The person needs urgent treatment.
- The person is unable to make reasonable judgments in respect of the treatment.
- It is not practicable for the health professional who proposes to provide the *treatment* to determine whether or not the person has made an advance health directive containing a *treatment decision* that is inconsistent with providing the *treatment*.
- It is not practicable for the health professional to obtain a *treatment decision* in respect of the *treatment* from the person's guardian, enduring guardian or *person responsible*.

If these circumstances apply to a human research project, then it is possible that *treatment* could be given to an adult with impaired capacity to provide informed consent in the course of that research without the requirement for a *treatment decision* to be made. In practice, there may be few human research projects which would satisfy the above requirements.

### **Is there a requirement for the State Administrative Tribunal of Western Australia to approve the research?**

The State Administrative Tribunal (**SAT**) of Western Australia does not have a specifically defined or direct role in relation to the approval of human research or a clinical trial or the giving of consent for an adult with impaired capacity to provide informed consent to participate in a human research project (including a clinical trial). In particular, there is no requirement to submit a research project or a clinical trial to the SAT for approval.

However, the SAT may have an indirect role in relation to issues concerning the conduct of a human research project to the extent that it has certain powers regarding the making of *treatment decisions* in relation to an adult who lacks the capacity to provide informed consent. For example, the SAT can determine issues regarding advanced health directives and can make declarations regarding who may make *treatment decisions* for a person who has impaired capacity to provide informed consent. Further, in a 2013 Position Statement, the Office of the Public Advocate of WA advised that an application for a guardianship order should be made to the SAT when 'an ethically contentious treatment or procedure is proposed, for example, clinical drug trials'.

#### **Checklist of matters for an HREC to consider**

- Does the research involve participants who lack the capacity to provide informed consent?
- Does the clinical trial involve the provision of *treatment* as defined in the GAAWA to an impaired capacity person?
- Does the proposal clearly document how the researcher will seek consent from any substitute decision maker?
- Has the HREC approval been given subject to the research being conducted in accordance with all relevant legal requirements regarding the obtaining of consent for participants who lack the capacity to provide informed consent?
- Having considered the above, does the HREC need to seek further advice from the researcher?