

# Guide to the legislation relating to the provision of consent for an adult with impaired capacity to provide informed consent to participate in the conduct of human research

## Victoria

This guide provides an outline of the relevant legal requirements in the State of Victoria regarding the provision of consent for an adult who lacks the capacity to provide informed consent to participate in the conduct of human research. It has been prepared to assist researchers, HRECs and other stakeholders to understand the relevant legal requirements.

**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.

**Note:** As of 3 March 2017, Victoria has not provided its advice on the accuracy of the following information.

### Relevant legislation

The following legislation may be relevant to considerations of whether an adult with impaired capacity to provide informed consent may participate or be enrolled in a '*medical research procedure*':

- *Guardianship and Administration Act 1986* (Vic) (**GAAV**)

### Where are the relevant requirements found?

The relevant requirements are set out in Part 4A of the GAAV.

### What types of research does Part 4A apply to?

Part 4A applies to the carrying out of a *medical research procedure* on a person who is at least 18 years of age and who lacks the capacity to provide informed consent.

A *medical research procedure* is a procedure carried out for the purposes of medical research, including, as part of a clinical trial, the administration of medication or the use of equipment or a device; it is also any procedure that is prescribed by the applicable regulations to be a *medical research procedure* for the purposes of the GAAV (there are none currently prescribed).

However, a *medical research procedure* does not include the following:

- A non-intrusive examination, including a visual examination of the mouth, throat, nasal cavity, eyes or ears or the measuring of a person's height, weight or vision.
- Observing a person's activities or undertaking a survey.
- Collecting or using information, including personal information (within the meaning of the *Privacy and Data Protection Act 2014* (Vic)) or health information (within the meaning of the *Health Records Act 2001* (Vic)).
- Any other procedure that is prescribed by the applicable regulations not to be a *medical research procedure*.

**What are the specific requirements under the GAAV for the conduct of a *medical research procedure*?**

The GAAV sets out a four step process for authorising the carrying out of a *medical research procedure* on an adult patient who lacks the capacity to provide informed consent. The steps are described below.

1. Step 1 - Approval by relevant human research ethics committee

A Human Research Ethics Committee (**HREC**) must have approved the conduct of the medical research procedure. A *medical research procedure* must not be carried out on a patient if the relevant research project has not been approved by the relevant HREC.

The GAAV defines a HREC as:

- a human research ethics committee established in accordance with the requirements of the National Statement; or
- an ethics committee established under the by-laws of a public hospital, public health service, denominational hospital or multi-purpose service (within the meaning of the *Health Services Act 1988* (Vic)).

2. Step 2 - Is person likely to recover the capacity to consent?

The second step is to determine whether the patient is likely to recover the capacity to consent to the *medical research procedure* within a *reasonable time*.

The *reasonable time* is the time by which the *medical research procedure* would need to be performed on the patient, given the nature of the relevant research project and having regard to the medical or physical condition of the patient, the stage of treatment or care and other circumstances specific to the patient.

If the patient is likely to recover within that time, a registered practitioner must not carry out, or supervise the carrying out of, a *medical research procedure* on the patient and the matter must not proceed to Step 3 or Step 4.

3. Step 3 - Consent given by person responsible

The third step is to seek the consent of the *person responsible* for the patient.

A *person responsible* is the first person listed in the hierarchy below who is responsible for the patient and who, in the circumstances, is reasonably available and willing and able to make a decision under Part 4A of the GAA:

- A person appointed by the patient under section 5A of the *Medical Treatment Act 1988* (Vic).
- A person appointed by VCAT to make decisions in relation to the proposed procedure or treatment.
- A person appointed under a guardianship order with power to make decisions in relation to the proposed procedure or treatment.
- A person appointed by the patient (before the patient became incapable of giving consent) as an enduring guardian with power to make decisions in relation to the proposed procedure or treatment.

- A person appointed in writing by the patient (being the person appointed last in time before the patient became incapable of giving consent) to make decisions in relation to medical research procedures that include the proposed procedure or medical or dental treatment which includes the proposed treatment.
- The patient's spouse or domestic partner.
- The patient's primary carer.
- The patient's nearest relative. The patient's nearest relative for the purposes of the GAA is the spouse or domestic partner of that person or, if that person does not have a spouse or domestic partner, the relative of that person listed first below who is at least 18 years of age:
  - Son or daughter.
  - Father or mother.
  - Brother or sister.
  - Grandfather or grandmother.
  - Grandson or granddaughter.
  - Uncle or aunt.
  - Nephew or niece.

The *person responsible* may only consent to the carrying out of the procedure if he or she believes that the carrying out of the procedure would not be contrary to the best interests of the patient.

The GAAV provides that in determining whether a *medical research procedure* would or would not be contrary to the best interests of a patient, the following matters must be taken into account:

- The wishes of the patient, so far as they can be ascertained.
- The wishes of any nearest relative or any other family members of the patient.
- The nature and degree of any benefits, discomforts and risks for the patient in having or not having the procedure.
- Any other consequences to the patient if the procedure is or is not carried out.

#### 4. Step 4 - Procedural Authorisation

If the *person responsible* cannot be ascertained or contacted after reasonable steps have been taken to do so, a registered practitioner may carry out, or supervise the carrying out of, a *medical research procedure* on a patient pursuant to procedural authorisation.

In order to carry out, or supervise the carrying out of, a *medical research procedure* on a patient pursuant to procedural authorisation, the registered practitioner must ensure that all of the requirements set out in section all of the requirements set out in section 42T are satisfied. Some of these requirements include the following:

- The registered practitioner must believe on reasonable grounds that inclusion of the patient in the relevant research project would not be contrary to the best interests of the patient.
- The registered practitioner does not have any reason to believe that the carrying out of the procedure would be against the patient's wishes.
- The registered practitioner must believe on reasonable grounds that one of the purposes of the relevant research project is to assess the effectiveness of the therapy being researched

and the medical research procedure poses no more of a risk to the patient than the risk that is inherent in the patient's condition and alternative treatment.

- The registered practitioner must believe on reasonable grounds that the relevant research project is based on valid scientific hypotheses that support a reasonable possibility of benefit for the patient as compared with standard treatment.

If a registered practitioner carries out, or supervises the carrying out of, a *medical research procedure* pursuant to procedural authorisation, the registered practitioner must then do the following:

- Before (or as soon as practicable after) the medical research procedure is carried out, the registered practitioner must sign a certificate certifying each of the requirements of section 42T have been satisfied and stating that the *person responsible* (if any) or the patient (if the patient gains or regains capacity) will be informed.
- The registered practitioner must inform the *person responsible* (if any) or the patient (if the patient gains or regains capacity) as soon as reasonably practicable of the patient's inclusion in the relevant research project and of their option to refuse consent for the procedure to be continued and withdraw the patient from future participation in the project.
- The registered practitioner must forward a copy of the relevant certificate to the Public Advocate of Victoria and the relevant HREC as soon as practicable (and in any event within 2 working days) after supervising the carrying out of, or carrying out, the procedure and ensure that the certificate is kept in the patient's clinical records.

#### **Can a medical research procedure be carried out on an impaired capacity patient without consent in emergency circumstances?**

Under section 42A of the GAAV, a registered practitioner may carry out, or supervise the carrying out of, a *medical research procedure* on a patient without consent or without the requirement to follow the procedural authorisation process if the practitioner believes on reasonable grounds that the procedure is necessary, as a matter of urgency to:

- save the patient's life
- prevent serious damage to the patient's health, or
- prevent the patient from suffering or continuing to suffer significant pain or distress.

In practice, there may be few circumstances where section 42A could be relied upon.

#### **Is there a requirement for the Victorian Civil and Administrative Tribunal to approve the research?**

There is no requirement to submit any research proposal to the Victorian Civil and Administrative Tribunal (**VCAT**) for approval and VCAT has no direct role in relation to the conduct of the research. However, VCAT has jurisdiction to hear disputes arising under Part 4A, to give advice to a person responsible upon application and to determine other issues which may be relevant such as those concerning guardianship.

**Checklist of matters for HRECs to consider**

- Does the research involve participants aged 18 years or older who lack the capacity to provide informed consent?
- Does the research constitute a *medical research procedure* as defined in the GAAV?
- Does the consent model for the research project properly consider the four step process in Part 4A of the GAA?
- Will the circumstances of the conduct of the research generally allow a patient's person responsible to be identified in time?
- If the researcher contemplates that the research might be conducted under procedural authorisation, does the research satisfy all the relevant requirements for it to proceed under procedural authorization?
- Has the researcher prepared participant information sheet and consent forms that adequately deal with the proposed model to obtain consent?
- 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?