

Laws relating to the provision of consent for persons that do not have decision-making capacity to participate in research

OFFICIAL

Introduction

This guide provides an outline of the relevant legal requirements in Victoria regarding the provision of consent for an adult who does not have decision-making capacity to provide informed consent to participate in human research.

It has been adapted from the *Laws relating to the giving of consent for persons with impaired capacity to provide informed consent to participate in research in each Australian State and Territory (2017)* report prepared by Rallis Legal for the National Health and Medical Research Council. The Victorian chapter in the report Section B, describes the relevant requirements contained in the *Medical Treatment Planning and Decisions Act 2016 (Vic)* which was applied in March 2018.

It has been prepared to assist researchers, Human Research Ethics Committees (HRECs), research governance officers and others involved in the conduct of human research to assist them in understanding the relevant requirements.

The information provided is not intended to provide legal advice and is applicable to laws from March 2018.

Legislation

Medical Treatment Planning and Decisions Act 2016 (Vic) (MTPDA)

Applicable requirements

Outline of requirements

- The MTPDA applies to the administration of a medical research procedure to a person 18 years of age or older who does not have decision-making capacity in relation to the procedure
- A medical research practitioner must ensure that the relevant research has been approved by a human research ethics committee
- A medical research practitioner may administer a medical research procedure to an adult who does not have decision-making capacity in relation to the procedure in the following circumstances:
 - The person has consented to the procedure being administered under an *instructive directive* made by way of an *advanced care directive*
 - If there is no relevant *advanced care directive*, the person's *medical treatment decision maker* has consented to the procedure being administered

Laws relating to the provision of consent for persons that do not have decision-making capacity to participate in research

- If the person does not have a *medical treatment decision maker*, the procedure is authorised under Division 3 of Part 5 of the MTPDA
- The Victorian Civil and Administrative Tribunal (VCAT) has a limited role in this process. It is not necessary to submit a research proposal to VCAT for approval
- Section 53 of the MTPDA allows a health practitioner to administer a medical research procedure on a person who does not have decision-making capacity in relation to the procedure without the requirement to obtain consent in certain emergency circumstances.

Definition of person who is incapable of giving consent

Part 5 of the MTPDA applies to the administration of a medical research procedure to a person of or above the age of 18 years who does not have decision-making capacity.

Under the MTPDA, the term administer includes supervising the administration of, and continuing to administer, the procedure. The MTPDA does not define or give guidance on what constitutes ‘supervision’ of a procedure by a medical research practitioner or (in the case of a procedure given in an emergency under Section 53) by a health practitioner. The MTPDA does not clarify whether a practitioner must be present at the time of the administration of the procedure and directly watch a person who is being supervised, or whether it is sufficient for the practitioner to merely have properly instructed the person being supervised on how to administer the procedure and to otherwise be responsible for overseeing the conduct of the relevant research. If the former interpretation applies, it is difficult to envisage how this approach could be workable for a vast number of research projects and, in particular, for the conduct of clinical trials. Current research practices suggest the latter interpretation is generally assumed to apply, even though this has not been judicially tested.

Rather than defining the state of impaired decision making, the MTPDA describes what constitutes decision-making capacity. A person has decision-making capacity if the person is able to do all of the following:

- Understand the information relevant to the decision and the effect of the decision information
- Retain that information to the extent necessary to make the decision
- Use or weigh that information as part of the process of making the decision
- Communicate the decision and the person’s views and needs regarding the decision in some way, including by speech, gestures or other means

The MTPDA codifies the principle that an adult is presumed to have decision-making capacity unless there is evidence indicating otherwise.

A medical treatment decision is a decision to consent to or refuse the commencement or continuation of medical treatment or a medical research procedure.

What is a medical research procedure?

The MTPDA defines medical research procedure as:

- a procedure carried out for the purposes of medical research, including, as part of a clinical trial the administration of pharmaceuticals or the use of equipment or a device, and
- a prescribed medical research procedure.

However, a medical research procedure does not include:

Laws relating to the provision of consent for persons that do not have decision-making capacity to participate in research

- any non-intrusive examination, including a visual examination of the mouth, throat, nasal cavity, eyes or ears or measuring person's height, weight or vision
- observing a person's activities
- 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), or
- any other procedure prescribed not to be a medical research procedure. As at the date of the 2016 report, no procedure has been so prescribed.

The administration of a medical research procedure

Part 5 of the MTPDA describes the circumstances where a medical research practitioner may administer a medical research procedure to a person aged 18 years or more who does not have decision-making capacity in relation to the procedure.

A medical research practitioner is:

- a registered medical practitioner, or
- a person registered under the Health Practitioner Regulation National Law to practise in the dental profession as a dentist (other than a student) and in the dentist division of that profession.

Obligations of a medical research practitioner before administering a medical research procedure

The MTPDA requires a medical research practitioner who proposes to administer a medical research procedure to do the following:

1. A medical research practitioner must not administer (which includes supervising the administration of) a medical research procedure to a person under Part 5 of the MTPDA if the person is likely to recover decision-making capacity within a reasonable time to make a medical treatment decision in relation to a medical research procedure.

The MTPDA states that a reasonable time is the time by which, given the nature of the relevant research project, the procedure would need to be administered to the person, having regard to:

- The medical or physical condition of the person
- the stage of medical treatment or care, and
- other circumstances specific to the person.

Section 78 of the MTPDA requires a medical research practitioner, before or as soon as practicable after, administering a medical research procedure to a person who does not have decision making capacity to record in writing in the person's clinical records:

- that the practitioner was satisfied that the person did not have decision-making capacity and was not likely to recover decision-making capacity within a reasonable time, and
 - the reason(s) for being so satisfied.
2. Before a medical research practitioner administers a medical research procedure to a person, the medical research practitioner must make reasonable efforts in the circumstances to ascertain if the person has any of the following:

An advance care directive

An *advance care directive* is a directive given by a person under Part 2 of the MTPDA in a document that sets out the person's binding instructions or preferences and values in relation to the administration of medical treatment to that person in the event the person does not have decision-making capacity for that medical treatment. In relation to an advance care directive, medical treatment includes the administration of a medical research procedure.

Therefore, a person may make an *advance care directive* in relation to a medical research procedure. A person's wishes with respect to a medical research procedure may be set out in an *instructional directive* or a *values directive* within their *advance care directive*.

A medical treatment decision maker

A medical treatment decision maker in relation to a person is, in order of priority, one of the following:

- An appointed *medical treatment decision maker* (an adult appointed as such by a person pursuant to the MTPDA) if the appointee is reasonably available and willing and able to make the medical treatment decision.
- A guardian appointed by VCAT under the *Guardianship and Administration Act 1986 (Vic)* who has the power under that appointment to make medical treatment decisions on behalf of a person if the guardian, in the circumstances, is reasonably available and willing and able to make the medical treatment decision
- The first of the following persons who is in close and continuing relationship with the person and who, in the circumstances, is reasonably available and willing and able to make the medical treatment decision:
 - a) the spouse or domestic partner of the person
 - b) the primary carer of the person, or
 - c) the first of the following and, if more than one person fits the description, the oldest of those persons:
 - i. an adult child of the person
 - ii. a parent of the person
 - iii. an adult sibling of the person.

Medical research practitioner must ensure research project is ethically approved

Before administering any medical research procedure to a person who does not have decision-making capacity to make a medical treatment decision in respect of that procedure, a medical research practitioner must ensure the research project has been approved by the relevant human research ethics committee.

Under the MTPDA, a human research ethics committee is any of the following:

- A human research ethics committee established in accordance with the requirements of the '*National Statement on Ethical Conduct in Research Involving Humans* published by the National Health and Medical Research Council in 1999 as in force from time to time' [sic] or that document's replacement.

Laws relating to the provision of consent for persons that do not have decision-making capacity to participate in research

- An ethics committee established under the by-laws of any of the following as defined under the *Health Services Act 1988* (Vic): a denominational hospital, a multi-purpose service, a public health service, or a public hospital.

The process of obtaining consent

Provided the above requirements have been satisfied, a medical research practitioner may administer a medical research procedure to a person who does not have capacity to make a medical treatment decision in respect of that procedure in the circumstances below.

1. The person has consented to the procedure being administered under an *instructional directive*.

An *instructional directive* is an express statement in an *advance care directive* of a person's medical treatment decision. An *instructional directive* may relate to particular form (or forms) of medical research procedure or generally about medical research procedures and may apply in all or specified circumstances in relation to those procedures (section 75(b)(i)).

2. If there is no relevant *instructional directive*, the person's medical treatment decision maker has consented to the procedure being administered.

Section 77 of the MTPDA provides that a person's medical treatment decision maker may consent to the administration of a medical research procedure to the person if the medical treatment decision maker reasonably believes that the person would have consented to the procedure if the person had decision-making capacity.

In making such a decision, a medical treatment decision maker must do the following:

- Consider any valid and relevant *values directive*. A *values directive* is a statement in an *advance care directive* of a person's preference and values as the basis on which the person would like any medical treatment decisions made on their behalf.
- Consider any other relevant preferences that the person has expressed and the circumstances in which those preferences were expressed.
- If no relevant preferences may be identified, give consideration to the person's values, expressed other than by way of a *values directive* or inferred from the person's life.
- Consider:
 - the likely effects and consequences of the medical research procedure, including the likely effectiveness of the procedure, and whether these are consistent with the person's preferences or values, and
 - whether there are any alternatives, including not administering the medical research procedure, that would be more consistent with the person's preferences or values.
- Act in good faith and with due diligence.

If a medical treatment decision maker is unable to apply the above process because it is not possible to ascertain the person's preferences or values, the medical treatment decision maker is required to:

- make a decision that promotes the personal and social wellbeing of the persons, having regard to the need to respect the person's individuality, and
- consider:

OFFICIAL

Laws relating to the provision of consent for persons that do not have decision-making capacity to participate in research

- the likely effects and consequences of the medical research procedure, including the likely effectiveness of the procedure, and whether these promote the person's personal and social wellbeing, having regard to the need to protect the person's individuality, and
- whether there are alternatives, including refusing the medical research procedure, that would better promote the person's personal and social wellbeing, having regard to the need to protect the person's individuality.

In making a decision, the medical treatment decision maker must also consult with any person who they reasonable believe the person would want to be consulted in the circumstances.

3. If the person does not have a medical treatment decision maker, the administration of the procedure is authorised under Division 3 of Part 5 of the MTDPA.

A medical research practitioner may only administer a medical research procedure by way of authorisation under Division 3 of Part 5 if the medical research practitioner has taken reasonable steps in the circumstances to locate a person's *instructional directive* and identify and contact the medical treatment decision maker of the person to obtain consent to the administration of a medical research procedure to the person but has been unable to do so in both cases.

Section 80(1) states that a medical research practitioner may administer a medical research procedure without consent to a person who does not have a medical treatment decision maker if **all** of the following apply:

- The medical research practitioner believes on reasonable grounds that inclusion of the person in the relevant research project would not be contrary to:
 - the person's values expressed by way of a *values directive* or otherwise or inferred from the person's life
 - any other relevant preferences that the person has expressed, and
 - the person's social and personal wellbeing, having regard to the need to respect their individuality.
- The medical research practitioner believes on reasonable grounds that the relevant human research ethics committee has approved the relevant research project in the knowledge that a person may participate in the project without a prior consent of the person or a medical treatment decision maker.
- The medical research practitioner believes on reasonable grounds that:
 - one of the purposes of the relevant research project is to assess the effectiveness of the procedure being researched, and
 - the medical research procedure poses no more of a risk to the person than the risk that is inherent in the person's condition and alternative medical treatment.
- The medical research practitioner believes on reasonable grounds that the relevant research project is based on valid scientific hypotheses that support a reasonable possibility of benefit for the person as compared with standard medical treatment.

Obligations of medical research practitioner after utilising Division 3 of Part 5

A medical research practitioner who administers a medical research procedure under Division 3 of Part 5 of the MTDPA must do **all** of the following:

- Continue to take reasonable steps to identify and contact the person's medical treatment decision maker to seek consent to the continuation of the procedure on the person.

Laws relating to the provision of consent for persons that do not have decision-making capacity to participate in research

- Before, or as soon as practicable after, administering a medical research procedure sign a certificate certifying the matters specified in section 81(1)(a) and stating the matters specified in section 81(1)(b) of the MTPDA. The certificate must be kept in the person's clinical records and a copy must be forwarded to the Victorian Public Advocate and the relevant human research ethics committee.
- Inform the person's medical treatment decision maker of the person (if the person recovers decision-making capacity) as soon as reasonably practicable of the person's inclusion in the research project and the option to refuse the continuation of the procedure and withdraw from the project.

Consent given under the *Guardianship and Administration Act 1986 (Vic)*

The MTPDA does not affect any consent under section 42S (person responsible) or section 42T (procedural authorisation) of the *Guardianship and Administration Act 1986 (Vic)* (**GAA**). Section 104 of the MTPDA provides that:

- upon the commencement of section 77 of the MTPDA, the consent of a person responsible under section 42S of the GAA to the administration of a medical research procedure to a person is taken to be consent of the medical treatment decision maker under section 77 of the MTPDA, and
- upon commencement of section 80(1) of the MTPDA, procedural authorisation under section 42T of the GAA to the administration of a medical research procedure to a person is taken to be authorisation under section 80(1) of the MTPDA.

The conduct of a medical research procedure in the emergency context

Section 53(1) of the MTPDA may apply in relation to a medical research procedure that is to be performed in an emergency context.

53(1) provides that a health practitioner (rather than a medical research practitioner) may administer a medical research procedure to a person without consent or authorisation under Part 5 of the MTPDA if the practitioner believes on reasonable grounds that the medical research procedure is necessary, as a matter of urgency to:

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

A health practitioner is:

- a registered health practitioner (as defined in the *Health Practitioner Regulation National Law*)
- an operational staff member within the meaning of the *Ambulance Services Act 1986 (Vic)*, or
- the holder of a non-emergency patient transport service licence within the meaning of the *Non-Emergency Patient Transport Act 2003 (Vic)* or an employee or contractor of such a holder who provides such a service.

The use of the term health practitioner in section 53 recognises that research projects conducted in emergency circumstances are often conducted in the ambulance setting.

However, a health practitioner is not permitted to administer a medical research procedure to a person under section 53(1) if the practitioner is aware that the person has refused the particular medical treatment or

Laws relating to the provision of consent for persons that do not have decision-making capacity to participate in research

procedure by way of an *instructional directive* or a legally valid and informed refusal of treatment by or under another form of informed consent. Notwithstanding this prohibition, a health practitioner is not required to search for an *advance care directive* that is not readily available to the practitioner if the circumstances set out in section 53(1) apply to the person to whom or a medical research procedure is being administered.

The onus will be on a health practitioner relying on section 53(1) to demonstrate that the relevant grounds apply. Given that a medical research procedure is typically conducted to ascertain the effectiveness of a particular procedure and to determine (or prove) whether the procedure can, in fact, save life or prevent damage or injury to health or prevent suffering, there may be limited circumstances where section 53 applies.

Role of Victorian Civil and Administrative Tribunal

VCAT does not have a role in relation to the approval of a medical research procedure, unlike some other jurisdictions. However, VCAT does have a role in relation to issues arising under Part 5 and other sections of the MTPDA which includes the following:

- VCAT may hear any matter, question or dispute relating to the administration of a medical research procedure to a person.
- VCAT may give to a person's medical treatment decision maker (upon their application) directions or an advisory opinion on any matter or question relating to the scope or exercise of the decision maker's authority to consent on behalf of the person.
- VCAT hears and determines issues relating to guardianship.

In exercising any power under the MTPDA, VCAT will also have regard to any relevant human rights as set out in the *Charter of Human Rights and Responsibilities Act 2006* (Vic). This principle is reinforced in *ZEH (Guardianship) [2015] VCAT 2051* (30 December 2015), where the VCAT Member ruled that in interfering the principles of the predecessor legislation to the MTPDA (the *Guardianship and Administration Act 1986* (Vic)), VCAT is generally bound to act compatibly with any relevant human rights set out in the *Charter of Human Rights and Responsibilities Act 2006* (Vic).

While *ZEH (Guardianship)* was determined in the context of the *Guardianship and Administration Act 1986* (Vic) and concerned an application regarding whether an impaired capacity person should be required to undergo sterilisation, the principle would appear to be generally applicable to issues and considerations regarding the conduct of a medical research procedure pursuant to the MTPDA.

Checklist of matters for HRECs to consider

- Does the research involve any participant aged 18 years or older who does not have decision-making capacity in relation to the procedure?
- Does the research constitute a medical research procedure as defined in the MTPDA?
- Does the consent model for the medical research procedure properly consider and address the requirements in Part 5 of the MTPDA, including whether there is a relevant *instructional directive* or a medical treatment decision maker?
- Will the circumstances of the conduct of the research generally allow a medical research practitioner to ascertain whether the person has made an *advance care directive* or to identify the medical treatment decision maker in time?
- If the medical research practitioner contemplates that the medical research procedure might be administered under section 80 of the MTPDA (administering the procedure if a person has no medical treatment decision maker), will the procedure satisfy all the relevant requirements for it to proceed under that section?
- Has the researcher prepared participant information sheet and consent forms, including for medical treatment decision makers, 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 persons who do not have decision-making capacity in relation to the procedure?
- Having considered the above, does the HREC need to seek further advice from the researcher?

To receive this document in another format, phone 0408 274 054, using the National Relay Service 13 36 77 if required, or [email Coordinating Office for Clinical Trial Research <multisite.ethics@health.vic.gov.au>](mailto:multisite.ethics@health.vic.gov.au).

Authorised and published by the Victorian Government, 1 Treasury Place, Melbourne.

© State of Victoria, Australia, Department of Health, March 2023.