# Consent process for research involving adults without decision-making capacity

## Medical Treatment Planning and Decisions Act 2016 (Vic) and the National Statement on Ethical Conduct in Human Research (2025)

The **Medical Treatment Planning and Decisions Act 2016 (Vic)** (the Act) provides a framework for making decisions about medical treatment, including medical research procedures, when adults do not have capacity to make their own decisions. This page explains how researchers at Austin Health obtain consent for these participants.

*This page is guidance only. It does not replace the Act, legal advice, or the conditions of a project's ethics approval. If you are unsure, contact the Discovery and Innovation Unit (DIU) early.*

## Medical Treatment Planning and Decisions Act 2016

The Act allows Victorians to:

- Make an **advance care directive** (an instructional directive, a values directive, or both)
- Appoint a **medical treatment decision maker** (MTDM) to make decisions for them if they lose decision-making capacity
- Appoint a **support person** to help them get, understand and communicate information about decisions. A support person does not make the decision.

Part 5 of the Act allows an MTDM to consent to a **medical research procedure** for an adult who does not have decision-making capacity for that procedure. Guardians appointed by VCAT under the Guardianship and Administration Act 2019 (Vic) can act as MTDM where their appointment covers medical treatment decisions.

**The Public Advocate does not consent to research.** The Office of the Public Advocate can consent to significant medical treatment when a person has no MTDM, but this does not extend to medical research procedures. If no MTDM can be found, only the pathway in Step 4 applies.

## The National Statement

The Act sets out **who may consent** and the steps that must be followed. The National Statement on Ethical Conduct in Human Research (2025) sets out whether including the person is **ethically acceptable** and what safeguards are needed. It applies to all human research, including research the Act does not cover.

Researchers must meet both. A lawful decision maker does not on its own make research ethical, and HREC approval does not on its own replace the legal consent steps in the Act.

## Process for obtaining consent

Part 5 of the Act sets out a four-step process for including adults without decision-making capacity in research involving a medical research procedure. Complete the steps in order.

### Step 1: Approval of the research by a Human Research Ethics Committee (HREC)

- A medical research procedure must not be given to a person without decision-making capacity unless the project has been approved by an HREC.
- The HREC must know that people without capacity may be included, and the procedure must follow any conditions of approval.
- Giving an unapproved medical research procedure is an offence under the Act.

### Step 2: Is the person likely to regain capacity within a reasonable time?

Assess whether the person has capacity for **this** decision. Do not assume a person lacks capacity because of their age, disability, diagnosis, or how they communicate.

A reasonable time is the time by which, given the nature of the project, the procedure would need to be done, having regard to:

- the person's medical or physical condition
- their stage of treatment or care
- other circumstances specific to the person.

If the person **is** likely to regain capacity within a reasonable time, you must not proceed under Part 5. Wait and ask the person.

If not, record in the person's **clinical record**, before or soon after the procedure: that you were satisfied they did not have capacity, that they were not likely to regain it within a reasonable time, and your reasons.

## Step 3: Find out whether there is an advance care directive or a medical treatment decision maker

Make reasonable efforts in the circumstances to find out. Depending on the situation, this may include:

- checking the clinical record
- asking family or friends who are present
- contacting the next of kin or emergency contact on the medical record
- contacting the person's GP
- contacting a residential care or other health facility the person has attended.

It is never reasonable to delay medical treatment to locate an advance care directive if this would cause the person's health to significantly deteriorate.

- If an **instructional directive** refuses the procedure, you must not proceed.
- A **values directive** must be considered by the MTDM.

The **MTDM** is the first person in this list who is reasonably available, willing and able to make the decision. There is only one MTDM at a time.

- An **appointed** medical treatment decision maker (including enduring powers of attorney for medical treatment made before March 2018). Sight the appointment document or confirm a copy is in the medical record, and check for any limitations.
- A **guardian appointed by VCAT** with power to make medical treatment decisions.
- Otherwise, the first of the following adults with a **close and continuing relationship** with the person: spouse or domestic partner; primary carer (not a paid carer); adult child; parent; adult sibling. Where two people rank equally, the eldest is the MTDM.

**How the MTDM decides.** The MTDM may consent only if they reasonably believe the person **would have consented** if they had capacity, considering any values directive and the person's other known preferences and values. Consent must meet the requirements of the HREC approval, and consent to treatment does not cover research.

If an MTDM is found and **decides the person will not take part, you must not proceed**.

## Step 4: If there is no advance care directive and no medical treatment decision maker

This pathway is mainly for acute and critical care research, and is only available if the HREC has **specifically approved** the project on the basis that participants may be included without prior consent. The medical research practitioner must believe on reasonable grounds that:

- including the person is **not contrary** to their known values, preferences, or personal and social wellbeing
- one purpose of the project is to assess the effectiveness of the procedure

- the procedure poses **no more risk** than the risk inherent in the person's condition and alternative treatment
- the project is based on valid scientific hypotheses supporting a **reasonable possibility of benefit** compared with standard treatment.

The practitioner must continue to take reasonable steps to find the MTDM and seek their consent to continue.

**Medical research practitioner's certificate.** Before, or as soon as practicable after, the procedure, the practitioner must sign a certificate stating that the person does not have capacity for the procedure, that their MTDM cannot be identified or contacted, and that the MTDM (if found) or the person (if they regain capacity) will be informed.

- Send a copy of the first certificate to the **Office of the Public Advocate and the HREC within 2 business days**.
- If the procedure continues, sign and send a new certificate at intervals of no more than 30 days.
- Keep each certificate in the clinical record.

## Medical research procedures in an emergency

In an emergency, a medical research procedure may be given without consent if the practitioner believes on reasonable grounds it is necessary, as a matter of urgency, to save the person's life, prevent serious damage to their health, or prevent significant pain or distress. The project must still have **prior HREC approval**.

This cannot be relied on if the practitioner knows the person has refused the procedure, for example in an instructional directive. The provision is intended for research into the effectiveness of emergency treatments (such as comparing two emergency treatments where there is clinical equipoise), not for routine recruitment.

## When capacity returns

Capacity often improves, for example after delirium, sedation, anaesthesia, stroke or critical illness. Your protocol should say how you will check for this. When the person regains capacity, or an MTDM is later found:

- As soon as reasonably practicable, tell them about the person's inclusion in the research and what has happened so far.
- Ask for the person's **own consent** to continue. If they decline, withdraw them from further research procedures.
- Make clear that withdrawing will not affect the person's access to care, and explain what will happen to information or samples already collected, as approved by the HREC.

## Definition of medical research procedure

A medical research procedure is a procedure carried out for medical research, including, as part of a clinical trial, giving a medicine or using equipment or a device. It does not include:

- a non-intrusive examination, such as looking in the mouth, throat, nose, eyes or ears, or measuring height, weight or vision
- observing a person's activities
- a survey
- collecting or using information, including health information or personal information.

**Research outside the Act**

- Research that only involves surveys, interviews, observation or health records is **not** covered by the Act's consent process, but **is** covered by the National Statement and privacy law (Health Records Act 2001 (Vic); Privacy Act 1988 (Cth)).
- The HREC will decide the consent pathway, such as consent from a person close to the participant or a waiver of consent under Chapter 2.3 of the National Statement.
- If you are unsure which applies, contact DIU before you submit.

## Links and documents

- National Statement on Ethical Conduct in Human Research (2025) (NHMRC)
- Medical Treatment Planning and Decisions Act 2016 (Health.vic)
- Guardianship and Administration Act 2019 (Justice.vic)
- Office of the Public Advocate
- Austin Health research policies, SOPs and Clinical Trial Governance Framework (OPPIC)

## Contacts

- **Austin Health Discovery and Innovation Unit:** Email research@austin.org.au
- **Austin Legal team:** Email legal@austin.org.au
- **Office of the Public Advocate advice service:** 1300 309 337
- **Austin Health Patient Experience** and the Health Complaints Commissioner (Victoria) for concerns or complaints

## Document control

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