

Alfred Health Alfred Hospital Ethics Committee

Information for researchers about changes to legislation

The *Medical Treatment Planning and Decisions (MTP&D) Act 2016 (Vic)* comes into effect on 12th March 2018. This new Act takes over from the *Guardianship & Administration (G&A) Act 1986 (Vic)* in governing the provision of medical research procedures (MRP) to participants without decision-making capacity. The 'changeover' affects research that (a) involves adult participants without decision making capacity *and* (b) involves a medical research procedureⁱ e.g. a clinical trial or other interventional study.

What's new or different?

The research provisions in the new Act are very similar to those in the G&A Act, but there are a few important changes to note:

- People can now make legally binding advance care directives. Advance Care Directives take two forms:
 - instructional directives that authoritatively state the person's consent or refusal to participate in specific treatments and trials; and
 - values directives which describe the person's views and values, which need to be taken into account by both the medical treatment decision maker and the medical research practitioner.
- Medical research practitioners must make reasonable efforts to locate both a medical treatment decision maker [formerly the Person Responsible] and an advance care directive (ACD) when including a patient without decision-making capacity in research that involves a medical research procedure. [Section 73]
- The list of people who can be medical treatment decision maker has fewer options (no longer includes grandparents, aunts/uncles/niece/nephew) and the decision maker needs to be someone in a close and continuing relationship with the person for whom they are making the decision. [Section 55]
- The focus of decision-making has shifted from the person's best interests to the person's preferences, values, and personal and social well-being (i.e. what the person would have chosen to do, if the person had been competent to make the decision).
- Where there is no medical treatment decision maker and the medical research practitioner administers the medical research procedure without consent [formerly Procedural Authorisation], there are some new factors that the medical research practitioner needs to take into account, including the person's expressed or inferred values and preferences. [Section 80/81]
- The certificate that the medical research practitioner must sign and submit to the Office of the Public Advocate (OPA) and the Ethics Committee is now referred to as the Section 81 Certificate [formerly Section 42T Certificate].

- For medical research procedures conducted in an emergency situation [formerly referred to as 'under Section 42A'], the provisions in Section 53 of the new Act include that a person's advance care directive must be taken into account if readily available to the medical research practitioner but the practitioner is not required to search for one.

Changes to terms and references:

Old reference – G&A Act	New reference – MTP&D Act
Section 42A - Emergency treatment	Section 53 - Medical treatment and medical research procedures in an emergency
Person Responsible	Medical Treatment Decision Maker (Section 77) (Note: 'hierarchy' has fewer eligible categories)
Procedural Authorisation	Section 80/81 (Administering a medical research procedure if person has no medical treatment decision maker)
Section 42T certificate	Section 81 certificate (Medical research practitioner's certificate)

How does this affect my current approved project?

For projects already approved to be conducted under the G&A Act research provisions:

- Overall ethical approval of the project stands.
- Any participants who have already undergone the MRP don't need to consent again.
- Researchers should:
 - Comply with the MTP&D Act's provisions from 12th March 2018 onwards when recruiting/consenting new participants and administering a medical research procedure.
 - Familiarise themselves with the research provisions in the new MTP&D Act.
 - Review their consent processes, taking into account the new Act (particularly the steps to check for an ACD).
 - Develop a Standard Operating Procedure or Flow Chart to describe the consent process steps and provide this to those involved in recruiting/consenting participants to the study. *This is recommended but does not need to be submitted to the Ethics Committee for approval.*
 - For projects approved for Procedural Authorisation, replace pre-populated S42T certificates with S81 certificates (to use from 12th March 2018 onwards).
- The currently approved PICFs can still be used for prospective recruitment.

- The Medical Treatment Decision Maker Checklist (which replaces the Person Responsible Checklist) should be used together with the PICF for the medical treatment decision maker from 12th March 2018.
- If/when amendments are next submitted, the Protocol and PICFs for Person Responsible (PR), PR following Procedural Authorisation (PA), Participant following PR, Participant following PA, and Participant following PA and PR should be updated. [Refer to the DHHS [PICF templates](#).]

How does this affect new projects?

- New projects should be submitted on the latest versions of the Victorian Specific Module (VSM) and PICF templates. These were updated by DHHS in late February 2018 to reflect the new Act. Access the current forms via the [Ethics & Research Governance section](#) of the Alfred Health website.
- Note that the VSM has new questions in Section One about including people without decision-making capacity in research that involves a medical research procedure. Answering these questions will help researchers to comply with the new Act.
- The VSM Guidelines have useful information and specific instructions for completing the form.
- Note that the term ‘person responsible’ is retained alongside ‘medical treatment decision maker’ on the PICF templates as the former term is used in other jurisdictions.

Revised Alfred Health/Alfred Hospital Ethics Committee documents

The following Alfred Health documents have been amended to reflect the new Act and are available [here](#):

- Medical Treatment Decision Maker Checklist. This helps to establish the appropriate decision maker and includes the key considerations that the decision maker must make. All projects that involve consent from the medical treatment decision maker for an Alfred Health patient must use the Medical Treatment Decision Maker Checklist with the PICF.
- Guideline: Obtaining telephone consent from the medical treatment decision maker. This guideline sets out the Ethics Committee’s expectations when ‘in person’ consent cannot be obtained from the medical treatment decision maker.

Further information

The *Medical Treatment Planning & Decisions Act 2016* (Vic) and a useful Guide and Summary are available from the Department of Health & Human Services website [here](#).

ⁱ ‘Medical research procedure’ is defined in the MTP&D Act as follows:

“Medical Research Procedure” means—

- (a) a procedure carried out for the purposes of medical research, including, as part of a clinical trial—
 - (i) the administration of pharmaceuticals; or
 - (ii) the use of equipment or a device; or
- (b) a prescribed medical research procedure, but does not include any of the following—
- (c) any non-intrusive examination including—
 - (i) a visual examination of the mouth, throat, nasal cavity, eyes or ears; or
 - (ii) the measuring of a person’s height, weight or vision;

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- (d) observing a person's activities;*
 - (e) undertaking a survey;*
 - (f) collecting or using information, including either of the following—*
 - (i) personal information within the meaning of the Privacy and Data Protection Act 2014;*
 - (ii) health information [as that term is used in the Health Records Act];*
 - (g) any other procedure prescribed not to be a medical research procedure.*