Office of the Public Advocate

March 2018

Medical research procedures flowchart

Process under the *Medical Treatment Planning and Decisions Act 2016*

www.publicadvocate.vic.gov.au

Is there an emergency?

- **No** → **Does the patient have capacity to make a decision?**
- **Yes** → **Medical research practitioner can administer the procedure** unless aware of refusal in directive or certificate

Does the patient have capacity to make a decision?

- **No** → **Has the patient refused the procedure in a directive or certificate?**
- **Yes** → **Patient can consent to or refuse the medical research procedure**

Has the patient refused the procedure in a directive or certificate?

- **No** → **Is there a medical treatment decision maker?**
- **Yes** → **Do not proceed with the procedure**

Is there a medical treatment decision maker?

- **No** → If section 80 requirements are met, medical research procedure can be administered without consent.

  A section 81 certificate must be completed by the medical research practitioner and copies provided to:

  - the Office of the Public Advocate (OPA)
  - the relevant human research ethics committee.

  See the OPA website for the section 81 certificate.
- **Yes** → **Medical treatment decision maker consents to, or refuses, the procedure**

The research project must have been approved by the relevant human research ethics committee. Any medical research procedure must be administered in accordance with that approval.

In an emergency

Where the patient is unable to make the decision, a health practitioner may administer a medical research procedure without consent if it 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 may administer emergency treatment to a patient without consent, unless they are aware that the patient has refused the treatment in a directive or certificate.

Decision-making capacity

The patient is able to understand the information relevant to the decision, 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, and is able to communicate their decision in some way. Sometimes a relevant specialist may be required to make a capacity assessment.

Directive or certificate refusing the medical research procedure

The procedure must not proceed if:

- there is a valid refusal of medical treatment certificate, made prior to 12 March 2018 in accordance with the *Medical Treatment Act 1988*
- the patient has refused the procedure in an instructional directive (in a valid advance care directive) in accordance with the *Medical Treatment Planning and Decisions Act 2016.*

A medical research practitioner must make reasonable efforts in the circumstances to ascertain if the patient has an advance care directive, or medical treatment decision maker.

Medical treatment decision maker

See the information for health practitioners page of the OPA website to identify the patient's medical treatment decision maker.

Section 80 requirements

Firstly, the medical research practitioner must believe on reasonable grounds that inclusion of the patient in the relevant research project would not be contrary to the following:

- the patient's values, whether expressed by way of a values directive in an advance care directive or otherwise, or inferred from the person's life
- any other relevant preferences that the patient has expressed, having regard to the circumstances in which those preferences were expressed
- the personal and social wellbeing of the patient, having regard to the need to respect the person's individuality.

Secondly, the medical research practitioner must believe on reasonable grounds that the relevant human research ethics committee has approved the research project in the knowledge that a person may participate who:

- does not have decision-making capacity to consent nor
- a medical treatment decision maker who can consent on their behalf.

Thirdly, the medical research practitioner must believe on reasonable grounds that:

- one of the purposes of the relevant research projects is to assess the effectiveness of the procedure being researched and
- the procedure poses no more of a risk to the patient than the risk that is inherent in the patient's condition and alternative medical treatment.

Fourthly, the medical research 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 medical treatment.

Fifthly, the medical research practitioner must continue to take reasonable steps to identify and contact the patient's medical treatment decision maker to seek consent.