Office of the Public Advocate

MEDICAL RESEARCH PROCEDURES WITHOUT CONSENT

Certificate for medical research practitioners to complete for Medical Research Procedures without consent pursuant to s.81 of the *Medical Treatment Planning and Decisions Act* 2016 ('MRP Certificate')

What you need to do

- The MRP Certificate must be completed before, or as soon as practicable after a medical research procedure is carried out on a person without consent
- The medical research practitioner must sign the certificate
- The medical research practitioner must provide the Public Advocate and the relevant human research ethics committee with a copy of this certificate:
    - in the case of the first certificate, as soon as practicable (and in any event within 2 business days) after administering the procedure; or
    - in any other case, at intervals of no more than 30 days
- Submit the completed document to OPA, by emailing it to: OPA-Medforms@justice.vic.gov.au and to the relevant human research ethics committee
- It is the responsibility of the medical research practitioner to ascertain the contact details of the relevant Human Research Ethics Committee.

What the Office of the Public Advocate (OPA) will do

The role of OPA is not to provide consent to the medical research procedure but to ensure that the legislative requirements have been met.

OPA's Medical Decisions Team will telephone the medical research practitioner to confirm receipt of the MRP certificate and to note whether the legislative requirements have been met.

If OPA is concerned about whether a medical research procedure should be performed on a person, or about the continuation of medical research procedures on a person, then we will discuss such concerns with the medical research practitioner. If following any discussion, we continue to have concerns OPA may choose to apply to VCAT for an appropriate order.

Further information is available from the OPA Advice Service on 1300 309 337 or www.publicadvocate.vic.gov.au.

Office of the Public Advocate

MEDICAL RESEARCH PROCEDURES WITHOUT CONSENT

MEDICAL RESEARCH PRACTITIONER'S CERTIFICATE and STATEMENT PURSUANT TO SECTION 81 OF THE MEDICAL TREATMENT PLANNING AND DECISIONS ACT 2016 ('MRP CERTIFICATE')

To:

The Medical Decisions Team

Office of the Public Advocate

Level 1, 204 Lygon St

Carlton 3053

and

To:

_____

(insert the name of the relevant Human Research Ethics Committee)

_____

(insert address of the Human Research Ethics Committee)

Phone: _____ **Fax:** _____

HREC project number: _____

Medical Research Practitioner who will administer / has administered the medical research procedure and who is making this certification and statement	
Name of medical research practitioner	

The person to whom the medical research procedure is to be / has been administered	
Name of the person	
Address of the person	
Date of person's birth	

The medical research procedure	
Describe the medical research procedure, including what would be / was involved for the person.	
What is the proposed commencement date, or what was the commencement date, of the medical research procedure?	

I CERTIFY THAT:

1. The person does not have decision making capacity to make a medical treatment decision in respect of this medical research procedure. (MTPDA s.81(1)(a)(i))

2. The patient's medical treatment decision maker cannot be identified or contacted. (MTPDA s.81(1)(a)(ii))

3. I believe on reasonable grounds that inclusion of the person in this medical research project and the person's being the subject of the proposed medical research procedure, are not contrary to the person's *values*, *preferences* and their *personal and social wellbeing*. (MTPDA s.81(1)(a)(iii) & s.80(1)(a))

   In forming this belief, I have considered:

   a. the person's *values*, whether expressed by way of a values directive or otherwise, or as inferred from the person's life

   b. any other relevant *preferences* the person has expressed, having regard to the circumstances in which those preferences were expressed

   c. the person's *personal and social wellbeing*, having regard to the need to respect the person's individuality.

4. I believe on reasonable grounds that the relevant human research ethics committee has approved this medical research project in the knowledge that a person may participate in the project without the prior consent from the person or a medical treatment decision maker. (MTPDA s.81(1)(a)(iii) & s.80 (1)(b))

5. I believe on reasonable grounds that one of the purposes of the medical 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 is inherent in the person's condition and alternative medical treatment. (MTPDA s.81(1)(a)(iii) & s.80 (1)(c))

6. I believe on reasonable grounds that the medical research project is based on valid scientific hypotheses that support a reasonable possibility of benefit for the person as compared with standard medical treatment. (MTPDA s.81(1)(a)(iii) & s.80(1)(d))

7. I will 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. (MTPDA s.81(1)(a)(iii) & s.80(2))

AND I STATE THAT:

8. If the person's medical treatment decision maker is subsequently identified that person will be informed of -

   a. the procedure,

   b. the person's inclusion in the research project, and

   c. the option to refuse the continuation of the procedure in the project without compromising the person's ability to receive any available alternative medical treatment. (MTPDA s.81(1)(b)(i) & s.81(2))

9. If the person recovers decision-making capacity, the person will be informed of –

   a. the procedure,

   b. the person's inclusion in the research project, and

c. the option to refuse the continuation of the procedure in the project without compromising the person's ability to receive any available alternative medical treatment. (MTPDA s.81(1)(b)(ii) & s81(2))

Signature of the medical research practitioner	
Signed by the medical research practitioner	
Date	
Contact address	
Contact numbers	Phone: Fax: Email:
Other information	
Name of person submitting the certificate (if not the medical research practitioner)	
Signature of person submitting the certificate	
Contact numbers (if different from above)	Phone: Fax: Email:

Submit this form to Medical Decisions Team at OPA by emailing it to: OPA-Medforms@justice.vic.gov.au and to the relevant human research ethics committee

The submission of these forms will only be checked Monday to Friday between 9am and 4.45pm. If submitted outside of these hours it will not be attended to until the next working day. If the matter is urgent outside of office hours, call 1300 309 337 for advice.

It is the responsibility of the medical research practitioner to ascertain the contact details of the relevant Human Research Ethics Committee.

Office of the Public Advocate

MEDICAL RESEARCH PROCEDURES WITHOUT CONSENT

Information for medical research practitioners who are completing an MRP Certificate pursuant to Section 81 of the Medical Treatment Planning and Decisions Act 2016

A reference to 'the Act' is a reference to the *Medical Treatment Planning and Decisions Act 2016.*

Refer to part 5 of this information guide for definitions of the following terms:

- Decision making capacity
- Instructional directive
- Medical research practitioner
- Medical research procedure
- Medical treatment decision
- Medical treatment decision maker

1. *Legislative criteria* to be satisfied before a medical research practitioner may *administer* a medical research procedure to a person who lacks decision making capacity to consent to the procedure

(a) s.72(1): The medical research practitioner has determined that the person does not have decision making capacity to make a medical treatment decision in relation to the proposed medical research procedure; **and**

(b) s.72(2): The medical research practitioner has determined that the person is not likely to recover decision-making capacity within a reasonable time to make the medical treatment decision in relation to the proposed medical research procedure; **and**

(c) s.73(1): The medical research practitioner has made reasonable efforts in the circumstances to ascertain if the person has either or both an advance care directive and a medical treatment decision maker; **and**

(d) s.75(a): The medical research practitioner has ascertained that the research project has been approved by the relevant human research ethics committee; **and**

(e) s.75(b): The medical research practitioner must not administer the proposed medical research procedure unless the person consented in an instructional directive, or the person's medical treatment decision maker consented to the procedure or the procedure is authorised under Division 3 of the Act (medical research procedures without consent); **and**

(f) s.76: A medical research procedure must be administered in accordance with the relevant human research ethics committee approval; **and**

(g) s.78: Before, or as soon as practicable after, administering a medical research procedure to a person who does not have decision making capacity in relation to the procedure, the medical research practitioner must document in the person's clinical records that they were satisfied the person did not have decision making capacity and the person was unlikely to recover decision making capacity within a reasonable time and their reasons for being satisfied.

2. *Further legislative criteria* to be satisfied before a medical research practitioner may *administer* a medical research procedure to a person without consent (when there is no instructional directive or medical treatment decision maker)

(a) s.79(a): A medical research practitioner must take reasonable steps in the circumstances to locate a person's instructional directive (if any) but has been unable to do so; **and**

(b) s.79(b): A medical research practitioner must take reasonable steps in the circumstances to identify and/or contact the medical treatment decision maker of the person to obtain consent to the administration of the medical research procedure; **and**

(c) s.80(1)(a):The medical research practitioner may administer a medical research procedure without consent if he/she believes on reasonable grounds that inclusion of the person in the relevant research project would not be contrary (i) to the person's values, (ii) preferences or (iii) personal and social wellbeing being of the person; **and**

(d) s.80(1)(b):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 the person may participate in the project without the prior consent of the person or a medical treatment decision maker; **and**

(e) s.80(1)(c): 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 that the procedure poses no more risk to the person than the risk that is inherent in their condition and alternative medical treatment; **and**

(f) s.80(1)(d): 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; and

(g) s.81(1): Before, or as soon as practicable after, administering a medical research procedure under a medical research practitioner a must sign a certificate pursuant to the requirements of this section – as described below in part 3 of this information guide.

3. *Further legislative criteria* to be satisfied if a medical research practitioner does commence to administer a medical research procedure to a person without consent

(a) s.78: If the medical research practitioner did not comply with point 1(g) described above in this information guide, prior to the commencement of the medical research procedure, they must do so, as soon as practicable after commencing to administer the procedure; **and**

(b) s.80(2): The medical research practitioner must 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; **and**

(c) s.81(1): If the medical research practitioner did not comply with point 2(g) described above in this information guide, prior to the commencement of the medical research procedure, they must do so, as soon as practicable after commencing to administer the procedure; **and**

(d) s.81(3): The medical research practitioner must provide a copy of the s.81 Certificate to the Public Advocate and to the relevant human research ethics committee; in the case of the first

certificate as soon as practicable (and in any event within 2 business days) after administering the procedure or in any other case, at intervals of no more than 30 days.

4. Medical Research Practitioner's Certificate (MRP Certificate)

Before, or as soon as practicable after, administering a medical research procedure without consent (and in the case of a procedure lasting longer than 30 days, at intervals of no longer than 30 days) a medical research practitioner a must sign a certificate certifying the following:

(a) s.81(1)(a)(i): that the person to whom the medical research procedure is being administered does not have decision-making capacity to make a medical treatment decision in respect of that procedure; **and**

(b) s.81(1)(a)(ii): that the person's medical treatment decision maker cannot be identified or contacted (as the case may be); **and**

(c) s.81(1)(a)(iii) as to each of the matters set out in section 80 (described in (d), (e), (f), (g) below

(d) s.80(1)(a):The medical research practitioner believes on reasonable grounds that inclusion of the person in the relevant research project would not be contrary (i) to the person's values, (ii) preferences or (iii) personal and social wellbeing being of the person; **and**

(e) s.80(1)(b):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 the person may participate in the project without the prior consent of the person or a medical treatment decision maker; **and**

(f) s.80(1)(c): 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 that the procedure poses no more risk to the person than the risk that is inherent in their condition and alternative medical treatment; **and**

(g) 80(1)(d): 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; **and**

(h) s.81(1)(b)(i): stating that the person's medical treatment decision maker (if one is subsequently identified) will be informed of the procedure; **or**

(i) s.81(1)(b)(ii):if the person recovers decision-making capacity, the person will be informed of the procedure; **and**

(j) s.81(2):The medical research practitioner must inform the person's medical treatment decision maker (if one is subsequently identified) or, if the person recovers decision-making capacity, the person, as soon as reasonably practicable of (a) the person's inclusion in the relevant research project and (b) the option to refuse the continuation of the procedure and withdraw the person from future participation in the project without compromising the person's ability to receive any available alternative medical treatment or care; **and**

(k) s.81(3)(a) The medical research practitioner must (a) forward a copy of each certificate referred to in subsection (1) to the Public Advocate and the relevant human research ethics committee— in the case of the first certificate, as soon as practicable (and in any event within 2 business days) after administering the procedure or in any other case, at intervals of no more than 30 days; **and**

(l) s.81(3)(b) The medical research practitioner must ensure that each certificate is kept in the person's clinical records.

s.81(4): A medical research practitioner must not sign a certificate under this section that the practitioner knows to be false. Penalty: 120 penalty units.

5. Definitions

The following are simplified summaries of the definitions. Refer to the Act for the full legal definition.

Decision making capacity
(1) A person has decision-making capacity to make a decision to which this Act applies if the person is able to do the following—
(a) understand the information relevant to the decision and the effect of the decision;
(b) retain that information to the extent necessary to make the decision;
(c) use or weigh that information as part of the process of making the decision;
(d) communicate the decision and the person's views and needs as to the decision in some way, including by speech, gestures or other means.

Instructional directive:
An instructional directive is an express statement in an advance care directive of a person's medical treatment decision and takes effect as if the person who gave it has consented to, or refused the commencement or continuation of, medical treatment, as the case may be.

An instructional directive is binding upon a health practitioner.

Medical research practitioner
(a) a registered medical practitioner; or
(b) a person registered under the Health Practitioner Regulation National Law— (i) to practise in the dental profession as a dentist (other than as a student); and (ii) in the dentist division of that profession.

Medical research procedure
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; but does not include non-intrusive examinations such as visual examinations, measuring a person, observing a person, undertaking a survey or collecting or using personal or health information.

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

Medical treatment decision maker
A person identified in the Act authorised to make medical treatment decisions for a person who does not have decision making capacity to do so.