



Section 42T Certificate

Medical research procedure on a patient who is unable to consent and there is no person responsible to provide consent

Section 42T of the Guardianship and Administration Act 1986

About this Certificate

Patients are sometimes incapable of giving informed consent to medical research procedures as well as medical and dental treatment. It is essential to allow people with decision-making disabilities to enrol in medical research projects when it is suitable. Usually the person responsible for the patient can consent to treatment¹.

Medical research used to be a *special procedure* that required the consent of VCAT before it could be carried out on a person who has a decision-making disability². Under changes to the *Guardianship and Administration Act 1986* in July 2006 the person responsible may now consent to a medical research procedure.

The Act provides that where steps that are reasonable in the circumstances have been taken to contact a person responsible for a patient, but it has not been possible to identify or contact such a person, a registered medical practitioner can still carry out, or supervise the carrying out, of a medical research procedure on that patient if certain criteria are met. This is the case where:

- the procedure is for the purposes of a medical research project
- the research project has been approved by a Human Research Ethics Committee
- the procedure is not contrary to the best interests, or wishes, of the patient
- the patient will not regain capacity within a reasonable time, and
- the registered practitioner complies with the other requirements set out in the *Guardianship and Administration Act 1986*.

What are the procedural authorization requirements of a medical research procedure under the *Guardianship and Administration Act 1986*?

Practitioners or supervising practitioners will now need to follow a process prior to performing medical research on a patient in certain circumstances as detailed below

Please note the following provisions that affect practitioners:

S42T(1) Procedural authorisation for the carrying out of the medical research procedure on the patient only applies if the person responsible for the patient cannot be ascertained or contacted.

S42T(2) A registered practitioner may carry out, or supervise the carrying out of, a medical research procedure on a patient without the consent under section 42S of the person responsible for the patient if all the criteria in ss42T(2)(a)(b)(c)(d)(e)(f) and (g) of the *Guardianship and Administration Act 1986* are satisfied.

¹ For an explanation of who is the 'person responsible' and their role - see the Office of the Public Advocate Fact Sheet "Medical/Dental treatment for patients who cannot consent – person responsible".

² Applications will still need to be made to VCAT for consent to other types of 'special procedure' including sterilisation, termination of pregnancy and removal of tissue.

These safeguards are set out in full in the attached certificate. **The procedure can only be performed on a patient if the practitioner answers “yes” to all of these questions in the certificate in relation to that patient.**

S42T(3) Before, or as soon as practicable after, the medical research procedure is carried out, the practitioner supervising the carrying out of the procedure (or, if there is no such person, the practitioner carrying out the procedure) must sign a certificate:

- (a) certifying as to each of the matters set out in sub-section (2)*
- (b) stating that the person responsible (if any) or the patient (if the patient gains or regains capacity) will be informed as required by sub-section (4).*

S42T(4) A registered practitioner involved in the relevant research project must inform the person responsible (if any) or the patient (if the patient gains or regains capacity) as soon as reasonably practicable of:

- (a) the patient's inclusion in the relevant research project; and*
- (b) the option to refuse consent for the procedure to be continued and withdraw the patient from future participation in the project without compromising the patient's ability to receive any available alternative treatment or care.*

S42T(5) The registered practitioner supervising the carrying out of the procedure (or, if there is no such person, the registered practitioner carrying out the procedure) must:

- (a) forward a copy of the certificate referred to in sub-section (3) to the Public Advocate and the relevant human research ethics committee as soon as practicable (and in any event within 2 working days) after supervising the carrying out of, or carrying out, the procedure; and*
- (b) ensure that the certificate is kept in the patient's clinical records.*

S42T(6) If:

- (a) the medical research procedure is a procedure extending over a period exceeding one month after a copy of the certificate is forwarded to the Public Advocate and the relevant human research ethics committee under subsection (5) and*
- (b) the registered practitioner supervising the carrying out of the procedure (or, if there is no such person, the registered practitioner carrying out the procedure) believes on reasonable grounds that:*
 - (i) the requirements of sub-sections (2)(b) and (8) (if applicable) have been met but the person responsible has not been able to be ascertained or contacted; and*
 - (ii) the patient has not gained or regained the capacity to consent—**the practitioner must, at intervals of not more than one month while the procedure continues, sign a certificate, and forward a copy to the Public Advocate and the relevant human research ethics committee, certifying that each of the matters set out in subsection (2) continue to apply.*

In such a case, the attached certificate can be completed, noting that this is a case of a continuing medical research procedure.

S42T(7) The registered practitioner supervising the carrying out of the procedure (or, if there is no such person, the registered practitioner carrying out the procedure) must ensure that each certificate under sub-section (6) is kept in the patient's clinical records.

S42T(8) If a medical research procedure is being carried out on a patient under the authority of this section, steps that are reasonable in the circumstances must continue to be taken (as the case requires)—

(a) to ascertain whether there is a person responsible and, if so, who that person is; and

(b) if the person responsible is ascertained, to contact that person to seek his or her consent to the proposed procedure.

Note: If the person responsible is contacted and is willing and able to make a decision (see section 37³), section 42S⁴ applies. If the patient gains or regains capacity to consent, his or her consent must be sought, as he or she will no longer be a person to which this Division applies.

Practitioners should be aware of s42R(3), which states:

If a patient is likely to be capable, within a reasonable time as determined in accordance with sub-section (2), of giving consent to the carrying out of a medical research procedure, a registered practitioner must not carry out, or supervise the carrying out of, the procedure under the authority of a consent under section 42S or procedural authorisation under section 42T.

Further information

- about how to determine what is a “reasonable time” in relation to the particular research project, and
- regarding the other aspects of procedural authorisation,

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

³ Section 37 of the Act states that 1) In this Part, “**person responsible**”, in relation to a patient and in relation to a proposed medical research procedure or proposed medical or dental treatment, means the first person listed below who is responsible for the patient and who, in the circumstances, is reasonably available and willing and able to make a decision under this Part— (a) a person appointed by the patient under section 5A of the **Medical Treatment Act 1988**; (b) a person appointed by the Tribunal to make decisions in relation to the proposed procedure or treatment; (c) a person appointed under a guardianship order with power to make decisions in relation to the proposed procedure or treatment; (d) a person appointed by the patient (before the patient became incapable of giving consent) as an enduring guardian with power to make decisions in relation to the proposed procedure or treatment; (e) a person appointed in writing by the patient (being the person appointed last in time before the patient became incapable of giving consent) to make decisions in relation to medical research procedures that include the proposed procedure or medical or dental treatment which includes the proposed treatment; (f) the patient's spouse or domestic partner; (g) the patient's primary carer; (h) the patient's nearest relative within the meaning of paragraphs (a) to (g) of the definition of “nearest relative” in section 3.

⁴ Section 42S concerns the ability of the person responsible to provide consent to treatment.

The Office of the Public Advocate has prepared the attached certificate for practitioners to sign for procedural authorisation to undergo a medical research procedure

- Use the 'tab' key or use your mouse to move through the certificate and type, or click on the appropriate check box.
- Please ensure that the practitioner performing or supervising the procedure signs the certificate.
- Someone authorised to do so by the practitioner may submit the certificate.
- Fax the completed document to the Office of the Public Advocate on 1300 787 510 with a cover sheet addressed for the urgent attention of the Advice Service.

The Advice Service will telephone the registered practitioner to confirm receipt of the certificate and to note whether the legislative requirements of s42T, in relation to procedural authorisation have been met. It is not the role of the Office of the Public Advocate to provide consent under S42T. Please note that under the Guardianship and Administration Act 1986, if the Office of the Public Advocate is concerned about whether a medical research procedure should be performed on a patient, or about the continuation of medical research procedures on a patient, then they may contact you to discuss the case. If the concerns remain, the Office may apply to VCAT for an appropriate order.



Section 42T Certificate

Medical research procedure on a patient who is unable to consent and there is no person responsible to provide consent

Section 42T of the Guardianship and Administration Act 1986

In accordance with the *Guardianship and Administration Act 1986* it is necessary for the section 42T certificate to be completed before, or as soon as practicable after, a medical research procedure is carried out on a patient under section 42T. This certificate must be completed by the registered practitioner who is supervising the carrying out of the procedure (or if there is no such person, the practitioner carrying out the procedure)⁵.

The registered practitioner supervising the carrying out of the procedure (or if there is no such person, the registered practitioner who carries it out) must provide the Office of the Public Advocate and the relevant human research ethics committee⁶ with a copy of this certificate as soon as practicable (and no later than within two working days of the procedure being performed).

Someone authorised to do so by the registered practitioner supervising or carrying out the procedure may submit the certificate; however, the registered practitioner **must sign** the certificate

To:

Advice Service
Office of the Public Advocate
Level 5, 436 Lonsdale Street
Melbourne, Victoria 3000
Ph: 1300 309 337
Fax: 1300 787 510

To:

_____ **(Insert the name of the relevant human research ethics committee)**

_____ **Postcode:** _____
(Insert address of relevant human research ethics committee)

Phone: _____ **Fax:** _____
(Insert the phone number and fax of the relevant human research ethics committee)

HREC Project Number: _____

⁵ Some research projects may only involve one practitioner, in which case there will not be a supervising practitioner.

⁶ This is the HREC that is responsible for approving the project.

This Certificate is provided by:

1. Practitioner supervising or carrying out the medical research procedure	
Name of supervising practitioner who is completing this certificate Or If there is no supervising practitioner, specify the name of the practitioner carrying out the medical research procedure who is completing this certificate.	

Regarding:

2. The patient	
Name of patient	
Address of patient	
Date of patient's birth	
What is the patient's disability ?	

3. Information about the medical research procedure	
What is the medical research ?	
What does the medical research procedure involve?	
What was the date , or what is the proposed date , of the medical research procedure?	

4. Criteria for procedural authorisation	
1. I certify that I believe that the patient is not likely to be capable, within a reasonable time ⁷ of giving consent to the carrying out of the procedure. As per s42T2(a) of the <i>Guardianship and Administration Act</i> 1986.	Yes <input type="checkbox"/>

⁷ This is determined in accordance with section 42R(2) and (3) of the Act. The reasonable time is the time by which, given the nature of the relevant research project, the procedure would need to be performed on the patient, having regard to— (a) the medical or physical condition of the patient; or (b) the stage of treatment or care; or (c) other circumstances specific to the patient. For more information refer to the document entitled “Medical Research Procedures involving Patients under a Legal Incapacity”

<p>2. I certify that steps that are reasonable in the circumstances have been taken as follows:</p> <ul style="list-style-type: none"> • to ascertain whether there is a person responsible⁸, and if so, who that person is, but it has not been possible to ascertain whether there is a person responsible or who that person is; OR • the person responsible has been ascertained, but it has not been possible to contact that person <p><i>As per s42T2(b) of the Guardianship and Administration Act 1986</i></p>	<p>Yes <input type="checkbox"/></p> <p>OR</p> <p>Yes <input type="checkbox"/></p>
<p>3. I certify that I believe on reasonable grounds that the inclusion of the patient in the research project, and being the subject of the proposed procedure, would not be contrary to the best interests of the patient.</p> <p><i>As per s42T2(c) of the Guardianship and Administration Act 1986</i></p>	<p>Yes <input type="checkbox"/></p>
<p>In forming this view in relation to the best interests of the patient, I have taken into account:</p> <p>a. The wishes of the patient, so as far as they can be ascertained</p> <p>b. The wishes of any⁹ nearest relative or any other family members of the patient.</p> <p>c. The nature and degree of any significant benefits, discomforts and risks to the patient in having or not having the procedure</p> <p>d. Any other consequences to the patient if the procedure is or is not carried out</p> <p><i>As per s42T(2) (c) and 42U(1) of the Guardianship and Administration Act 1986.</i></p>	<p>Yes <input type="checkbox"/></p> <p>Yes <input type="checkbox"/></p> <p>No Family Available <input type="checkbox"/></p> <p>Yes <input type="checkbox"/></p> <p>Yes <input type="checkbox"/></p>
<p>4. I certify that I have no reason to believe that the carrying out of the procedure would be against the patient's wishes.</p>	<p>Yes <input type="checkbox"/></p>

⁸ This relates to the person responsible giving consent to the carrying out of the medical research procedure on the patient under section 42S of *Guardian and Administration Act 1986*. The person responsible can only give this consent if he or she believes that the carrying out of the procedure would not be contrary to the best interests of the patient. In addition, the consent must be consistent with the requirements for consent, if any, specified in the relevant human research ethics committee approval for the relevant research project or the conditions of that approval. Note that Section 42A of the *Guardian and Administration Act 1986* provides for the carrying out of a medical research procedure without consent in emergency situations.

⁹ This only applies if a near relative or other family member is available and it is possible to ascertain their wishes. If they are not available, tick yes and also the “no family available” box.

As per s42T2(d) of the <i>Guardianship and Administration Act 1986</i> .	
<p>5. I certify that I believe on reasonable grounds that the relevant human research ethics committee has approved the research project in the knowledge that a patient may participate in the project without the prior consent of the patient or the person responsible.</p> <p>As per s42T2(e) of the <i>Guardianship and Administration Act 1986</i>.</p>	Yes <input type="checkbox"/>
<p>6. I certify that I believe on reasonable grounds that:</p> <p>(i) one of the purposes of the relevant research project is to assess the effectiveness of the therapy being researched</p> <p>and</p> <p>(ii) the medical research procedure poses no more of a risk to the patient than the risk that is inherent in the patient's condition and alternative treatment.</p> <p>As per s42T2(f) of the <i>Guardianship and Administration Act 1986</i>.</p>	<p>Yes <input type="checkbox"/></p> <p>Yes <input type="checkbox"/></p>
<p>7. I certify that I 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 treatment.</p> <p>As per s42T2(g) of the <i>Guardianship and Administration Act 1986</i>.</p>	Yes <input type="checkbox"/>

Please note that, pursuant to the legislation, if the medical research procedure is ongoing, practitioners are required to take steps that are reasonable in the circumstances to continue to try to ascertain whether there is a person responsible. If such a person is located, or if the patient gains or regains capacity, that person (as the case may be) must be informed of the patient's inclusion in the relevant research project and given the option to refuse consent or withdraw the patient from future participation.

<p>8. I certify that a registered medical practitioner involved in the relevant research project will inform the person responsible (if any) or the patient (if he or she gains or regains capacity) as soon as reasonably practicable of-</p> <p>(a) the patient's inclusion in the relevant research project; and</p> <p>(b) the option to refuse consent for the procedure to be continued and withdraw the patient from future participation in the project without compromising the patient's ability to receive any available alternative treatment or care.</p> <p>As per s42T (3)(b) of the <i>Guardianship and Administration Act 1986</i>.</p>	Yes <input type="checkbox"/>
--	------------------------------

5. Clinical notes
The registered practitioner must put in writing in the patient's clinical notes their reasons for believing that, at the time of the procedure, the patient is or was not likely to be capable of giving consent within a reasonable time.
The registered practitioner must also ensure that a copy of this certificate is kept in the patient's clinical records.

6. Signature and contact information of practitioner who is supervising or carrying out the medical research procedure		
Name of the practitioner supervising, or carrying out the research		
Signature of practitioner supervising, or carrying out the research		
Name of person submitting the certificate (if different from above)		
Signature of person submitting the certificate		
If person submitting the certificate is not supervising or carrying out the research, state how authorised by supervisor to submit certificate		
Date		
Address of the treating/supervising registered practitioner		
Contact numbers	Treating/supervising practitioner	Phone: Fax:
	Person submitting the certificate (if different from above)	Phone: Fax:

7. Fax this notice to the Office of the Public Advocate on 1300 787 510 and the relevant human research ethics committee.

Note: The above fax number is only checked Monday to Friday between 9am-5pm. If faxed outside of these hours it will not be attended to until the next working day. If the matter is urgent outside office hours, call 1300 309 337. The practitioner or supervising practitioner will have to ascertain the fax and contact details of the relevant human research ethics committee.

Office of the Public Advocate
 Level 5, 436 Lonsdale Street, Melbourne, Victoria 3000
 PO Box 13175 Law Courts, Victoria 8010. DX 210293
 Tel: 1300 309 337 Fax: 1300 787 510
www.publicadvocate.vic.gov.au