Section 42T Certificate – Continuing Medical research procedure

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

About this certificate

In accordance with section 42T(6) of the *Guardianship and Administration Act 1986* if:

1. the medical research procedure extends over a period exceeding one month after a copy of the original certificate has been forwarded to the Public Advocate and the relevant human research ethics committee, and
2. the patient has not regained the capacity to consent, and
3. the supervising practitioner has been unable to ascertain or contact the person responsible,

the practitioner must, at intervals of not more than one month while the procedure continues, sign a certificate and provide a copy of this certificate stating that all the criteria of section 42T(2) continue to apply.

To:
Advice Service
Office of the Public Advocate
Level 1, 204 Lygon Street, Carlton, Victoria 3053
DX 210293 Local Call: 1300 309 337
TTY: 1300 305 612 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: _____

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 original certificate	
The date of the original certificate provided to the Public Advocate and human research ethics committee	

4. Certification	
1. I certify that I believe that the patient is not likely to be capable, within a reasonable time[1] of giving consent to the carrying out of the procedure. (As per s42T2(a) of the *Guardianship and Administration Act 1986*.)	Yes ☐
2. I certify that steps that are reasonable in the circumstances have been taken as follows: • to ascertain whether there is a person responsible[2], 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 (As per s42T2(b) of the *Guardianship and Administration Act 1986*.)	Yes ☐ OR Yes ☐
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. (As per s42T2(c) of the *Guardianship and Administration Act 1986*.)	Yes ☐

[1] 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*.

[2] 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.

In forming this view in relation to the best interests of the patient, I have taken into account: a. the wishes of the patient, so as far as they can be ascertained b. the wishes of any[3] nearest relative or any other family members of the patient. c. the nature and degree of any significant benefits, discomforts and risks to the patient in having or not having the procedure d. any other consequences to the patient if the procedure is or is not carried out (As per s42T(2) (c) and 42U(1) of the *Guardianship and Administration Act 1986*.)	Yes ☐ Yes ☐ Yes ☐ No family available ☐ Yes ☐
4. I certify that I have no reason to believe that the carrying out of the procedure would be against the patient's wishes. (As per s42T2(d) of the *Guardianship and Administration Act 1986*.)	Yes ☐
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. (As per s42T2(e) of the *Guardianship and Administration Act 1986*.)	Yes ☐
6. I certify that I believe on reasonable grounds that: (i) one of the purposes of the relevant research project is to assess the effectiveness of the therapy being researched and (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. (As per s42T2(f) of the *Guardianship and Administration Act 1986*.)	Yes ☐ Yes ☐
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. (As per s42T2(g) of the *Guardianship and Administration Act 1986.)*	Yes ☐

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.

[3] 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.

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: (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. (As per s42T (3)(b) of the *Guardianship and Administration Act 1986*.)	Yes ☐

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 the 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		
Contact address of the treating/supervising registered practitioner		
Contact numbers	treating/supervising practitioner	Phone: ( ) Fax: ( )
	person submitting the certificate (if different from above)	Phone: ( ) Fax: ( )

Please fax this form to the Advice Service, Office of the Public Advocate, on 1300 787 510, and the relevant human research ethics committee.

Please note: The fax number for the Office of the Public Advocate 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 and it is outside the Office of the Public Advocate office hours please 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.