

Instructions for completing

Application for approval to conduct special medical research – *Guardianship and Administration Act 2000*

The *Guardianship and Administration Act 2000* (the Act) provides that tribunal may approve special medical research.

Special medical research is:

- medical research relating to a condition the adult has or to which the adult has a significant risk of being exposed, or
- medical research intended to gain knowledge that can be used in the diagnosis, maintenance or treatment of a condition the adult has or has had.

NOTE: special medical research does not include psychological research or approved clinical research.

The tribunal may consent, for an adult with impaired capacity for the special health matter concerned, to the adult's participation in special medical research only if the tribunal is satisfied about the following matters:

- the special medical research is approved by an ethics committee
- the risk and inconvenience to the adult and the adult's quality of life is small
- the special medical research may result in significant benefit to the adult, or other persons with the condition
- the potential benefit can not be achieved in another way
- the special medical research can not reasonably be carried out without a person who has or has had the condition taking part
- the special medical research will not unduly interfere with the adult's privacy.

NOTE: the tribunal may not consent to the adult's participation in special medical research if the adult objects to the special medical research, or the adult, in an enduring document, indicated unwillingness to participate in the special medical research.

Form Number 13 (version 1)

Queensland Civil and Administrative Tribunal Act 2009

Application for approval to conduct special medical research – *Guardianship and Administration Act 2000*

Refer to attached instructions at the front of this application prior to filling out this form.

For office use only

Case number and type:	
Adult number:	
Date:	
Registry:	
Sent to:	

PART A DETAILS TO BE COMPLETED BY THE APPLICANT

1. Name and details of applicant (*individual researcher or research entity*):

Name

Address

<input type="text"/>	
<input type="text"/>	Postcode <input type="text"/>

Telephone
 ()
Home
 ()
Business

*Mobile***Email**

2. Brief description and background of research:

PART A DETAILS TO BE COMPLETED BY THE APPLICANT *(continued)*

3. Does the special medical research relate to a condition the adult has or to which the adult has a significant risk of being exposed?

- no
- yes *(please give details)*

4. Is the special medical research intended to gain knowledge that can be used in the diagnosis, maintenance or treatment of a condition the adult has or has had?

- no
- yes *(please give details)*

5. How will the proposed medical research affect the adult's quality of life?

PART A DETAILS TO BE COMPLETED BY THE APPLICANT *(continued)*

6. Has the medical research been approved by an ethics committee?

- no
- yes – what is the name of the ethics committee?

(please attach a copy of the ethics committee approval)

**7. Will the special medical research involve any known substantial risk or inconvenience to the participants, OR
If there is existing health care for the particular condition, will the research involve known material risk to the participants greater than the risk associated with the existing health care?**

yes *(please describe risk or inconvenience)*

no – why is there no known substantial or material risk?

8. Will the research result in a significant benefit to the adult or others?

yes *(please give details)*

no – why will it not be adverse?

PART A DETAILS TO BE COMPLETED BY THE APPLICANT *(continued)*

9. Can the potential benefit from the special medical research be achieved in another way?

yes *(please give details)*

no *(please give details)*

10. Can the special medical research be reasonably carried out without a person who has or has had the condition taking part?

yes *(please give details)*

no *(please give details)*

11. Will the special medical research unduly interfere with the adult's privacy?

yes *(please give details)*

no *(please give details)*

PART A DETAILS TO BE COMPLETED BY THE APPLICANT *(continued)*

12. Is the experimental health care part of a multicentre trial?

If so, please advise the names of the other Queensland centres participating in the trial.

13. Has this special medical research already received approval from any tribunal in other Australian States or Territories?

- no
- yes *(please give details)*

14. What is the proposed duration of the experimental health care?

days weeks months years

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▶ Please attach a copy of the following documents:

- (1) ethics committee approval
- (2) protocol for research

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PART B CAPACITY REPORT

Note: this report is not to be completed by the applicant

Basic information about the adult

Name

<input type="text"/>	<input type="text"/>	<input type="text"/>
<i>Title</i>	<i>Given name/s</i>	<i>Surname/Family name</i>

Address

<input type="text"/>	
<input type="text"/>	Postcode <input type="text"/>

Date of birth

<input type="text"/>	/	<input type="text"/>	/	<input type="text"/>
<i>Day</i>		<i>Month</i>		<i>Year</i>

Information about the adult's capacity

Indicate cause of the adult's impaired capacity and provide more specific details

- acquired brain injury
- intellectual disability
- psychiatric disability/mental illness
- dementia
- other (*specify*)

More specific details: (<i>e.g. name of condition and date of onset</i>)

Level of impairment

- mild
- moderate
- profound

PART B CAPACITY REPORT *(continued)*

Information about the adult's capacity *(continued)*

Capacity as defined in the Act

The *Guardianship and Administration Act 2000* defines capacity in Schedule 4. Please indicate the adult's capacity to make decisions about the matter of special medical research.

The adult	yes	no
• understands the nature and effect of decisions about the matter?	<input type="checkbox"/>	<input type="checkbox"/>
• can freely and voluntarily make decisions about the matter?	<input type="checkbox"/>	<input type="checkbox"/>
• can communicate the decisions in some way?	<input type="checkbox"/>	<input type="checkbox"/>

In your opinion, does that adult have capacity to consent to participation in special medical research?

- yes
 no

In your opinion, does that adult have capacity to make complex decisions about health care?

- yes
 no

Details about the professional completing this form

Name

<input type="text"/>	<input type="text"/>	<input type="text"/>
<i>Title</i>	<i>Given name/s</i>	<i>Surname/Family name</i>

Qualifications

Address

<input type="text"/>	
<input type="text"/>	Postcode <input type="text"/>

Telephone

<input type="text"/>	<input type="text"/>	<input type="text"/>
<i>Home</i>	<i>Business</i>	<i>Mobile</i>

Fax

Email

Details about the professional completing this form *(continued)*

Relationship to adult (e.g. GP, specialist, etc)

How long have you known the adult?

When did you last see the adult?

PART C QUESTIONNAIRE BY THE ADULT'S LEGALLY AUTHORISED REPRESENTATIVE

Note: this questionnaire is not to be completed by the applicant

I,

(insert full name)

of *(insert address)*

<input type="text"/>		
<input type="text"/>	Postcode	<input type="text"/>

am the legally authorised representative

of

(insert adult's full name)

1. Has the adult made an advance health directive recording personal views about participation in this type of research?

- no
- don't know
- yes *(please give details)*

PART C QUESTIONNAIRE BY THE ADULT'S LEGALLY AUTHORISED REPRESENTATIVE *(continued)*

2. Has the adult made an enduring power of attorney recording personal views about participation in this type of research?

- no
- don't know
- yes *(please give details)*

3. Has the adult verbally expressed views about participation in this type of research?

- no
- don't know
- yes *(please give details)*

4. Has the former Guardianship and Administration Tribunal or QCAT appointed a guardian for health care for the adult?

- no
- don't know
- yes *(please give details)*

5. Are you a statutory health attorney for the adult?

- no
- yes *(please give details of your relationship to the adult)*

Note: For a health matter, an adult's statutory health attorney is the first, in listed order, of the following people who is readily available and culturally appropriate to exercise power for the matter:

- a spouse of the adult if the relationship between the adult and the spouse is close and continuing,
- a person who is 18 years or more and who has the care of the adult and is not a paid carer for the adult,
- a person who is 18 years or more and who is a close friend or relation of the adult and is not a paid carer for the adult.

Warning

Section 216 of the *Queensland Civil and Administrative Tribunal Act 2009* makes it an offence for a person to knowingly give the registry documents containing false or misleading information.

Maximum penalty for such an offence – \$10,000.

SIGN AND DATE HERE

The information in this application is true to the best of my knowledge.

Applicant/s sign here

Date

If more than one person is named all must sign the application.

LODGEMENT DETAILS

Deliver to:	Mail to:	Fax to:	Email to:
Queensland Civil and Administrative Tribunal Floor 9, 259 Queen Street Brisbane Qld 4000 or at any local Magistrates Court	Queensland Civil and Administrative Tribunal GPO Box 1639 Brisbane Qld 4001	(07) 3221 9156	applications@qcat.qld.gov.au