QCAT
Queensland **Civil and Administrative Tribunal**

Instructions for completing

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

The *Guardianship and Administration Act 2000* (the Act) provides that the Queensland Civil and Administrative Tribunal (the tribunal) may approve clinical research. Clinical research is:

(a) medical research intended to diagnose, maintain or treat a condition affecting the participants in the research, or

(b) a trial of drugs or techniques involving the carrying out of health care that may include the giving of placebos to some of the participants in the trial.

NOTE: A comparative assessment of health care already proven to be beneficial to participants is not medical research as defined by the Act, and does not need approval by QCAT.

Approved clinical research is clinical research approved by the tribunal. The tribunal may approve clinical research, which seeks to include persons with impaired decision making capacity, only if QCAT is satisfied about the following:

(a) the clinical research is approved by an ethics committee

(b) any drugs or techniques on trial in the clinical research are intended to diagnose, maintain or treat a condition affecting the participants in the research

(c) the research will not involve any known substantial risk to the participants or, if there is existing health care for the particular condition, the research will not involve known material risk to the participants greater than the risk associated with the existing health care

(d) the development of any drugs or techniques on trial has reached a stage at which safety and ethical considerations make it appropriate for the drugs or techniques to be made available to the participants despite the participants being unable to consent to participation

(e) having regard to the potential benefits and risks of participation, on balance it is not adverse to the interests of the participants to participate.

Once the proposed clinical research has been approved by the tribunal, then it is considered a health matter, and section 66 of the Act determines who may consent to the adult's participation in the approved clinical research. Participation in approved clinical research without consent may only occur in accordance with section 63 of the Act, which involves urgent health care; and section 64 which involves minor and uncontroversial health care. All trials are subject to the National Health Medical Research (NHMRC) Guidelines.

QCAT
Queensland **Civil and Administrative Tribunal**

Form Number 16 (version 1)
Queensland Civil and Administrative Tribunal Act 2009 (section 33)

Application for approval to conduct clinical 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:	

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

Name

Address

Postcode

Telephone ( ) *Daytime phone* | *Mobile phone* | ( ) *After hours number (if different)*

Email

2. Brief description and background of research:

3. Will the research involve a comparative assessment of health care already proven to be beneficial?

☐ No

☐ Yes *(please give details)*

4. Is the research intended to diagnose, maintain or treat a condition affecting the participants in the research?

☐ No

☐ Yes *(please give details)*

5. Will the trial of any drugs or techniques in the research involve health care that may include giving placebos to some participants?

☐ No

☐ Yes *(please give details)*

6. Has the 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. (i) Will the research involve any known substantial risk to the participants, OR (ii) 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)*

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

8. Has the development of any drugs or techniques on trial reached a stage at which safety and ethical considerations make it appropriate for the drugs or techniques to be made available to the participants despite the participants being unable to consent to participation?

☐ Yes *(please give details)*

☐ No *(please give details)*

9. Having regard to the potential benefits and risks of participation, on balance will it be adverse to the interests of the participants to participate?

☐ Yes *(please give details)*

☐ No *(why it will not be adverse)*

10. Is the research part of a multicentre trial?

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

11. Has this study already received approval from any guardianship tribunal in other Australian states or territories?

☐ No

☐ Yes *(please give details)*

12. What is the proposed duration of the research?

▶ Please attach a copy of the following documents:

(1) research proposal/protocol describing the clinical research

(2) patient information sheet

(3) consent form

(4) ethics committee approval

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.

	Select Date
Applicant/s sign here	*Date*

LODGEMENT DETAILS

Deliver to:	Mail to:	Fax to:	Email to:
Queensland Civil and Administrative Tribunal Floor 11, 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