QCAT

Queensland Civil and Administrative Tribunal

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Form Number 16 (version 2)
Queensland Civil and Administrative Tribunal Act 2009
Guardianship and Administration Act 2000

Application for approval to conduct clinical research

Refer to the attached instructions prior to filling out this form

Part A APPLICANT (individual researcher or research entity)

Name

Title | Given name/s | Surname/Family name

Full postal address

Suburb | **State/Territory** | **Postcode**

Email

Telephone

Mobile phone | Daytime phone

1. Provide a brief description and background of research

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

☐ No

☐ Yes - please give details

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

☐ No

☐ Yes - please give details

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

☐ No

☐ Yes - please give details

5. What is the proposed duration of the research?

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6. Has the clinical 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 any of the drugs, devices, biologicals or techniques to be trialled in the clinical research be intended to diagnose, maintain or treat a condition affecting the participants in the research?

☐ No

☐ Yes - please give details

8. Will the clinical research involve any known substantial risk 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?

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

☐ Yes - please describe the risk

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9. Has the development of any drugs, devices, biologicals or techniques to be trialled in the clinical research reached a stage at which safety and ethical considerations make it appropriate for the drugs, devices, biologicals or techniques to be made available to participants in the research despite the participants being unable to consent to participation?

☐ No - please give details

☐ Yes - please give details

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

☐ No - why will it not be adverse? Please give details

☐ Yes - please give details

PLEASE NOTE

A copy of the following documents must be attached:

- research proposal/protocol describing the clinical research
- patient information sheet
- consent form
- ethics committee approval

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CHECKLIST

- ☐ I have completed all questions on the application according to the instructions.
- ☐ I have attached all relevant documents.
- ☐ I am ready to proceed with this application.

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 – 100 penalty units.

Sign and date here

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

Applicant/s sign here _____ Date _____

Print your name/s here _____

Lodgement Details

Deliver to:	**Mail 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	enquiries@qcat.qld.gov.au

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INSTRUCTIONS FOR COMPLETING FORM 16

Application for approval to conduct clinical research

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:

- medical research intended to diagnose, maintain or treat a condition affecting the participants in the research; or
- a trial of drugs, devices, biologicals 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 the Tribunal.

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 the Tribunal is satisfied about the following:

- the clinical research is approved by an ethics committee,
- any drugs, devices, biologicals or techniques on trial in the clinical research are intended to diagnose, maintain or treat a condition affecting the participants in the research,
- 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,
- the development of any drugs, devices, biologicals 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,
- 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.

Protecting your privacy

We collect your contact details to ensure QCAT proceedings comply with the *Queensland Civil and Administrative Tribunal Act* 2009. We may contact you to help evaluate QCAT operations. You do not have to participate in feedback or surveys. If you do participate, no identifying information will be published. We will not disclose your contact details or any other personal information to a third party unless required by law.