

Guide to the legislation relating to the provision of consent for an adult with impaired capacity to provide informed consent to participate in the conduct of human research

Queensland

This guide provides an outline of the relevant legal requirements in the State of Queensland regarding the provision of consent for an adult who lacks the capacity to provide informed consent to participate in the conduct of human research. It has been prepared to assist researchers, HRECs and other stakeholders to understand the relevant legal requirements.

Disclaimer: The information provided in this guide is an overview of the relevant legal requirements and is of a general nature only. The guide does not provide legal advice in relation to any specific human research project or clinical trial. You should obtain legal or other professional advice appropriate to your circumstances before acting or relying on any matter referred to in this guide.

Note: As of 3 March 2017, Queensland has not provided its advice on the accuracy of the following information.

Relevant legislation

The following legislation may be relevant to considerations of whether an adult with impaired capacity can participate or be enrolled in certain human research projects:

- *Guardianship and Administration Act 2000* (Qld) (**GAAQ**)

Where are the relevant requirements found?

The relevant requirements are set out in Chapter 5 of the GAAQ.

What types of research does the GAAQ apply to?

The GAAQ applies to the conduct of *special medical research or experimental health care* and *clinical research* involving an adult (that is, a person who is 18 years of age or older) who has impaired capacity to provide informed consent.

What are the specific requirements under the GAAQ for the conduct of human research?

The GAAQ distinguishes two broad categories of research: the first is *special medical research or experimental health care*; the second is *clinical research*. The specific requirements for each differ.

1. *Special medical research or experimental health care*

Special medical research or experimental health care for an adult is:

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

However, *special medical research or experimental health care* does not include *psychological research or approved clinical research*.

A research project that will involve the performance of *special medical research or experimental health care* on a person with impaired capacity must be submitted to the Queensland Civil and Administrative Tribunal (**QCAT**). Only QCAT has authority to give consent to the participation of an adult with impaired capacity in *special medical research or experimental health care*.

The procedure for seeking the granting of approval and the giving of consent by QCAT for special medical research or experimental health care involves the completion and submission of a prescribed form (http://www.qcat.qld.gov.au/data/assets/pdf_file/0009/100899/form-13-app-conduct-special-med-research.pdf; http://www.qcat.qld.gov.au/__data/assets/pdf_file/0013/100903/form-14-app-to-conduct-exp-health-care.pdf).

QCAT may consent for an adult with impaired capacity to the adult's participation in *special medical research or experimental health care* if it is satisfied of the following matters:

- The special medical research or experimental health care is approved by a human research ethics committee.

The GAAQ defines 'ethics committee' as:

- a Human Research Ethics Committee registered by the Australian Health Ethics Committee established under the *National Health and Medical Research Council Act 1992* (Cth), or
- if there is no committee mentioned in the above paragraph:
 - an ethics committee established by a public sector hospital within the meaning of the *Hospital and Health Boards Act 2011* (Qld)
 - an ethics committee established by a university and concerned, wholly or partly, with medical research, or
 - an ethics committee established by the NHMRC.
- The risk and inconvenience to the adult and the adult's quality of life is small.
- The special medical research or experimental health care may result in significant benefit to the adult or other persons with the condition.
- The potential benefit cannot be achieved in another way.

2. *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 or techniques involving the carrying out of health care that may include the giving of placebos to some of the participants in the trial. The GAAQ provides that a comparative assessment of health care already proven to be beneficial is not medical research. Many clinical trials of drugs or devices may fall within the definition of *clinical research*.

The process for the giving of consent for an impaired capacity adult to participate in *clinical research* involves two steps.

A. Step 1 - submission to QCAT for approval

The first step is to submit the clinical research proposal to QCAT on the prescribed form for approval (http://www.qcat.qld.gov.au/data/assets/pdf_file/0015/100905/form-16-app-to-conduct-clinical-research.pdf).

QCAT may approve the *clinical research* proposal if is satisfied of all of the following matters:

- The *clinical research* is approved by an HREC.
- 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.
- 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 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.

Clinical research that has been approved by QCAT is referred to as *approved clinical research*.

B. Step 2 - obtaining consent following approval given by QCAT

The second step involves the giving of consent for each participant by their respective *substitute decision maker*.

Once the proposed clinical research has been approved by QCAT (that is, it is *approved clinical research*), it is considered a *health matter* under the GAAQ.

If an adult has impaired capacity, consent for the person to participate in the *approved clinical research* is determined or given in accordance with the first of the following to apply:

- The terms of any advance health directive made by the adult giving a direction about the matter.
- By any guardian appointed by QCAT for the adult or any order made by QCAT in respect of the matter.
- By an attorney for the matter appointed by the most recent enduring document made by the adult.
- By the *statutory health attorney* (as defined in the *Powers of Attorney Act 1998 (Qld)*). 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.

- If no-one listed above is readily available and culturally appropriate to exercise power for a matter, the public guardian is the adult's statutory health attorney for the matter.

Can a medical research procedure be carried out on an impaired capacity patient without consent in emergency circumstances?

There are no specific provisions in the GAAQ permitting the conduct of *special medical research or experimental health care or clinical research* in the emergency context on an impaired capacity patient without the requirement to obtain consent. However, to the extent that *approved clinical research* constitutes health care, it may fall within the GAAQ's exemption to obtain consent for *urgent health care*.

What other roles does QCAT have in relation to the conduct of a clinical trial?

Apart from the functions of QCAT described above, QCAT exercises other powers which may be relevant to the conduct of the relevant research. For example, QCAT determines issues relating to health directives and guardians and hears disputes relating to matters arising under the GAAQ.

Checklist of matters for an HREC to consider

- Does the research involve participants aged 18 years or older who lack the capacity to provide informed consent?
- Does the research constitute *special medical research or experimental health care or clinical research*?
- If the research constitutes *special medical research or experimental health care*, does the proposal satisfy the requirements for submission to QCAT?
- If the research constitutes *clinical research*, does the proposal satisfy the requirements for submission to QCAT?
- If the research constitutes *clinical research*, does the proposal outline the process and include the relevant documentation for the obtaining of consent from the appropriate substitute decision maker?
- Has HREC approval been given subject to the research being conducted in accordance with all relevant legal requirements regarding the approval of the research proposal by QCAT and the obtaining of consent for participants who lack capacity to provide informed consent?
- Having considered the above, does the HREC need to seek further advice from the researcher?