Australian Guardianship and Administration Council
'Medical research procedures and clinical trials involving adults who cannot consent'

This document contains a guide to the laws that exist throughout Australia concerning medical research procedures and clinical trials involving adults who are unable to consent to such procedures or trials.

The Australian Guardianship and Administration Council supports the right of people with cognitive impairments and mental illnesses to be involved in medical research. The Council also wishes to ensure that medical researchers are aware of the legal protections that exist where the prospective participants in the research are unable to consent to it.

In addition to being aware of the particular laws on this topic that apply throughout Australia, medical researchers are encouraged to consider the following extract from the National Health and Medical Research Council's 'National Statement on Ethical Conduct in Human Research' (2007, incorporating updates as at March 2014):

> 'People with a cognitive impairment, an intellectual disability, or a mental illness are entitled to participate in research. While research involving these people need not be limited to their particular impairment, disability or illness, their distinctive vulnerabilities as research participants should be taken into account.
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> The capacity of a person with any of these conditions to consent to research, and the ability to participate in it, can vary for many reasons, including:
> • the nature of the condition;
> • the person's medication or treatment;
> • the person's discomfort or distress;
> • the complexity of the research project;
> • fluctuations in the condition. For example, while intellectual disability is usually permanent, cognitive impairment and mental illness are often temporary or episodic.
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> Even when capable of giving consent and participating, people with these conditions may be more-than-usually vulnerable to various forms of discomfort and stress.'

Jurisdiction	Legislation	Provisions/Commentary
Commonwealth	Therapeutic Goods Act 1989, Therapeutic Goods Regulation 1990	Clinical Trial Notification Scheme, Clinical Trial Exemption Scheme Researcher must identify in the Application Form whether trial will involve participants who lack capacity to consent and how this will be managed.
New South Wales	Guardianship Act 1987	The Tribunal's approval of a clinical trial is required under s 45AA(1) before it may involve patients who do not have capacity. The Tribunal must be satisfied that the trial meets all of the requirements of s 45AA(2), including that the trial has been approved by an ethics committee and complies with any relevant NHMRC guidelines. If Tribunal grants approval, the Tribunal may determine whether consent may be given by person responsible or whether consent for each individual patient must be obtained from the Tribunal (ss 45AA(4) and 45AB(1)). Before making this determination, the Tribunal must be satisfied that the consent form and the information that is given to the person responsible is sufficient to enable them to make an informed decision (s 45AB(2)). Person responsible must give or withhold consent in accordance with Division 3 of Part 5 of the Act. If the Tribunal provides consent for the patient, it must be given in accordance with Division 4 of Part 5 (s 45AB(1)).

Jurisdiction	Legislation	Provisions/Commentary
Victoria	Guardianship and Administration Act 1986	Research project must have ethics committee approval (s 42Q). If patient is likely to be capable of giving consent within a reasonable time, patient cannot be given treatment under the research project in any circumstances (s 42R(3)). If patient is not likely to be capable of giving consent within a reasonable time, treatment may be given under the research project with the consent of the person responsible (s 42R(4)). Certificate under s 42T required to be submitted with the Public Advocate if research project will involve patients who are not likely to be capable of giving consent within a reasonable time and there is no person responsible. None of the above apply if the medical research procedure is being carried out in an emergency situation. Under s 42A, medical research procedures may be carried out without consent if the practitioner believes the procedure is necessary, as a matter of urgency: (a) To save the patient's life (b) To prevent serious damage to the patient's health or (c) To prevent the patient from suffering or continuing to suffer significant pain or distress. VCAT has jurisdiction to make orders in respect of any matter, question or dispute arising from the medical research provisions relating to a particular patient (s 42V).

Jurisdiction	Legislation	Provisions/Commentary
Queensland	Guardianship and Administration Act 2000	*Special medical research or experimental health care provisions:* Section 72(1): Tribunal may consent for an adult with impaired capacity to the adult's participation in special medical research or experimental health care relating to a condition which the adult has. Section 72(2): Tribunal may consent for adult's participation in special medical research or experimental health care intended to gain knowledge that can be used in diagnosis, maintenance or treatment of a condition. Schedule 2, cl 12(2): Special medical research or experimental health care is: (1) Special medical research or experimental health care, for an adult, means— (a) 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 (b) 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. (2) Special medical research or experimental health care **does not include**— (a) psychological research; or (b) **approved clinical research**. *Approved clinical research provisions: Schedule 2, cl 13* (1) 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. QCAT may approve clinical research only if satisfied of a number of matters, similar to the requirements of the NSW Guardianship Act (see cl 13(3), sch 2). This does not act as consent for any particular individual to participate in the research. The approved clinical research then becomes a 'health care matter', where consent may be given under s 66 of the Act by: 1. Following advance health directive 2. Guardian appointed by Tribunal with heath care power 3. Enduring attorney appointed by person with health care power 4. Statutory health attorney (spouse then carer then close friend or relative)

Queensland ***cont***	Guardianship and Administration Act 2000	The Public Guardian may be requested by a health provider to provide consent for an adult with impaired capacity to participate in approved clinical research in the capacity of guardian or attorney, including statutory health attorney. When QCAT approve clinical research, the decision, a copy of the original application and associated documents are provided to the Office of the Public Guardian (OPG). The material is recorded in the OPG database. If a health care provider contacts the OPG requesting consent for an adult with impaired capacity to participate in approved clinical research a specific OPG form is completed. The authority to consent to participation in approved clinical research has not been delegated within the OPG and therefore only the Public Guardian can consent. Participation in approved clinical research may occur without consent under s 63: urgent health care to meet imminent risk to life or health or to prevent significant pain or distress. It may also occur without consent if the treatment is minor or uncontroversial (s 64).

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ACT	Powers of Attorney Act 2006 Guardianship and Management of Property Act 1991	Sections 35-37: Prohibits an attorney appointed under an enduring power from giving consent to a 'special health care' matter, which includes participation in medical research or experimental health care. This Act contains no reference to participation in medical research or clinical trials. A guardian may be appointed by the Tribunal with power to give any consent required for a medical procedure or treatment, other than a prescribed medical procedure. The definition of prescribed medical procedure does not include research or trials. It appears that a guardian can consent to participation in research or a trial if it involves a medical procedure or treatment. There has been no judicial or tribunal consideration of this issue.
Northern Territory	Adult Guardianship Act Advance Personal Planning Act	No specific provisions in guardianship legislation. **Advance Personal Planning Regulation:** A person appointed under an advance personal planning instrument cannot consent to special medical research, experimental health care or new health care of a kind that is not yet accepted as evidence-based, best practice health care by a substantial number of health care providers specialising in the relevant area of health care (reg 4(1)). Special medical research or experimental health care means medical research or experimental health care: (a) relating to a condition the adult has or to which the adult has a significant risk of being exposed; or (b) intended to gain knowledge that can be used in the diagnosis, maintenance or treatment of a condition the adult has or has had (reg 4(2)). However, psychological research or approved clinical research is not special medical research or experimental health care (reg 4(3)).
Tasmania	Guardianship and Administration Act 1995	No provisions.
Western Australia	Guardianship and Administration Act 1990	No provisions.
South Australia	Guardianship and Administration Act 1993 / Consent to Medical Treatment and Palliative Care Act 1995	No provisions.