

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

Australian Capital Territory

This guide provides an outline of the relevant legal requirements in the Australian Capital Territory 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: The legislative regime for the giving of consent for impaired capacity persons to participate in research in the ACT has recently undergone significant amendment: *Powers of Attorney Amendment Act 2016* (PAAA). The PAAA amended all three of the Acts listed below and introduced specific provisions dealing with the giving of consent for an impaired capacity person to participate in research.

Relevant legislation

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

- *Guardianship and Property Management Act 1991* (GPMA)
- *Medical Treatment (Health Directions) Act 2006* (MTA)
- *Powers of Attorney Act 2006* (PAA)

What types of research does the legislation apply to?

The legislation applies to the conduct of *low-risk research* and *medical research* that involves the participation of an adult with impaired decision-making capacity.

Low-risk research is research carried out for medical or health purposes that poses no foreseeable risk of harm to the person, other than any harm usually associated with the person's condition and that does not change the treatment appropriate for the person's condition. *Low risk research* does not include any activity that is part of a clinical trial.

Medical research is research in relation to the diagnosis, maintenance or treatment of a medical condition that the person has or has had or to which the person has a significant risk of being exposed. It includes experimental health care, the administration of medication or the use of equipment or a device as part of a clinical trial and research prescribed by regulation as medical

research. *Medical research* does not include *low-risk research* or research prescribed by regulation not to be medical research.

What are the specific legal requirements for the conduct of research?

The ACT legislation imposes different requirements in relation to the categories of research regarding who may give consent for an impaired capacity person to participate in such research.

Who may consent?

1. *Attorney appointed under PAA may consent to low risk research and medical research*

An attorney authorised under a medical research power of attorney (made pursuant to the PAA) may consent to an impaired capacity person participating in:

- *low-risk research*, provided the research has been approved by a human research ethics committee (which is constituted in accordance with, and acting in compliance with, the *National Statement on Ethical Conduct in Human Research (2007)*), or
- *medical research*, provided:
 - the research has been approved by a human research ethics committee (**HREC**);
 - the person is not likely to regain decision-making capacity (as assessed by an independent doctor) before the latest time he or she may meaningfully participate in the research; and
 - the attorney is satisfied on reasonable grounds that:
 - the research relates to the diagnosis, maintenance or treatment of a condition that the person has or has had or to which the person has a significant risk of being exposed
 - the research may result in benefit to the person or others with the condition
 - the potential benefit to the person, or others with the condition, of participating in the research outweighs any potential risk or inconvenience to the person, or any potential adverse impact on his or her quality of life, and
 - participating in the research will not unduly interfere with the person's privacy.

An attorney must exercise their power to consent for the impaired capacity person according to the decision making principles set out in section 41B of the PAA. The decision making principles are the following:

- The attorney must give effect to the person's wishes (as far as those wishes can be worked out) unless making the decision in accordance with those wishes is likely to significantly adversely affect the person's interests.
- If giving effect to the person's wishes is likely to significantly adversely affect the person's interests - the attorney must give effect to the person's wishes as far as possible without significantly adversely affecting the person's interests.
- If the person's wishes cannot be given effect to at all, the person's interests must be promoted.
- The person's life (including their lifestyle) must be interfered with to the smallest extent necessary.

- The person must be encouraged to look after himself or herself as far as possible.
- The person must be encouraged to live in the general community, and take part in community activities, as far as possible.

2. *Health attorney*

A *health attorney* may give consent for an impaired capacity adult who has not appointed an enduring power of attorney and who does not have an appointed guardian to participate in *low-risk research* only.

An impaired capacity person's *health attorney*, in order of priority is:

- the protected person's domestic partner
- a carer for the protected person, or
- a close relative or close friend of the protected person.

The specific requirements for the *health attorney* to provide consent for an impaired capacity person to participate in *low-risk research* include:

The research must be approved by a HREC.

- A health professional believes on reasonable grounds that the impaired capacity person would, or is likely to, benefit from participating in *low-risk research* and the health attorney is best able to represent the views of that person.
- A health professional who asks a *health attorney* to consent to the protected person participating in *low-risk research* must give the *health attorney* all relevant information to enable the *health attorney* to make a decision, including information regarding the condition of the impaired capacity person, the relevant *low-risk research* for which consent is sought, the nature and degree of any significant risks involved and the decision-making principles.
- In making any decision in relation to these issues, a health professional must follow the decision-making principles described above. In considering whether to provide consent, a *health attorney* must also follow those decision-making principles.
- A *health attorney's* power to consent to the protected person participating in *low-risk research* must be exercised in a way that is consistent with any existing health direction made by the protected person under the MTA, unless it is not reasonable to do so.

3. *Guardian*

A person may be appointed as a *guardian* by order of ACAT (under section 7 of the GMPA) for a person with impaired decision-making ability to exercise the power to give, for the person, a consent required for *medical research* or *low risk research*.

A. Low-risk research

A *guardian* who has been given the power to give consent for a person to participate in *low-risk research* or *medical research* may consent to the protected person participating in *low-risk research* if the research has been approved by a HREC. The guardian must exercise their power to consent to the protected person participating in *low-risk research* in a way that is consistent with any existing health direction made by the protected person under the MTA.

B. Medical research

A *guardian* who has been appointed and given the power to give consent for an impaired capacity person to participate in *low-risk research* or *medical research* may consent to the protected person participating in *medical research* if all of the following requirements are satisfied:

- The research is approved by an HREC.
- The person is not likely to regain decision-making capacity (as assessed by an independent doctor) before the latest time that the person may meaningfully participate in the research.
- The *guardian* is satisfied on reasonable grounds that:
 - the research relates to the diagnosis, maintenance or treatment of a condition that the person has or has had or to which the person has a significant risk of being exposed
 - the research may result in benefit to the person or others with the condition
 - the potential benefit to the person, or others with the condition, of participating in the research outweighs any potential risk or inconvenience to the person, or any potential adverse impact on the person's quality of life, and
 - participating in the research will not unduly interfere with the person's privacy.

A guardian must exercise their power to consent to the impaired capacity person participating in medical research in a way that is consistent with any existing health direction made by the protected person under the MTA and having regard to the decision-making principles set out above.

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

There are no specific provisions in the ACT legislation permitting the conduct of research in the emergency context on an impaired capacity patient without consent.

What role the Australian Capital Territory Civil and Administrative Tribunal (ACAT) have in relation to the conduct of research?

ACAT has a limited role in relation to the decision for the giving of consent for an adult with impaired capacity to participate in research activities. ACAT's role includes giving an opinion to assist the substitute decision maker to decide whether to give consent, if the substitute decision maker makes application to ACAT, and reviewing a substitute decision maker's decision to provide or refuse consent for a person to participate in *medical research*. ACAT also has a role in issues regarding the appointment of guardians and the exercise of their powers.

Checklist of matters for HRECs to consider

- Does the research involve adult participants who lack the capacity to provide informed consent?
- Does the research constitute *low-risk research* or *medical research* as defined in the ACT legislation?
- Does the proposal include appropriate documentation to enable the substitute decision maker to consider a request to provide consent and to give that consent?
- Has the HREC's approval been given subject to the research being conducted in accordance with all relevant legal requirements and the obtaining of consent for participants who lack the capacity to provide informed consent?
- Having considered the above, does the HREC need to seek further advice from the researcher?