

**Laws relating to the giving of consent
for persons with impaired capacity
to provide informed consent to
participate in research in each
Australian State and Territory**

**Report to the National Health and Medical Research
Council**

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Definition of terms and abbreviations used in this report

Commonwealth: Commonwealth of Australia.

HREC: A human research ethics committee which:

- is constituted under and acting in accordance with the National Statement and with any guidelines issues by the Chief Executive Officer of NHMRC;
- is registered with NHMRC; and
- has notified its existence to the Australian Health Ethics Committee established under the *National Health and Medical Research Council Act 1992 (Cth)*.

National Statement: *National Statement on Ethical Conduct in Human Research (2007)*.

NHMRC: National Health and Medical Research Council.

State: a state of the Commonwealth.

Territory: a territory of the Commonwealth.

Note on terminology: In this report, the reference to a person as having impaired capacity means the person lacks the capacity to provide informed consent. As identified in later sections of this report, a number of jurisdictions define the concept of impaired capacity in their relevant legislation. These differences are noted where appropriate; however, for ease of reading, 'persons with impaired capacity to provide consent' or is the default phrase applied throughout this report.

Disclaimer

The information provided in this report is an overview of the relevant legal requirements and is of a general nature only. The report does not provide legal advice in relation to any specific human research project or clinical trial.

The report should not be relied upon by any person as a definitive statement of their legal obligations in relation to the conduct of human research that may involve participants who lack the capacity to provide informed consent. You should obtain legal or other professional advice appropriate to your circumstances before acting or relying on any matter referred to in this report.

Views and opinions set out in this report are those of the author only and do not necessarily reflect those of NHMRC.

The author does not accept any liability if this report is used for an alternative purpose from which it is intended, or to any third party in respect of any issue raised in this report.

The information in this report is current as at June 2016.

A General background and issues

Description and purpose of this report

This report sets out the legal requirements in each State and Territory and the Commonwealth for the giving of consent for persons with impaired capacity to provide informed consent to participate in human research. In this report, the reference to a person as having impaired capacity means the person lacks the capacity to provide informed consent. As identified in later sections of this report, a number of jurisdictions define the concept of impaired capacity in their relevant legislation.

The report considers the requirements relating to all types of human research, including clinical trials. It focusses on the relevant requirement for adults with impaired capacity; it also summarises the applicable legal principles regarding the giving of consent for minors to participate in human research. The report provides an explanation of the applicable requirements and, where appropriate, includes comments that may assist in the practical application of the relevant requirements. In most cases, and where appropriate, the report adopts the terminology used in the relevant legislation in describing the requirements of that legislation so that readers are familiar with that terminology and might more readily identify the relevant requirements when referring to the specific legislation.

The report also identifies the legal principles arising from any judicial decisions that have considered those requirements. However, there is not an abundance of such judicial decisions.

The report has been prepared to assist researchers, members of HRECs, research governance officers and others involved in the conduct of human research to assist them in understanding the relevant requirements in each jurisdiction. The purpose of the report is to provide an understanding of the legislative framework regarding the giving of consent for persons with impaired capacity to participate in human research in the applicable jurisdiction. It may be particularly useful for those proposing to conduct research in jurisdictions outside their own and for HRECs that might be required to review such a research project. It is anticipated that the provision of this guidance will facilitate the timely approval and commencement of human research projects that will be conducted in more than one jurisdiction and are submitted in accordance with single ethical review processes.

Jurisdictional approaches

The report demonstrates that there are significant differences in the approach of the various jurisdictions in relation to the requirements and processes for the giving of consent for an adult with impaired capacity to provide informed consent to participate in human research. The jurisdictions broadly fall into two categories: those that have specific legislative provisions that deal directly with this issue and prescribe specific requirements and a clear process for the giving of such consent and those that do not. This report also identifies the differences between jurisdictions regarding the giving of consent for minors to participate in human research.

Jurisdictions with specific legislation

The jurisdictions that have specific legislation utilise different concepts, terminology and processes. The definitions relating to research and the activities that constitute research are different across those jurisdictions. The requirements within a jurisdiction may also differ according to the type of research, for example - jurisdictional laws variously distinguish between research categories including 'clinical trial', 'clinical research', 'experimental health care' and 'comparative research'. In addition, the provisions dealing with the giving of consent for adults with impaired capacity to provide consent to participate in research are, with the exception of one jurisdiction, often scattered across different parts of the relevant Act or even across more than one Act.

As a result, it is challenging for HRECs, researchers and others who require this information to navigate the legislation and to identify (and then apply) the specific legal requirements that might be applicable to their research project.

A number of the jurisdictions require the submission of certain research proposals to an independent tribunal (the tribunal is typically the relevant State's or Territory's civil and administrative tribunal). These tribunals may be responsible for approving the research proposal and/or giving consent on behalf of the person with impaired capacity, or they may have a more limited role. New South Wales and Queensland are examples of the former; Victoria is an example of the latter.

The jurisdictions that prescribe a process for a substitute decision maker to provide consent on behalf of an adult with impaired capacity to provide consent to participate in a research project typically require the decision maker to exercise that authority on the basis of certain principles. One of those principles which appears throughout the relevant legislation is that the decision maker must have regard to whether the person's participation in the research is in the person's 'best interests'.

While these differences might create legal and administrative hurdles for a researcher who wishes to conduct a research project in more than one jurisdiction, the presence of dedicated legislative provisions nevertheless provides clarity and specific guidance as to what is required to comply with the applicable law.

Jurisdictions without specific legislation

The jurisdictions that have no legislation that directly deals with the process for the giving of consent for an adult with impaired capacity to provide informed consent to participate in human research fail to provide the same degree of clarity and guidance. This does not necessarily mean that it is more difficult to commence a research project in those jurisdictions. The absence of specific requirements might even be perceived to be advantageous, arguably making it easier to commence a research project, as there may be fewer requirements to satisfy and fewer administrative and legal hurdles to overcome. For example, this might be the case in a jurisdiction where there is no requirement to submit a research project to an independent tribunal for approval. However, the absence of specific provisions dealing with the giving of consent for research may create uncertainty as to the lawfulness of a model for consent for a particular research project. It may, for example, cause researchers to be uncertain about whether the model for consent they are proposing for their research project is lawful and it may cause HRECs to have reservations about approving that research.

In certain cases, it could be argued that, if there are no specific requirements, then the principles for the giving of consent for an adult with impaired capacity to participate in research might be the same principles that apply to the making of other types of decisions (by a substitute decision maker or through a substitute decision making process) for such a person in the relevant jurisdiction. All jurisdictions have guardianship and similar laws that provide for a substitute decision maker to make decisions for an adult with impaired capacity to provide consent on a range of matters, including the provision of medical care or treatment to that person, their living arrangements and financial matters. It could be argued that research (whether involving the carrying out of activities that might constitute medical care or treatment or not) falls within one of the matters in respect of which a substitute decision maker could lawfully exercise a power on behalf of the impaired capacity person. Of course, this is a legal question which is distinct from whether it might be ethical to enrol such a person into research. Some of the relevant ethics considerations are identified in the next section.

Therefore, if under applicable guardianship or similar laws a substitute decision maker has authority to consent to the giving of medical care or treatment to an adult with impaired capacity and if the research involves the provision of 'medical care or treatment' (the most common example of such research being a clinical trial), the substitute decision maker could arguably consent to the giving of medical care and treatment to the person in the course of that research – in this way, the substitute decision maker would effectively be giving consent for the person to participate in the research. Of course, in this analysis, there is an assumption that the relevant research activities and procedures would constitute medical care or treatment under the applicable laws. There are at least three considerations that could potentially challenge such an assumption.

The first consideration is whether the therapy being given in the course of research does, in fact, constitute medical care or treatment, however the concept of treatment is defined in the applicable laws. A research project that involves the provision of some form of medical or clinical intervention will usually be trialling a therapy that is unproven. One of the major purposes of the research will often be to determine whether the therapy being trialled is effective – it may prove to be ineffective or not sufficiently effective to be subsequently adopted as an accepted treatment. Furthermore, many research projects (clinical trials in particular) are designed so that they have a placebo arm and many (perhaps most) are also double blinded and randomised. In such cases, in the ordinary course of the research it is not possible to determine which patients are receiving the placebo and which are receiving active therapy. Therefore, given that it is doubtful that it could be asserted that those receiving placebo are receiving medical care or treatment, there are limitations to the applicability of the argument.

The second consideration is the requirement in most of the applicable laws that the substitute decision maker's authority to give consent to the provision of medical care and treatment to an adult with impaired capacity is only exercisable if it is in the person's 'best interests' or that there is some degree of necessity. Again, given the nature of research and the uncertainty around whether any therapies given in the course of research constitute medical care and treatment, it may be challenging in many cases to assert that the person's involvement in the research is in their best interest or is necessary in the context of their individual circumstances.

The third consideration is whether the person's participation in such research would be incidental to the giving of medical care or treatment which the person might require or whether it is the main or primary purpose of the activity. This may be a distinction that is relevant to a substitute decision

maker's ability to provide consent and the types of considerations the decision maker must take into account in exercising such authority.

It is submitted that the research sector would benefit from the clarity and certainty that would result from the introduction of specific legislative provisions regarding the giving of consent for adults with impaired capacity to provide consent to participate in research in those jurisdictions that currently do not have them.

The interaction of legal and ethical considerations

The *National Statement* is the guideline which is most relevant to a discussion of the ethical issues regarding the giving of consent for persons with impaired capacity to participate in research.

Chapter 4.4 of the *National Statement* describes the ethical considerations regarding the conduct of research involving people highly dependent on medical care whose capacity to give consent is limited or non-existent. In this report, such a person is generally referred to as a person with impaired capacity to provide informed consent or a person who lacks the capacity to provide informed consent.

Paragraph 4.4.9 of the *National Statement* states that consent should be sought from people highly dependent on medical care wherever they are capable of giving consent and it is practicable to approach them. This report describes the legal requirements where such person is incapable of giving consent.

Paragraph 4.4.10 of the *National Statement* provides that where it is not practicable to approach a person highly dependent on medical care, or the person is not capable of making such a decision, consent should be sought from the participant's guardian, or person or organisation authorised by law. The conduct of the research must have regard to the ethical principles described in the *National Statement* and the applicable legal requirements in the relevant jurisdiction. In nearly all cases, the ethical and legal requirements will be consistent. In circumstances where they are not, the applicable legal requirements must prevail.

The introduction to Chapter 4.4 of the *National Statement* states that in relation to the conduct of research involving people highly dependent on medical care whose capacity to give consent is limited or non-existent '*in every instance, relevant jurisdictional laws will need to be taken into account.*' This report sets out those jurisdictional laws.

Legal concepts of capacity and substitute decision-making should be seen within a broader context of ethical and respectful research. Where possible, an individual who lacks capacity to consent should be encouraged to express their own views and opinions and to have those views and opinions considered with due respect by researchers, guardians and other decision-makers.

Finally, this report does not include a review/assessment framework for assessing a person's level of capacity; however, a number of State and Territory resources exist which may be of assistance to researchers and HRECs, for example the New South Wales Government Attorney-General's Department's Capacity Toolkit available at:

http://www.justice.nsw.gov.au/diversityservices/Documents/capacity_toolkit0609.pdf

B The legal requirements concerning the giving of consent for minors to participate in human research

The legal principles regarding the giving of consent for children and young people to participate in research activities have regard to the unique issues that apply to children and young persons, including: children and young people's capacity to understand what the research entails; their possible susceptibility to coercion by parents, peers, researchers or others to participate in research; and conflicting values and interests of parents and children. The principles set out in Chapter 4.2 of the *National Statement* regarding the particular ethical concerns that arise in relation to research involving children and young people are consistent with those legal principles.

The definition of a minor

In Australian jurisdictions, a child or a minor is generally considered to be a person who is less than 18 years of age. The legislation relating to the giving of consent for a person with impaired capacity to give consent to participate in human research generally apply to adults only and do not specifically apply to the giving of consent for minors to participate in human research. However, in some cases those laws may be relevant to the participation of a minor in human research where the laws specify that they apply to persons of or from a particular age – for example, in New South Wales the *Guardianship Act 1987* (NSW) applies to clinical trials which might involve participants who are 16 years or older.

Parental or guardian authority to give consent for a minor

The common law principles regarding who may give consent for a minor to receive medical treatment also typically apply in relation to who may give consent for a minor to participate in human research. Generally, either parent or a guardian may consent to the giving of medical treatment to a minor. Section 61C (1) of the *Family Law Act 1975* (Cth) provides that 'each of the parents of a child who is not 18 has parental responsibility for the child'. This principle is subject to any parenting order a court might make or a parenting plan (as defined in section 63C of the *Family Law Act 1975* (Cth)) into which the parents have entered. Parental responsibility is defined in that Act as 'all the duties, powers, responsibilities and authority which, by law, parents have in relation to children.' 'Parental responsibility' includes the giving or withholding of consent for a minor to receive medical treatment.

Accordingly, it follows that either parent who maintains parental responsibility in respect of a minor or a guardian may consent to the participation of a minor in a human research project. The parent or guardian must be given the same types of information about the research project as would be given in relation to a research project involving adults – this will enable the parent or guardian to make an informed decision.

Older minors

The common law recognises that in some cases an older minor (or in the language of the *National Statement*, a 'young person') may have the maturity and capacity to independently provide consent to medical treatment. However, the determination of the competence of an older minor or young person can be complex and must have regard to a number of considerations. The assessment of a minor's competence must be undertaken by an appropriately qualified professional and must have

regard to issues including: the minor's age, the minor's level of maturity and autonomy, the minor's capacity to understand the relevant issues, the type of information that will be discussed and the nature and complexity of the research, including the possible consequences and risks of any treatments or procedures.

The principles concerning the capacity of a minor to independently consent to his or her treatment have their origins in the English case of *Gillick v West Norfolk & Wisbech Area Health Authority and Department of Health & Social Security* [1986] AC 112 House of Lords (**Gillick**). Essentially, a minor has capacity to provide consent to treatment (independently of his or her parents) if the minor understands the nature of the advice being given and has 'a sufficient maturity to understand what is involved'.

The principles established by *Gillick* were approved by the High Court of Australia in *Secretary, Department of Health and Community Services v JWB and SMB* [1992] 175 CLR 218 (**Marion's Case**) and have since been applied in Australian jurisdictions. A minor who has been assessed as possessing the requisite capacity in the particular circumstances is often referred to as 'Gillick competent' or a 'mature minor'. On the basis of these principles, a relatively young child may be able to consent to a very simple procedure, such as the taking of their temperature; however, more complex, risky or contentious procedures will require a higher level of maturity and understanding.

Marion's Case also established principles concerning the limitations of a *Gillick* competent child's decision making ability. In particular, in *Marion's Case*, the High Court determined that the courts have authority to override a decision of a parent and a *Gillick* competent child if the parent or child (as the case may be) has refused treatment and that a court may authorise such treatment if it is considered to be in the best interests of the child.

A number of jurisdictions have codified or otherwise given statutory recognition to some of these common law principles:

- In New South Wales, section 49(2) of the *Minors (Property and Contracts) Act 1970* (NSW) provides that if a minor aged fourteen years or over has consented to his or her medical or dental treatment, the minor's consent will be effective in relation to defending a claim by the minor for assault or battery in relation to the treatment. However, while these provisions recognise the right of a minor over 14 years of age to consent to treatment, their primary focus relates to establishing a defence for medical or dental practitioners, rather than defining the scope of a minor's ability to provide consent.
- In South Australia, section 6 of the *Consent to Medical Treatment and Palliative Care Act 1995* (SA) provides that a 'person of or over 16 years of age may make decisions about his or her own medical treatment as validly and effectively as an adult.' Further, section 12(b) of that Act allows a medical practitioner to administer medical treatment to a child if the child consents and the medical practitioner is of the opinion that the child is capable of understanding the nature, consequences and risks of the treatment. The medical practitioner must also be of the opinion that that the treatment is in the best interest of the child's health and well-being and his or her opinion must be supported by the written opinion of at least one other medical practitioner.

The above principles regarding the ability of a mature minor or *Gillick* competent minor to consent to medical treatment may, in theory, be applied in relation to the giving of consent by a minor to

participate in a human research project. However, those principles were primarily developed, and have been applied by the courts, in the context of the provision of medical treatment required to promote or preserve the health or life of a child, rather than in the context of the provision of any therapy or the administration of a procedure in the course of a human research activity.

A research project is relatively more likely to involve issues and activities that are more complex and perhaps even contentious in comparison to the giving of medical treatment that is required to preserve the health of the child; the research may also potentially expose the child to risks to which the child would not otherwise be exposed. Permitting a *Gillick* competent child to independently consent to undergoing medical treatment or a procedure will usually be uncontroversial if the treatment or procedure promotes or preserves the health or life of the child. However, different considerations apply in relation to a child's possible participation in human research and the rationale for permitting a *Gillick* competent child to independently provide consent may be less compelling, particularly where the research offers no proven health or other benefit for the child and may even expose the child to additional risks. These factors would need to be taken into account in the assessment of a minor's maturity and capacity to understand what is proposed.

Therefore, an institution which, or a person who, proposes to rely on these principles must have regard to whether and how they should be applied in the context of a mature minor having the capacity to consent to participate in human research. In this respect, the ethical principle of whether the child's participation in the research is in their best interests will be a relevant factor in that assessment. The 'best interests' principle is enshrined in the law and is given specific recognition in the *National Statement* (paragraph 4.2.13) and the *United Nations Convention on the Rights of the Child*.

In some circumstances, parents or guardians and mature minors may hold overlapping rights under the law in relation to the giving of consent for the minor's participation in a human research project. Many organisations which conduct research activities that involve a mature minor will, as a matter of practice, seek the consent of the mature minor and their parent. It is submitted that it is prudent for institutions and researchers who conduct research that involves mature minors to implement processes that have regard to the rights and interest of all affected parties, while ensuring compliance with the relevant legal requirements.

C The legal requirements in each jurisdiction regarding the giving of consent for adults with impaired capacity to provide informed consent to participate in research

Commonwealth

Legislation

Family Law Act 1975 (FLA)

Applicable requirements

There is no specific Commonwealth legislation that deals with the legal requirements for giving of consent for an adult who lacks capacity to provide consent to participate in a human research activity.

The FLA is relevant in respect of the giving of consent for minors to participate in research activities to the extent that it defines parental responsibility and deals with issues concerning the exercise of parental authority.

Section 61C provides that each of the parents of a child who is not 18 has 'parental responsibility' for the child. 'Parental responsibility' is defined in section 61B as 'in relation to a child, all the duties, powers, responsibilities and authority which, by law, parents have in relation to children'. A person's parental responsibility may be modified by a parenting order made by a court or by a parenting plan (as defined in section 63C of the FLA) entered by the parents.

Parental responsibility includes a parent's authority to give consent for their child to participate in a research activity. However, parental authority cannot be exercised capriciously and it is not without constraints. The exercise of parental authority must have regard to what is in the best interests of the child. Further, there are certain treatments and procedures that only a court has the power to authorise. For example, in *Marion's Case*, the High Court held that only a court could provide consent to an invasive and irreversible sterilisation procedure that was carried out on a minor for a non-therapeutic purpose.

Australian Capital Territory (ACT)

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.

Legislation

Guardianship and Property Management Act 1991 (GPMA)

Medical Treatment (Health Directions) Act 2006 (MTA)

Powers of Attorney Act 2006 (PAA)

Applicable requirements

Outline of requirements

- The ACT legislation establishes three categories of substitute decision makers who may provide consent for a person with impaired capacity to provide informed consent to participate in research activities:
 - An enduring power of attorney appointed under the PAA may give consent for a person with impaired capacity person to participate in *medical research* (including clinical trials) and *low-risk research*.
 - A guardian appointed under the GMPA may provide consent for a person with impaired capacity to participate in *medical research* (including clinical trials) and *low-risk research*.
 - A health attorney may give consent for a person with impaired capacity to participate *low-risk research* only.
- The ACT legislation applies to adults – that is, a person over the age of 18 years.
- There are no specific provisions permitting the conduct of research on a person with impaired capacity in the emergency context without a requirement to obtain consent.
- The ACT Civil and Administrative Tribunal has a limited role in the decision making process.

PAA – Specific requirements

A person who has been appointed *medical research power of attorney* may make decisions about *low-risk research* and *medical research* for a person (**principal**) who has appointed them to do so. A *medical research power of attorney* is:

- an enduring power of attorney under which the principal authorises an attorney to exercise power in relation to a *medical research* matter; or
- an enduring power of attorney under which the principal authorises an attorney to exercise power in relation to a health care matter (but not specifically a *medical research* matter) that was made before the commencement of the PAAA.

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*. However, the definition of *medical research* may not apply to a study to the extent that it involves a research participant who is a healthy volunteer. A healthy volunteer would not have or have had a significant risk of being exposed to the relevant medical condition. Practically, however, this may not be of much significance given that it is unlikely a person with impaired capacity would be considered for involvement in a research project as a healthy volunteer participant.

Attorney's consent for low-risk research

An attorney authorised under a *medical research power of attorney* may consent to the principal participating in *low-risk research* if the principal has impaired decision-making capacity and the research is approved by a HREC.

Attorney's consent for medical research

An attorney authorised under a *medical research power of attorney* may consent to the principal participating in *medical research* if the principal has impaired decision-making capacity and all of the following apply:

- The research is approved by an HREC constituted in accordance and acting in compliance with the *National Statement*.
- The principal is not likely to regain decision-making capacity before the latest time that the principal may meaningfully participate in the research. The likelihood of the principal regaining decision-making capacity must be assessed by an independent doctor who must state in writing his or her belief in this respect and the reasons for the belief.
- The attorney is satisfied on reasonable grounds that
 - the research relates to the diagnosis, maintenance or treatment of a condition that the principal has or has had or to which the principal has a significant risk of being exposed
 - the research may result in benefit to the principal or others with the condition
 - the potential benefit to the principal, or others with the condition, of participating in the research outweighs any potential risk or inconvenience to the principal, or any potential adverse impact on the principal's quality of life, and
 - participating in the research will not unduly interfere with the principal's privacy.

Attorney must follow decision-making principles

An attorney who is asked to consent to the participation of a principal (who has impaired decision-making capacity) in *low-risk research* or *medical research* must exercise the power according to the decision making principles set out in section 41B of the PAA. The decision making principles are the following:

- The principal's wishes, as far as they can be worked out, must be given effect to, unless making the decision in accordance with the wishes is likely to significantly adversely affect the principal's interests.

- If giving effect to the principal's wishes is likely to significantly adversely affect the principal's interests - the attorney must give effect to the principal's wishes as far as possible without significantly adversely affecting the principal's interests.
- If the principal's wishes cannot be given effect to at all, the principal's interests must be promoted.

In *JOAN WHYTE (Guardianship and Management of Property)* [2010] ACAT 23 (21 April 2010), the Australian Capital Territory Civil and Administrative Tribunal determined that the attorneys' compliance with the principal's earlier expressed wishes was likely to significantly adversely affect her interests. The Tribunal held that the attorneys' decision to act contrary to those wishes for the purpose of her care and protection was appropriate and consistent with the decision making principles.

- The principal's life (including the principal's lifestyle) must be interfered with to the smallest extent necessary.
- The principal must be encouraged to look after himself or herself as far as possible.
- The principal must be encouraged to live in the general community, and take part in community activities, as far as possible.

GMPA – Specific requirements

The GMPA provides that a *health attorney* or a guardian may provide consent for an impaired capacity person to participate in research.

Health attorney's power

The GMPA provides that a *health attorney* may give consent for a *protected person* to participate in *low-risk research* only. A *protected person* is an adult who has impaired decision-making ability for the giving of consent to medical treatment:

- who has not appointed an attorney with authority to give consent for medical treatment by an enduring power of attorney under the PAA or under another similar law, and
- for whom the Australian Capital Territory Civil and Administrative Tribunal (**ACAT**) has not appointed a guardian under the GMPA with authority to give consent to medical treatment not involving consent.

A protected 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 a *protected person* to participate in *low-risk* research are:

- A health professional who believes on reasonable grounds that a person is a *protected person* and that such person would, or is likely to, benefit from participating in *low-risk research* may ask the *health attorney* who the health professional believes on reasonable grounds is best able to represent the views of the *protected person* to give a consent required for the *low-risk research*.
- A health professional who asks a *health attorney* to consent to the *protected person* participating in *low-risk research* must give the *health attorney* information about the following:

- the reasons why the person is a *protected person* and the condition of *the protected person*
 - the *low-risk research* for which consent is sought
 - any available, alternative *low-risk research*
 - the nature and degree of any significant risks involved with the *low-risk research* for which consent is sought
 - the likely effect of the *protected person* not participating in the *low-risk research* for which consent is sought
 - the decision-making principles, and
 - any other matter that the health professional believes on reasonable grounds is relevant to the provision of consent for the *low-risk research*.
- In making any decision in relation to these issues, a health professional must follow the decision-making principles set out in section 4(2) of the GMPA. In considering whether to provide consent, a *health attorney* must also follow those decision-making principles. The decision-making principles in the GMPA are practically identical to those listed above regarding the PAA.
 - 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.
 - A *health attorney* may consent to the protected person participating in *low-risk research* only if the research is approved by a HREC.
 - If, after receiving all relevant information, the *health attorney* gives consent for the *protected person* to participate in *low-risk research*, the health professional is not required to obtain any other consent for the person's participation in the research.

If consent for the *protected person* to participate in *low-risk research* has been given by a *health attorney* and the *protected person* continues to participate in the research in accordance with the consent six months after it was given, the health professional who is carrying out the research, must notify the ACT's public advocate.

Guardian's powers

1. Low-risk research

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 guardian who has been appointed and given the power to give consent for a *protected person* to participate in *low-risk research* only may consent to the *protected person* participating in *low-risk research* if the research has been approved by an HREC. Further, 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.

2. Medical research

A guardian who has been appointed and given the power to give consent for a *protected person* to participate in *low-risk research* and *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 *protected person* is not likely to regain decision-making capacity before the latest time that the *protected person* may meaningfully participate in the research. The likelihood of the *protected person* regaining decision-making capacity must be assessed by an independent

doctor who must state in writing his or her belief in this respect and the reasons for the belief.

- The guardian is satisfied on reasonable grounds that:
 - the research relates to the diagnosis, maintenance or treatment of a condition that the *protected person* has or has had or to which the *protected person* has a significant risk of being exposed
 - the research may result in benefit to the protected person or others with the condition
 - the potential benefit to the *protected person*, or others with the condition, of participating in the research outweighs any potential risk or inconvenience to the *protected person*, or any potential adverse impact on the protected person's quality of life, and
 - participating in the research will not unduly interfere with the *protected person's* privacy.

Furthermore, a guardian must exercise their power to consent to the *protected 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 in section 4(2) of the GMPA.

MTA – Specific requirements

The MTA is relevant to the extent that an impaired capacity person has made a health direction under the MTA (while the person had capacity) and a guardian, *health attorney* or enduring power of attorney proposes to exercise a power in relation that person. A health direction made by an adult (while competent) in writing to refuse, or require the withdrawal of, medical treatment generally or a particular kind of medical treatment.

Relationship between a health direction and enduring power of attorney

A person may make a health direction and an enduring power of attorney that deals with a *medical research matter*. In such a case, the following principles apply:

- If the health direction is consistent with the enduring power of attorney, the attorney must comply with the health direction when making a decision about the relevant *medical research matter*.
- If the health direction is not consistent with the enduring power of attorney, when making a decision about health care the attorney must comply with:
 - the power of attorney if the health direction was made before the power of attorney, and
 - the health direction if the health direction was made after the power of attorney.

Effect of health directions on later guardian or health attorney

A person who has made a health direction may subsequently lose the capacity to make informed decisions.

A guardian or health attorney exercising a power to consent to the person participating in *medical research* or *low-risk research* must exercise the power in a way that is consistent with the health direction, unless it is not reasonable to do so.

Role of ACAT

Unlike the situation in some other jurisdictions, ACAT has a limited role in relation to the decision for the giving of consent for an impaired capacity adult 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 decisions 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*.

Interpretation of ACT legislation

It is a requirement under section 30 of the *Human Rights Act 2004 (ACT) (HRA)* that, so far as it is possible to do so consistently with their purpose, the laws of the Australian Capital Territory must be interpreted in a way that is compatible with 'human rights' (as that term is defined in Part 3 and Part 3A of the HRA).

The conduct of research in the emergency context

There are no specific provisions in the ACT legislation permitting the conduct of research in the emergency context involving a person with impaired capacity without a requirement to obtain consent.

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?

New South Wales

Legislation

Guardianship Act 1987 (NSW) (**GA**)

Guardianship Regulation 2010 (NSW) (**GR**)

Applicable requirements

Outline of requirements

- A *clinical trial* which might involve participants who are 16 years or older who lack the capacity to provide informed consent must be submitted to the NSW Civil and Administrative Tribunal (**NSW Tribunal**) for approval. Not all interventional research may fall within the scope of 'clinical trial' under the GA.
- The NSW Tribunal's approval does not amount to consent for the recruitment of individual participants into the clinical trial.
- If the clinical trial is approved, the NSW Tribunal determines whether consent for the carrying out of *medical or dental treatment* on patients in the course of the trial may be given by the *person responsible* for that patient or by the NSW Tribunal itself.
- Consent for each person to participate in the clinical trial must then be given by either the *person responsible* or the NSW Tribunal (as applicable).
- There is no requirement to submit a human research project that is not a *clinical trial* (and that does not involve the administration of *medical treatment or dental treatment*) that will involve the participation of a person with impaired capacity to the NSW Tribunal for approval. Consent for the impaired capacity person's participation in such research project may be given by their *person responsible*.
- Section 37 of the GA allows for the carrying out of a *medical treatment* on an impaired capacity patient without the requirement to obtain consent in limited (emergency) circumstances – these provisions may apply to certain *clinical trials*.

Relevant requirements applying to a *person who is incapable of giving consent*

The relevant requirements of the GA apply in respect of a person who is incapable of giving consent to the carrying out of the relevant procedure or activity. Section 33(2) of the GA provides that a person is incapable of giving consent to the carrying out of *medical or dental treatment* if the person is incapable of:

- understanding the general nature and effect of the proposed treatment, or
- indicating whether or not he or she consents or does not consent to the treatment being carried out.

Clinical trials

The specific provisions regarding the giving of consent for an impaired capacity person to participate in a clinical trial are set out in Division 4A of Part 5 of the GA.

A *clinical trial* which is to be conducted in New South Wales and which may include a person who is 16 years of age or older who is unable to provide informed consent to participate must be submitted to the NSW Tribunal for approval.

The approval process involves two elements: the first involves the NSW Tribunal deciding whether to approve the *clinical trial* to proceed; the second involves the NSW Tribunal determining whether consent for an individual impaired capacity person to participate in the (approved) *clinical trial* may be given by the NSW Tribunal or that person's *person responsible*.

A *clinical trial* is defined as a trial of drugs or techniques that necessarily involves the carrying out of *medical or dental treatment* on the participants in the trial. The definition is therefore quite broad – it includes drug trials and trials of techniques – for example, surgical techniques. The trial must also involve the carrying out of *medical or dental treatment*.

Medical or dental treatment is defined as:

- medical treatment (including any medical or surgical procedure, operation or examination and any prophylactic, palliative or rehabilitative care) normally carried out by or under the supervision of a medical practitioner
- dental treatment (including any dental procedure, operation or examination) normally carried out by or under the supervision of a dentist, and
- any other act declared by the GR to be treatment for the purposes of Part 5 of the GA.

In the case of treatment in the course of a *clinical trial*, *medical or dental treatment* includes the giving of placebos to some of the participants in the trial. However, *medical or dental treatment* does not include:

- any non-intrusive examination made for diagnostic purposes (including a visual examination of the mouth, throat, nasal cavity, eyes or ears)
- first-aid medical or dental treatment
- the administration of a pharmaceutical drug for the purpose, and in accordance with the dosage level, recommended in the manufacturer's instructions (being a drug for which a prescription is not required and which is normally self-administered), or
- any other kind of treatment that is declared by the regulations not to be treatment for the purposes of Part 5 of the GA.

Two decisions of the NSW Tribunal suggested that the definition of *clinical trial* for the purposes of the GA is relatively broad. However, a recent appeal decision in one of those cases has somewhat confined the definition of *clinical trials*.

In *Application for approval for adults unable to consent to their own treatment to participate in a clinical trial (AMOUNT Rehabilitation Trial)* [2015] NSWCATGD 1 (6 January 2015), the NSW Tribunal held that a research project that proposed to use commercially available technologies, such as Nintendo Wii and Fitbit, to evaluate the use of technology on rehabilitative care was a clinical trial for the purposes of the GA, reasoning that the definition of clinical trial is 'unambiguously wide'. The NSW Tribunal opined that if the legislature had intended to limit the definition of 'clinical trial', it 'could have easily done so by excluding research or non-intrusive procedures from the definition of treatment'. In this case, the NSW Tribunal's opinion was heavily influenced by the fact that the study involved randomisation, with the NSW Tribunal ruling that 'once there is randomisation of treatment, the treatment must necessarily be part of a trial.'

In *Re Application for Approval for Adults Unable to Consent to Their Own Treatment to Participate in a Clinical Trial (Spice III Trial)* [2014] NSWCATGD 44 (23 December 2014), the NSW Tribunal considered whether a prospective, multicentre, randomised controlled trial of early goal directed sedation compared with standard care in mechanically ventilated patients in intensive care constituted a ‘clinical trial’ for the purposes of the GA. The study proposed to trial a drug which was listed on the Therapeutic Goods Administration’s (TGA) Australian Register of Therapeutic Goods, although the drug was to be used in the study outside of its approval – specifically, the study drug was to be used for a longer treatment period than the period that applied to its TGA approval. The researcher argued that the definition of ‘clinical trial’ applied only to new or experimental drugs or treatments. The NSW Tribunal rejected that submission and determined that the study fell within the GA’s definition of ‘clinical trial’. The NSW Tribunal reasoned that as long as the study drug ‘retains its current TGA registration and is therefore captured by the clinical trial notification scheme’ of the *Therapeutic Goods Act 1989* (Cth) (because it was to be used ‘beyond its licensed parameters’), it amounted to a ‘clinical trial’ under the GA.

NHMRC notes that since the original report was prepared, the decision in *SPICE III* has been appealed and overturned. The decision in *Spice III Trial* was appealed to the Appeal Panel of the Civil and Administrative Tribunal New South Wales: *Shehabi v Attorney General (NSW)* [2016] NSWCATAP 137 (24 June 2016).

In *Shehabi v Attorney General (NSW)* the Appeal Panel allowed the appeal against the decision of the Guardianship Division. In particular, the Appeal Panel held that the *Spice III* trial was *not* a ‘clinical trial’ falling within Pt 5 of the *Guardianship Act*.

After considering the purpose of the *Guardianship Act* as a whole; gaining a detailed understanding of the only part of the Act in which *clinical trials* are mentioned, and the definition of ‘clinical trial’ contained in that Part; and ‘the legislative history of the clinical trial provisions and the mischief that the introduction of those provisions was designed to overcome’, the Appeal Panel preferred a construction of ‘the words “clinical trial” ... which is limited to trials of drugs or techniques that necessarily involve new medical (or dental) treatment that has not yet gained the support of a substantial number of medical practitioners (or dentists) specialising in the area of practice...’ This construction, the Appeal Panel argued, ‘would be consistent with the text of s 45AA [and] gives the offence provisions ... and other provisions ... an harmonious operation and does not lead to incongruous or absurd results.’ [84], [118].

In contrast to the decision in *AMOUNT Rehabilitation Trial*, the Appeal Panel also held that ‘whether or not a study is required to be notified under the [*Therapeutic Goods Act 1989* (Cth)] and whether or not it falls within the NHMRC’s explanation of “clinical trial” [i.e. it involves randomisation] cannot be determinative of whether the study is a “clinical trial” for the purposes of the *Guardianship Act*.’ [158].

It is important to note the converse of this finding: just because a clinical trial does *not* need to be notified to the TGA or does *not* involve randomisation, does not mean it is *not* a ‘clinical trial’ for the purpose of the *Guardianship Act*.

Other earlier decisions of the NSW Tribunal have explored and identified some of the limits to the definition of ‘clinical trial’:

In *Application for approval for adults unable to consent to their own treatment to participate in a clinical trial (ADRENAL Trial)* [2015] NSWCATGD 23 (19 June 2015), the NSW Tribunal considered whether a randomised, blinded, placebo controlled trial of hydrocortisone in critically ill patients

with septic shock amounted to a 'clinical trial' for the purposes of the GA. The study involved the comparison of two widely accepted, standard forms of critical care treatment.

The NSW Tribunal determined that the study was trialling a pharmaceutical that had been used generally by practitioners for a long period of time in the treatment of the condition which was the subject of the study and that it was to be used in the trial in accordance with, and 'not administered beyond' its Therapeutic Goods Administration registration. For this reason, the study did not fall within the GA's definition of 'clinical trial'.

In *Application for approval for adults unable to consent to their own treatment to participate in a clinical trial (TRANSFUSE Trial) [2015] NSWCATGD 18*, the study in question was a multi-centre randomised, double blinded, phase III trial which compared the effect of the use of standard issue red blood cell blood units on mortality to the use of freshest available red blood cell units. The study sought to test the hypothesis that in critically ill patients who require a red blood cell transfusion the administration of the freshest available compatible red blood cells reduces 90-day patient mortality; it was to compare this against the standard practice of using the oldest stored blood first. The NSW Tribunal determined that the trial was neither a trial of drugs nor a trial of techniques and therefore did not fall within the GA's definition of a 'clinical trial'. It reasoned that that the substance that formed the basis of the trial – blood – does not fall within the ordinary meaning of 'drug'. Further, the NSW Tribunal concluded that the study was not trialling a technique – it was merely testing and comparing the impact of the relative age of the blood available for transfusion on 90-day patient mortality outcomes.

Requirements to be satisfied for NSW Tribunal's approval (section 45AA)

If a clinical trial is within the scope of the GA, the NSW Tribunal *may* approve a *clinical trial* as a trial in which patients who lack capacity to provide consent may participate.

The NSW Tribunal may give approval to a *clinical trial* only if it is satisfied of all of the following:

- The drugs or techniques being tested in the *clinical trial* are intended to cure or alleviate a particular condition from which the patients suffer.
- The trial will not involve any known substantial risk to the patients or, if there are existing treatments for the condition concerned, will not involve material risks greater than the risks associated with those treatments.
- Having regard to the potential benefits, as well as the potential risks, of participation in the trial, it is in the best interests of patients who suffer from that condition that they take part in the trial.
- The trial has been approved by a relevant *ethics committee* and complies with any relevant guidelines issued by the NHMRC.
- The development of the drugs or techniques has reached a stage at which safety and ethical considerations make it appropriate that the drugs or techniques be available to patients who suffer from that condition even if those patients are not able to consent to taking part in the trial.

In relation to this last factor, neither the GA nor the GR provide any guidance as to which categories of research or, for example, phase of a clinical trial would satisfy this requirement. For example, will a phase 1 clinical trial (which is ordinarily conducted to evaluate the safety of a biomedical intervention) be generally regarded as having 'reached a stage at which ethical and safety

considerations' to make it appropriate to give the intervention to a patient? If the wording of section 45AA is not interpreted as being broad enough to accommodate all phases of clinical trials, it might restrict the NSW Tribunal's ability to exercise its powers in relation to those trials.

Section 45AA of the GA defines an *ethics committee* as one of the following:

- As long as there is any relevant Institutional Ethics Committee registered by the Australian Health Ethics Committee established under the *National Health and Medical Research Council Act 1992* (Cth) - an Institutional Ethics Committee so registered.
- In the absence of such a committee, an ethics committee established by:
 - a local health district or a public hospital; or
 - a university, if that ethics committee is concerned, with medical research; or
 - the NHMRC.

There are two important things to note in relation to the operation of section 45AA of the GA:

- The fact that a *clinical trial* will or may involve the giving of a placebo to some of the trial participants does not prevent the NSW Tribunal from being satisfied that it is in the best interests of patients that they take part in the trial.
- The NSW Tribunal's approval of a clinical trial under this section does not operate as consent to the participation in the trial of any particular patient.

Who can provide consent on behalf of a patient who cannot consent?

Before any *medical or dental treatment* can be given to any patient in the course of the *clinical trial*, an appropriate consent must be obtained by one of the two methods described in this section.

If the NSW Tribunal approves a *clinical trial*, it will determine who will exercise the function of giving or withholding consent for the participation of an individual in that *clinical trial*. Before making this determination, the Tribunal must be satisfied that the form for granting consent and the information available about the *clinical trial* provide sufficient information to enable the *person responsible* to decide whether or not it is appropriate that the patient should take part in the trial.

For a *clinical trial* that it approves under the GA, the NSW Tribunal will determine that consent for the carrying out of *medical or dental treatment* on patients in the course of the trial may be given by either the patient's *person responsible* or by the NSW Tribunal itself. The NSW Tribunal has, in most cases, determined that consent is to be given by the *person responsible*.

However, in *Application for approval for adults unable to consent to their own treatment to participate in a clinical trial (SPICE III Trial)* [2014] NSWCATGD 44 (23 December 2014) the NSW Tribunal decided to exercise the function of giving or withholding consent to an individual patient's participation in the trial because it considered that the *person responsible* forms submitted to it did not meet the requirements of the GA and did not provide sufficient information to enable a *person responsible* for a patient to decide whether or not the patient should enter into the trial. The decision in *SPICE III Trial* was appealed and overturned on a different basis in *Shehabi v Attorney General (NSW)* [2016] NSWCATAP 137 (24 June 2016)

The relevant requirements regarding each approach are discussed below.

1. Consent given by the *person responsible* for the patient

A *person responsible* may be requested to provide consent to the carrying out of *medical or dental treatment* on the patient in the course of a *clinical trial*.

A *person responsible* is, in descending order of hierarchy, one of the following:

- The person's guardian, if any, but only if the order or instrument appointing the guardian provides for the guardian to exercise the function of giving consent to the carrying out of *medical or dental treatment* on the person
- The spouse of the person, if any, if:
 - the relationship between the person and the spouse is close and continuing, and
 - the spouse is not a person under guardianship.
- A person who has the care of the person
- A close friend or relative of the person.

The process for obtaining the consent of the person responsible

A request made to a *person responsible* must specify the following details:

- The grounds on which it is alleged that the patient is a patient to whom the relevant GA provisions apply
- The particular condition of the patient that requires treatment
- The alternative courses of treatment that are available in relation to that condition
- The general nature and effect of each of those courses of treatment
- The nature and degree of the significant risks (if any) associated with each of those courses of treatment, and
- The reasons for which it is proposed that any particular course of treatment should be carried out.

In considering an application to provide consent for a patient, the *person responsible* for the patient must have regard to:

- the views (if any) of the patient
- the matters referred to above, and
- the objects of the GA regarding these matters.

The request for a *person responsible* to provide consent must be made in writing (Regulation 13, GR). The consent given by *person responsible* must be given in writing (Regulation 14, GR). It would be expected that both of these requirements would ordinarily be discharged by the use of an appropriate participant information sheet and consent form.

2. Consent given by the NSW Tribunal itself

The application process

Any person may apply to the NSW Tribunal for consent to the carrying out of *medical or dental treatment* on a patient in the course of a *clinical trial*.

The application must specify all of the following:

- The grounds on which it is alleged that the patient is a patient to whom the relevant GA provisions apply
- The particular condition of the patient that requires treatment
- The alternative courses of treatment that are available in relation to that condition
- The general nature and effect of each of those courses of treatment
- The nature and degree of the significant risks (if any) associated with each of those courses of treatment, and
- The reasons for which it is proposed that any particular course of treatment should be carried out.

The applicant must serve the applications

The applicant for consent must, as soon as practicable after the application has been made, cause a copy of the application to be served on all of the following:

- The patient
- The person who is proposing that *medical or dental treatment* be carried out on the patient
- Each person responsible for the patient who can reasonably be located.

NSW Tribunal may give consent

The NSW Tribunal will conduct a hearing into an application for consent to the carrying out of *medical or dental treatment* on a patient in the course of a *clinical trial*. If the NSW Tribunal is satisfied that it is appropriate for the treatment to be carried out, it may consent to the carrying out of the treatment.

In considering such an application, the NSW Tribunal has regard to:

- the views (if any) of:
 - the patient
 - the person who is proposing that medical or dental treatment be carried out on the patient, and
 - any *persons responsible* for the patient;
- the matters which the application must address, and
- the objects of the GA.

Other considerations of NSW Tribunal

If it is not satisfied that the applicant has a sufficient interest in the health and well-being of the patient, the NSW Tribunal may not consider an application relating to a patient.

The NSW Tribunal will not give consent to the carrying out of *medical or dental treatment* on a patient (in the course of a *clinical trial*) unless the NSW Tribunal is satisfied that the treatment is the most appropriate form of treatment for promoting and maintaining the patient's health and well-being.

The NSW Tribunal can also confer on guardians the authority to override a patient's objections in limited circumstances (section 46A).

Human research that is not a clinical trial or special research

The GA does not contain any provisions that specifically relate to the consent requirements for the participation of an impaired capacity adult in research that is not a *clinical trial* and does not otherwise involve the carrying out of *medical treatment or dental treatment*. Examples of such research include observational studies and studies that might involve participation in an interview.

There is no requirement under the GA for a human research project that is not a *clinical trial* and that will involve the participation of impaired capacity persons to be submitted to the NSW Tribunal for approval. In relation to such a research project, consent for an impaired capacity adult to participate in the research project may be given by the *person responsible* for that person.

The conduct of research in the emergency context

The GA does not contain any specific provisions that deal with the recruitment of a person with impaired capacity to provide consent into a research project (in the emergency context, for example) without a requirement to obtain consent.

Section 37 of the GA provides that *medical or dental treatment* may be carried out on an impaired capacity patient without consent given in accordance with the provisions of the GA described above if the medical practitioner or dentist carrying out or supervising the treatment considers the treatment is necessary, as a matter of urgency to:

- save the patient's life,
- prevent serious damage to the patient's health, or
- prevent the patient from suffering or continuing to suffer significant pain or distress.

To the extent that *medical or dental treatment* is given in the course of a *clinical trial*, section 37 may arguably apply to that *clinical trial*. However, section 37 contains no reference to *clinical trials*.

Further, given that a *clinical trial* is typically conducted to ascertain the effectiveness of a particular therapy and to determine (or prove) whether the therapy can, in fact, be used to save life, prevent damage to health or alleviate suffering or pain, there may be few circumstances in the clinical trials context where section 37 would actually apply.

Current Review of the GA

The GA is currently being reviewed by the NSW Law Reform Commission. Relevantly, the NSW Attorney-General has asked the Law Reform Commission to consider the 'provisions of Division 4A of Part 5 of the Guardianship Act 1987 relating to clinical trials'. As of 7 February 2017 the Law Reform Commission's review is continuing.

Checklist of matters for HRECs to consider

- Does the research involve participants aged 16 years or older who lack the capacity to provide informed consent?
- Does the research constitute a *clinical trial* as defined in the GA?
- If the research constitutes a *clinical trial*, does the proposal satisfy the requirements for submission to the NSW Tribunal for approval?
- In the event the NSW Tribunal determines that consent is to be given by the *person responsible* for that *clinical trial*, does the proposal include appropriate documentation to ensure that the request to the *person responsible* to provide consent and any consent given by the *person responsible* will be in writing?
- If the research is not a *clinical trial*, does the proposal include appropriate documentation to enable the *person responsible* to consider a request to provide consent and to give that consent?
- Is the HREC's approval conditional on the research being conducted in accordance with all relevant legal requirements regarding the approval of the research proposal by the NSW Tribunal 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?

Northern Territory

Current law

Relevant legislation

Guardianship of Adults Act (NT) (GAANT)

Guardianship of Adults Regulations (NT) (GAANTR)

Advance Personal Planning Act (NT) (APPA)

Advance Personal Planning Regulations (NT) (APPR)

Outline of requirements

The legislation in the Northern Territory applies to the making of decisions on behalf of an adult with impaired capacity to provide informed consent. An adult is a person who is at least 18 years of age.

An adult with impaired capacity to provide informed consent may be recruited to participate in a research activity on the basis of: a consent decision specified in an advance personal plan (made by the adult while they did not have impaired capacity); consent provided by a guardian appointed under a guardianship order; consent provided by a decision maker appointed under an advance personal plan; or consent provided by the Northern Territory Civil and Administrative Tribunal (NTCAT).

The nature of the research activity will dictate who may provide consent of behalf of the adult with impaired capacity. The Northern Territory legislation refers to various types of research activities but does not define 'clinical trial'.

If an adult has made an advance consent decision under an advance personal plan about a research activity which involves the provision of health care, that decision has effect as if the decision had been made by the adult at the time it is proposed to take the health care action.

- As a general rule, if the research activity involves the provision of health care, neither a guardian nor a decision maker will have authority to provide consent for the adult to participate in the research activity. However, a guardian or a decision maker may have authority to provide consent for other types of research activities – for example, research involving the collection of information about the adult.
- Where there is no advance personal plan and where neither a guardian nor a decision maker has authority to provide consent for the research activity, NTCAT may provide the requisite consent.
- The Northern Territory legislation contains no specific provision permitting the conduct of research in the emergency context on a person with impaired capacity without a requirement to obtain consent. The common law principles regarding the provision of treatment may apply to certain research. After reviewing this document, a Northern Territory Department of Health representative informed NHMRC that for certain research studies – for example, an ambulance-administered trial for head injuries - consent is not ordinarily sought from NTCAT for an adult who meets the relevant study's enrolment criteria, unless that person is already subject to a guardianship order. However, there is no court or tribunal decision that supports this approach.

Applicable requirements

The requirements for the giving of consent for the participation of an adult person, being a person who is at least 18 years of age (section 17 *Interpretation Act* (NT)), with impaired decision-making capacity to participate in a research activity are described in the GAANT and the APPA.

The Northern Territory legislation describes who may make a *consent decision* - a decision to give or refuse consent for the giving or withdrawal of a *health care action* – in respect of a person with impaired decision making capacity. *Health care action* is defined as ‘for an adult, commencing, continuing, withholding or withdrawing health care for the adult.’ A number of human research activities might fall within the scope of *health care action*; the legislation specifies some activities that do not. The GAANT and the APPA set out which person (or category of persons) may make decisions on behalf of an impaired capacity person about various types of research activities.

There are four possible ways consent may be given for an impaired capacity adult to participate in research; the specific approach depends on the type of research activity.

1. The adult consents through an advance consent decision made under the APPA

An adult may (while he or she has full legal capacity) make an *advance personal plan* under the APPA through which the adult may: make consent decisions about future *health care action* (an *advance consent decision*), set out the adult’s views, wishes and beliefs as the basis on which he or she wants anyone to act if they make decisions for him or her; or, appoint one or more persons to make decisions for the adult if he or she loses decision-making capacity.

If an adult has made an advance consent decision about a research activity which involves a health care action, that decision has effect as if the decision had been made by the adult at the time the health care action will be performed. An example where this could potentially be applicable is the adult’s participation in a clinical trial.

In certain circumstances, the NTCAT may order that the *advance consent decision* be disregarded. NTCAT may do so if it is satisfied that:

- there is no reasonable possibility that the adult would have intended the *advance consent decision* to apply in the circumstances or
- taking health care action in reliance on the *advance consent decision* would cause the adult unacceptable pain and suffering or would otherwise be so wholly unreasonable that it is justifiable to override the adult's wishes.

The likelihood that an *advance consent decision* will have been made by a person in respect of a specific research activity is probably low - a person would have had to contemplate their possible participation in that specific research activity months or perhaps years in advance.

2. A guardian

A person appointed as a guardian for an adult under a guardianship order made by NTCAT has authority to make certain decisions on behalf of the person they have been appointed to represent (*represented adult*) regarding personal matters (including health care) and financial matters. The authority is always subject to the GAANT and the specific powers the guardian is given under the relevant guardianship order.

Significantly, section 23(2) of the GAANT states that a guardian does not have authority to make a consent decision about a *health care action for restricted health care*. If a research activity does not

involve the provision of *restricted health care*, a guardian may be able to provide consent for the represented person's participation in the research activity.

Under the GAANT, *restricted health care* includes 'health care provided for medical research purposes' and 'health care prescribed by regulation as not provided for medical research purposes'.

There is no definition, or explanation, of what constitutes *health care provided for medical research purposes* in the GAANT or the GAANTR. However, the GAANT states that *health care provided for medical research purposes* does not include:

- a non-intrusive examination of an adult
- observation of an adult's activities
- collecting information from or about an adult or
- health care prescribed by regulation as not provided for medical research purposes.

If a research project involves the provision of health care, it may constitute *health care provided for medical research purposes*.

Section 3 of the GANTR provides that *restricted health care* includes '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.' Many clinical trials, for example, may fall within that description.

Therefore, a guardian may have authority to provide consent on behalf of a represented adult to participate in a research project that does not involve the provision of health care (i.e. that rises to the level of *restricted health care*) – for example, research that involves a non-intrusive examination of an adult, the observation of an adult's activities or collecting information from or about an adult. A guardian does not have authority to provide consent for a represented adult to participate in a research project that involves the provision of health care - an example of which is a clinical trial.

3. A decision maker appointed in an advance personal plan

A *decision maker* – a person appointed by an adult in an advance personal plan (made under the APPA) to make decisions for the adult if he or she loses decision making capacity – may have authority to make a decision about the represented adult's participation in certain types of research.

However, the section 25(1) of the APPA provides that a decision maker cannot make a consent decision about *restricted health care action* for the represented adult.

Regulation 4 of the APPR, defines *restricted health care action* as including (a) *special medical research or experimental health care*; and (b) 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. Each is discussed further below.

(a) *Special medical research or experimental health care*

Special medical research or experimental health care is defined as 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
- intended to gain knowledge that can be used in the diagnosis, maintenance or treatment of a condition the adult has or has had.

The definition of *special medical research or experimental health care* states that ‘psychological research’ or ‘approved clinical research’ is excluded. The APPR fails to define ‘psychological research’ or ‘approved clinical research’.

A clinical trial may fall within the definition of *special medical research or experimental health care*. It is less clear what other types of research might fall into that definition. However, the definition of *special medical research or experimental health care* may not apply to a clinical trial to the extent that it involves a research participant who is a healthy volunteer.

Other types of research – for example, an observational study or a study that involves only collecting information about that person - would fall outside the definition of *special medical research or experimental health care*. A *decision maker* may have authority to provide consent for the participation of the represented adult in such research.

(b) *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.*

To the extent that a research project involves the provision of health care and that health care is not accepted evidence-based, best practice health care, a *decision maker* cannot provide consent for the participation of the represented adult in such research. It would appear that many clinical trials would satisfy this description.

4. NTCAT

NTCAT has authority to provide consent for an adult with impaired capacity to participate in a research project in cases where none of the first three decision making options described above apply. In particular, NTCAT may make a decision about an impaired capacity adult’s participation in a research project that involves *health care action* if:

- the adult has not made an advance consent decision about the *health care action* or NTCAT has made an order under section 41(2) of the APPA that the adult's advance consent decision be disregarded and
- there is no available guardian or *decision maker* who is willing and able to make a consent decision about the *health care action*. Of course, if there is an available guardian or *decision maker*, their authority is subject to the restrictions on the types of consent decisions they are permitted to make under the APPA and any restrictions relevant to their appointment.

Therefore, NTCAT may make a *consent decision* for an adult with impaired capacity to participate in research that involves *restricted health care or restricted health care action*. NTCAT’s decision has effect as if the decision had been made by the adult and at the time the decision was made, the adult had full legal capacity and was fully informed about the *health care action*.

If NTCAT makes a consent decision in relation to a course of action to be provided over a period of time (for example, the conduct of multiple procedures over a period of time under a clinical trial) a later consent decision to withhold or withdraw the health care may be made only by NTCAT or a decision maker or adult guardian authorised by NTCAT to make that decision.

The conduct of research in the emergency context

There are no specific provisions in the Northern Territory legislation permitting the conduct of research in the emergency context on a person with impaired capacity without a requirement to obtain consent. The common law principles regarding the provision of treatment may apply to

certain research. After reviewing this document, a Northern Territory Department of Health representative informed NHMRC that for certain research studies – for example, an ambulance-administered trial for head injuries - consent is not ordinarily sought from NTCAT for an adult who meets the relevant study's enrolment criteria, unless that person is already subject to a guardianship order. However, there is no decision of a Northern Territory court or NTCAT that supports this approach. Further, despite the absence of a guardianship order, the ability to enrol an individual in such circumstances may be limited by any advance consent decision.

Checklist of matters for HRECs to consider

- Does the research involve adult participants who lack the capacity to provide informed consent?
- Does the research involve *restricted health care* or *restricted health care action* as defined in the legislation?
- Has the researcher considered how he or she will ascertain whether a proposed participant has made an advance consent decision?
- Has the researcher considered how he or she will ascertain whether a guardian or a decision maker has been appointed in relation to a proposed participant?
- In respect of proposed participants who have not made an advance consent decision or in respect of whom a guardian or a decision maker has not been appointed, does the research proposal include the appropriate details for an application to be made to NTCAT to provide the requisite consent (where required for the specific type of research)?
- Is the HREC's approval conditional on the research being conducted in accordance with all relevant legal requirements regarding 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?

Queensland

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

Legislation

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

Applicable requirements

Outline of requirements

- The Queensland Civil and Administrative Tribunal (**QCAT**) plays a central role under the GAAQ in the approval of research that involves adults with *impaired capacity* to make decisions.
- An adult for the purposes of the GAAQ is a person who is 18 years of age or older.
- The GAAQ distinguishes between two broad categories of research:
 - *Special medical research or experimental health care.*
 - *Clinical research.*
- Proposals to conduct *special medical research or experimental health care* on an adult with *impaired capacity* must be submitted to QCAT. QCAT may:
 - approve that research, and
 - give consent for an adult person with impaired capacity to participate in the research.
- Proposals to conduct *clinical research* on an adult with *impaired capacity* must be submitted to QCAT for approval. Once QCAT approves the clinical research, it is referred to as *approved clinical research*.
- QCAT's approval does not amount to consent for an individual to participate in any *approved clinical research*.
- *Approved clinical research* is then treated as a *health matter* under the GAAQ. The principles described in section 66 of the GAAQ (and set out on page 33 of this report) for the provision of consent for a health matter for an adult with *impaired capacity* apply in relation to such person's participation in *approved clinical research*.
- There are no specific provisions in the GAAQ relating to 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 is impaired capacity?

Under the GAAQ, *capacity* for a person in relation to a 'matter' means the person is capable of:

- understanding the nature and effect of decisions about the matter;
- freely and voluntarily making decisions about the matter; and
- communicating the decisions in some way.

'Matters' include financial matters, personal matters, and health and healthcare matters. The GAAQ defines *impaired capacity* as meaning that, in relation to the matter, 'the person does not have capacity for the matter'.

Consent requirements for special medical research or experimental health care

The GAAQ distinguishes two broad categories of research:

- special medical research or experimental health care, and
- 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 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*.

For the purposes of the GAAQ, *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*. The GAAQ does not define 'psychological research'; the definition of 'approved clinical research' is discussed in the next section.

In *MP, Re* [2006] QGAAT 86 (5 December 2006), QCAT considered whether the only available treatment for a severely intellectually disabled 38 year old man with an extremely rare genetic condition constituted experimental health care. The Tribunal found that the treatment was not experimental health care (or special health care) despite the fact that it had not been included on the Therapeutic Goods Administration's Australian Register of Therapeutic Goods because it was the only treatment for the person's genetic condition and had been accepted as such and used by the medical community for a long period of time.

QCAT may approve *special medical research or experimental health care* to be performed on an adult with *impaired capacity* to make decisions.

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 one of the following prescribed forms:

- Form 13 - Application for approval to conduct special medical research - *Guardianship and Administration Act 2000*. (A copy may be downloaded from: http://www.qcat.qld.gov.au/_data/assets/pdf_file/0009/100899/form-13-app-conduct-special-med-research.pdf)
- Form 14 - Application for approval to conduct experimental health care - *Guardianship and Administration Act 2000*. (A copy may be downloaded from: http://www.qcat.qld.gov.au/_data/assets/pdf_file/0013/100903/form-14-app-to-conduct-exp-health-care.pdf)

Each application must be accompanied by the *ethics committee* approval and the protocol for the relevant research project.

Schedule 4 of 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.

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 all of the following matters:

- The special medical research or experimental health care is approved by an *ethics committee*.
- 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.

However, QCAT may not consent to the adult's participation in *special medical research or experimental health care* if:

- the adult objects to the special medical research or experimental health care, or
- the adult, in an enduring document, indicated unwillingness to participate in the special medical research or experimental health care.

Consent requirements for *clinical research*

The process for the giving of consent for an *impaired capacity* adult to participate in *clinical research* involves two steps. The first concerns the requirement for the research to be approved by QCAT. The second involves the giving of consent for each participant by their respective substitute decision maker.

1. Submission to QCAT for approval (Schedule 2, section 13)

A research proposal that falls within the GAAQ's definition of *clinical research* that might involve adults with *impaired capacity* must be submitted to QCAT for approval.

The GAAQ defines *clinical research* as:

- *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.

However, as explained in *Avent* [2011] QCAT 598, a comparative assessment of health care already proven to be beneficial is *not medical research*.

The GAAQ gives the following examples of projects that are not *medical research*:

- A comparative assessment of the effects of different forms of administration of a drug proven to be beneficial in the treatment of a condition, for example, a continuous infusion, as opposed to a once-a-day administration, of the drug.
- A comparative assessment of the angle at which to set a tilt-bed to best assist an adult's breathing.

In *Re application by Dr Matthew Hope* [2012] QCAT 191, QCAT determined that a purely observational study fell within the definition of *clinical research* because it involved a technique that was intended to diagnose a condition affecting participants in the research.

In *Avent* [2011] QCAT 598 (15 November 2011), QCAT held that a comparative study that proposed to compare the use of different types of antibiotic therapy did not fall within the definition of *clinical research*; the study was merely comparing treatments that were known to be beneficial.

A research project could potentially fall within the definition of *special medical research or experimental health care* or the definition of *clinical research*. However, it appears that most human clinical trials of a drug or device are likely to satisfy the definition of *clinical research*. Further, if a research project satisfies the definition of *clinical research*, then it will be excluded from the definition of *special medical research or experimental health care*.

Clinical research that has been approved by QCAT (in accordance with the procedures outlined below) is referred to as *approved clinical research*.

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

- The *clinical research* is approved by an *ethics committee*.
- 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.

The GAAQ does not provide any guidance as to which categories of research or, for example, phase of a clinical trial would satisfy this requirement. For example, will a phase 1 clinical trial (which is ordinarily conducted to evaluate the safety of a biomedical intervention) be generally regarded as having ‘reached a stage at which ethical and safety considerations’ make it appropriate to give the intervention to a patient? If the wording is not interpreted as being broad enough to accommodate all phases of clinical trials, it might prevent QCAT from approving those types of studies.

- Having regard to the potential benefits and risks of participation, on balance it is not adverse to the interests of the participants to participate.

A person wishing to conduct a *clinical research* project must submit to QCAT a [Form 16 - Application for approval to conduct clinical research](http://www.qcat.qld.gov.au/data/assets/pdf_file/0015/100905/form-16-app-to-conduct-clinical-research.pdf) - *Guardianship and Administration Act 2000*. (A copy may be downloaded from http://www.qcat.qld.gov.au/data/assets/pdf_file/0015/100905/form-16-app-to-conduct-clinical-research.pdf)

The form must attach copies of the following documents:

- The research proposal/protocol describing the *clinical research*.
- The patient information sheet.
- The consent form.
- The approval given by the reviewing *ethics committee*.

There are two important things to note in relation to this process:

- Even if a trial of drugs or techniques will or may involve the giving of placebos to some of the participants, this does not prevent QCAT from being satisfied it is, on balance, not adverse to the interests of the participants to participate.
- QCAT’s approval of clinical research does not operate as consent to the participation in the *clinical research* of any particular person.

2. Obtaining consent following approval given by QCAT

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. Section 66 of the GAAQ then determines who may consent to an adult's participation in the *approved clinical research*.

- If an adult has *impaired capacity*, consent is determined or given in accordance with the first of the following to apply:
 - The terms of any advance health directive giving a direction about the matter made by the adult.
 - By any guardian or guardians appointed by QCAT for the adult or any order made by QCAT in respect of the matter.
 - By an attorney or attorneys 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.

The conduct of research in the emergency context

There are no specific provisions in the GAAQ relating to 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, section 63 of the GAAQ provides that *health care* of an adult may be carried out without consent if the adult's health provider reasonably considers that:

- the adult has *impaired capacity* for the health matter concerned, and
- either:
 - the *health care* should be carried out urgently to meet imminent risk to the adult's life or health, or
 - the *health care* should be carried out urgently to prevent significant pain or distress to the adult and it is not reasonably practicable to get consent from a person who may give it under the GAAQ or the *Powers of Attorney Act 1998 (Qld)*.

Section 63 could potentially apply to a clinical research project to the extent the research involves the provision of *health care*. However, given that *clinical research* is typically conducted to ascertain the effectiveness of a particular therapy and to determine (or prove) whether the therapy can, in fact, be used to save life, prevent damage to health or alleviate suffering or pain, there may be few circumstances in the clinical trials context where section 63 would actually apply. Even if it applied, the *clinical research* proposal would still need to be submitted to QCAT for approval. Nonetheless, some research may fall outside the definition of *clinical research* as per the decision in *Avent* [2011] QCAT 598 (discussed above).

Section 63 could not be used in the context of the conduct of *special medical research or experimental health care* because that type of research is expressly excluded from the definition of *health care* in 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?

South Australia

Note: This section describes the legislation in South Australia regarding the giving of consent for the provision of **medical treatment** to a person who lacks the capacity to provide informed consent; it does so because there is no South Australian legislation that specifically refers to or directly deals with the giving of consent for an adult who lacks the capacity to provide consent to participate in a human research project or a clinical trial.

This section should be read subject to the comments set out in paragraph 2.2 of section A (page 5) of this report.

In the absence of any express provision to the contrary, it is arguable that the principles for the making of decisions for impaired capacity adults generally under South Australian legislation also apply to the making of consent decisions for an impaired capacity person to participate in human research. In the context of medical research (and clinical trials in particular) the principles concerning substitute decision making for the provision of health care or treatment will be most relevant. Those legislative provisions are discussed below. However, it can only be extrapolated that those principles apply to decisions regarding research given that the legislation discussed below makes no specific reference to human research or clinical trials.

Legislation

Advance Care Directives Act 2013 (SA) (ACDA)

Consent to Medical Treatment and Palliative Care Act 1995 (SA) (CMTPCA)

Guardianship and Administration Act 1993 (SA) (GAASA)

Applicable requirements

Outline of requirements

- There is no legislation in South Australia that deals specifically with the giving of consent for a person with impaired capacity to consent to participate in human research or a clinical trial.
- In the absence of an express provision to the contrary, it is arguable that the requirements for consent regarding the participation in research of an impaired capacity adult fall within the general requirements regarding the making of other decisions for that person, including decisions regarding the giving of consent for the provision of *medical treatment* to such person.
- The CMTPCA provides that consent to *medical treatment* of person who is 16 years or older who has impaired decision-making capacity may be given by a person appointed under an advance care directive or the *person responsible*.
- To the extent the research involves or constitutes the giving of *medical treatment*, similar principles regarding who may give consent for the giving of treatment to an impaired capacity person would arguably apply in respect of the giving of consent for such person to participate in the research.
- There is no requirement for any tribunal or court to give approval to the research or to otherwise give the requisite consent for a person who lacks the capacity to provide consent to participate in the research.

Consent to medical treatment if a person has impaired decision-making capacity

The procedures for the provision of consent to *medical treatment* of an adult who has impaired decision making capacity are set out in Part 2A of the CMTPCA.

Part 2A does not apply to a *child*. The CMTPCA defines a *child* as a person under the age of 16. Therefore, Part 2A of the CMTPCA applies to any person that is 16 years of age or older.

The CMTPCA defines *medical treatment* as the provision by a medical practitioner of physical, surgical or psychological therapy to a person (including the provision of such therapy for the purposes of preventing disease, restoring or replacing bodily function in the face of disease or injury or improving comfort and quality of life) and includes the prescription or supply of drugs.

Does medical treatment include participation in medical research or a clinical trial?

The CMTPCA does not specifically refer to research, medical research or clinical trials. There is no other legislation in South Australia which specifically refers to the giving of consent for patients who lack the capacity to provide consent to participate in research, medical research or clinical trials.

The former section 5 of an earlier version of the CMTPCA had stated:

This Act does not apply to medical procedures conducted for the purposes of research rather than for the purpose of treating, or determining the appropriate treatment for, the patient subjected to those procedures.

However, that provision was repealed with effect from 1 July 2014. Further, it has not been replaced with any other provision that refers to ‘medical procedures conducted for the purposes of research’.¹

Given the repeal of that section 5 and, in the absence of any express provision to the contrary, it is possible that medical procedures conducted for the purpose of research now fall within the definition of *medical treatment*, or that the principles regarding the provision of *medical treatment* to a patient who lacks capacity to consent prescribed in the CMTPCA would otherwise apply in relation to the giving of consent for such person’s participation in research. The conduct of a clinical trial typically involves one or more of the elements of the definition of *medical treatment* – for example, drug trials involve the supply of drugs and it might be argued that a device trial involves physical or surgical therapy.

In any event, as the South Australian legislation does not specifically refer to the giving of consent for patients with impaired capacity to consent to participate in the conduct of a clinical trial (unlike, for example, the legislation in Victoria, New South Wales and Queensland) the position in South Australia is less certain than in other jurisdictions and these assumptions regarding the application of the legislation to research discussed in this section could potentially be challenged.

Furthermore, it is uncertain how these provisions would apply to human research which does not involve *medical treatment*. While it might be argued that the conduct of a clinical trial constitutes or involves the giving of *medical treatment*, it may be more difficult to make such a case with other types of human research that are not a clinical trial. In those cases, it is questionable whether the procedures for giving consent for medical treatment for an impaired capacity adult will apply in the same manner.

¹ Section 5 of the CMTPCA was repealed by the *Advance Care Directives Act 2013* (Cth). No reference to ‘research’ was made in the Minister’s 2nd Reading Speech and no Explanatory Memorandum appears to exist.

Who may give consent?

In the event that a person is assessed as having impaired decision making capacity, consent to medical treatment for that person may be sought from a substitute decision-maker appointed in an *advance care directive* if the person has one in place. Alternatively, if there is no appointed substitute decision-maker, then the medical practitioner should seek consent for medical treatment from a *person responsible* as per the CMTPCA.

An *advance care directive* is a legal form where a person over 18 years of age is able to write down his or her instructions, wishes and preferences for future health care, accommodation and personal matters and/or to appoint one or more substitute decision makers who may make decisions on the person's behalf in any period of impaired decision making capacity, or as determined by the person.

A *person responsible* for a patient is in the following order of hierarchy:

- A guardian appointed in respect of the patient by the South Australian Civil and Administrative Tribunal (**SACAT**) (formerly called the Guardianship Board) who is available and willing to make a decision.
- A prescribed relative (that is an adult related to the patient by blood, marriage, adoption or Aboriginal kinship/ marriage and includes an adult domestic partner) who is available and willing to make a decision about consent (see section 14(1) of the CMTPCA for further guidance).
- An adult friend of the patient who has a close and continuing relationship with the patient who is available and willing to make a decision.
- An adult who is charged with overseeing the ongoing day-to-day supervision, care and well-being of the patient who is available and willing to make a decision.
- If none of the preceding paragraphs apply, and on application to SACAT by a prescribed relative of the patient, the medical practitioner proposing to give the treatment or any other person who SACAT is satisfied has a proper interest in the matter, SACAT itself.

However, a *person responsible* for a patient may not provide consent under Part 2A if that patient has given an *advance care directive* to the extent that the *advance care directive* makes specific provision in respect of the administration of *medical treatment* of the relevant kind to the patient. For example, a *person responsible* could not provide consent to the person's involvement in a clinical trial if the person's *advance care directive* expresses an unwillingness to participate in any clinical trial.

Consent requirements for human research that is not a clinical trial

While it might be argued that the conduct of a clinical trial constitutes or involves the giving of *medical treatment*, it may be more difficult to make such a case with other types of human research that are not clinical trials. In those cases, it is questionable whether the procedures for giving consent for *medical treatment* for an impaired capacity adult will apply in the same manner.

Depending on the research, it may be necessary to rely upon the substitute decision making principles that relate to matters other than the provision of medical treatment for an impaired capacity person. For example, if the research concerns the collection of information about an impaired capacity person's social and living arrangements, the person's *substitute decision maker* that has authority to make decisions about that person's financial and living arrangements would be most likely to have authority to give consent for the person to participate in that research.

Emergency medical treatment

Under section 13(1) of the CMTPCA, a medical practitioner may lawfully administer *medical treatment* to a patient if the patient is incapable of consenting if all of the following apply:

- The medical practitioner is of the opinion that the treatment is necessary to meet an imminent risk to life or health and that opinion is supported by the written opinion of another medical practitioner who has personally examined the patient.
- The patient (if 16 years of age or over) has not, to the best of the medical practitioner's knowledge, refused to consent to the treatment.
- The medical practitioner has made, or has caused to be made, reasonable inquiries to ascertain whether the patient (if the patient is 18 years of age or over) has given an advance care directive.

It is possible that section 13(1) might be relied upon by a medical practitioner for the provision of *medical treatment* in the course of a research project to a person who lacks the capacity to provide informed consent. Of course, the medical practitioner would have to ensure that all of the elements of section 13(1) are satisfied in respect of that treatment.

However, given that research is typically conducted to ascertain the effectiveness of a particular therapy and to determine (or prove) whether the therapy can, in fact, be used to meet an imminent risk to life or health, there may be few circumstances in the research context where section 13(1) could apply.

In some circumstances, a medical practitioner may lawfully administer *medical treatment* to a person even if the person has made an advance care directive that comprises a refusal of medical treatment. (The relevant details are specified in section 13(1a) of the CMTPCA). However, it is difficult to contemplate circumstances in the context of a person's possible participation in research where this provision might be relevant.

Role of SACAT

SACAT does not have a specifically defined or direct role in relation to the approval of human research or a clinical trial or the giving of consent for an impaired capacity person to participate in human research or a clinical trial. In particular, there is no requirement to submit a research project or a clinical trial to SACAT for approval.

SACAT may have an indirect role in relation to issues concerning the conduct of research, to the extent that it has certain powers regarding the giving of consent by a *substitute decision maker* for the giving of *medical treatment* to a person who lacks the capacity to provide informed consent. For example, SACAT can determine issues and disputes arising in relation to such issues, as well as make orders regarding *advance care directives* and guardianship.

Checklist of matters for an HREC to consider

- Does the research involve participants aged 16 years or older who lack the capacity to provide informed consent?
- Does the clinical trial involve the provision of *medical treatment* as defined in the CMTPCA?
- Does the proposal clearly document how the researcher will seek consent from any *substitute decision maker* appointed under an *advanced care directive* or the *person responsible*?
- Has the HREC approval been given subject to the research being conducted in accordance with all relevant legal requirements regarding 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?

Tasmania

Note: This section describes the legislation in Tasmania regarding the giving of consent for the provision of **medical or dental treatment** to a person who lacks the capacity to provide informed consent; it does so because there is no Tasmanian legislation that specifically refers to or directly deals with the giving of consent for an adult who lacks the capacity to provide consent to participate in a human research project or a clinical trial.

This section should be read subject to the comments set out in paragraph 2.2 of section A (page 5) of this report.

In the absence of any express provision to the contrary, it is arguable that the principles for the making of decisions for impaired capacity adults generally under Tasmanian legislation also apply to the making of consent decisions for an impaired capacity person to participate in human research. In the context of medical research (and clinical trials in particular) the principles concerning substitute decision making for the provision of medical or health care or treatment will be most relevant. Those legislative provisions are discussed below. However, it can only be extrapolated that those principles apply to decisions regarding research given that the legislation discussed below makes no specific reference to human research or clinical trials.

Legislation

Guardianship and Administration Act 1995 (Tas) (GAAT)

Guardianship and Administration Regulations 2007 (Tas) (GAAR)

The GAAT and GAAR facilitate the authorisation and approval of medical and dental treatment for persons with a disability who are incapable of giving informed consent to treatment. The legislation provides the support to help those that lack the capacity to make a reasonable decision on their own either because they are unconscious or have a severe cognitive disability.

Applicable requirements

Outline of requirements

- There is no legislation in Tasmania that deals specifically with the giving of consent for a person with impaired capacity to participate in human research or a clinical trial.
- In the absence of any express provision to the contrary, it is arguable that the principles for the making of decisions for impaired capacity adults generally under Tasmanian legislation also apply to the making of consent decisions for an impaired capacity person to participate in human research.
- The GAAT provides that a treatment decision for an impaired capacity person may be made by the Guardianship and Administration Board of Tasmania or the *person responsible* of the impaired capacity person.
- There is no specific requirement for any tribunal or court to give approval to a research project or to otherwise give the requisite consent for a person who lacks the capacity to provide consent to participate in the research project.
- Researchers may wish to consult the Guardianship and Administration board's existing resources on consent to medical or dental treatment available at:
http://www.guardianship.tas.gov.au/_data/assets/pdf_file/0005/67055/4_Consent_to_Medical_or_Dental_Treatment_.pdf

Consent to medical treatment if a person has impaired decision-making capacity

The procedures for the provision of consent to *medical or dental treatment* of a person who is incapable of giving consent to the carrying out of *medical or dental treatment* are set out in Part 6 of the GAAT. For the purposes of the GAAT, a person is *incapable of giving consent* to the carrying out of medical or dental treatment if the person is incapable of understanding the general nature and effect of the proposed treatment or is incapable of indicating whether or not he or she consents or does not consent to the carrying out of the treatment.

The GAAT refers to the concept of *medical or dental treatment or treatment* and defines it as:

- medical treatment (including any medical or surgical procedure, operation or examination and any prophylactic, palliative or rehabilitative care) normally carried out by, or under, the supervision of a medical practitioner
- dental treatment (including any dental procedure, operation or examination) normally carried out by or under the supervision of a dentist
- an intimate forensic procedure and a non-intimate forensic procedure normally carried out by a person authorised to carry out the procedure under section 40 of the *Forensic Procedures Act 2000* (Tas), or
- any other act declared by the GAAR to be medical or dental treatment.

However, *medical or dental treatment or treatment* does not include:

- any non-intrusive examination made for diagnostic purposes (including a visual examination of the mouth, throat, nasal cavity, eyes or ears)
- first-aid medical or dental treatment, or
- the administration of a pharmaceutical drug for the purpose, and in accordance with the dosage level, recommended in the manufacturer's instructions (if the drug is one for which a prescription is not required and which is normally self-administered).

Does *medical or dental treatment or special treatment* include participation in human research or a clinical trial?

The GAAT does not specifically refer to human research, medical research or clinical trials. There is no other legislation in Tasmania which specifically refers to the giving of consent for patients who lack the capacity to provide consent to participate in human research, medical research or a clinical trial.

To the extent that research involves *medical or dental treatment or special treatment* (as defined in section 3 of the GAAT and regulation 6 of the GAAR), it may fall within the definition of *medical or dental treatment or special treatment*. The provisions set out in the GAAT regarding the giving of consent for impaired capacity adults might therefore be applicable to the giving of consent for an impaired capacity adult to participate in research. However, as the GAAT does not specifically state that the conduct of research or a clinical trial constitutes *medical or dental treatment or special treatment*, and does not specify who may consent for a person with impaired capacity with respect to their participation in research or a clinical trial (unlike, for example, the legislation in Victoria, New South Wales and Queensland), the legislative position in Tasmania is uncertain and the assumptions regarding the operation of the GAAT to research discussed in this section could potentially be challenged.

Furthermore, it is even more uncertain how these provisions would apply to human research which does not involve *medical or dental treatment* or *treatment*. While it might be argued that the conduct of a clinical trial constitutes or involves the giving of *medical treatment*, it may be more difficult to make such a case with other types of human research that are not a clinical trial. In those cases, it is questionable whether the procedures for giving consent for medical or dental treatment for an impaired capacity adult will apply in the same manner.

Depending on the research, it may be necessary to rely upon the substitute decision making principles that relate to matters other than the provision of medical treatment for an impaired capacity person. For example, if the research concerns the collection of information about an impaired capacity person's social and living arrangements, the person's *substitute decision maker* that has authority to make decisions about that person's financial living arrangements would be most likely to have authority to give consent for the person to participate in that research.

Who may consent to medical or dental treatment or treatment for an impaired capacity person?

Section 39 of the GAAT provides that consent to the carrying out of *medical or dental treatment* on a person who has impaired capacity to provide consent may be given by the Guardianship and Administration Board of Tasmania (**GABT**) or by the *person responsible* for that person.

Consent given by GABT

Any person who has a proper interest in the matter may apply to the GABT for the GABT to give its consent to the carrying out of any *medical or dental treatment* on a person who is incapable of giving consent to the carrying out of *medical or dental treatment*.

The GABT may give consent to *medical or dental treatment* on behalf of a person who is incapable of giving consent in the following circumstances:

- The patient objects to treatment that is necessary to promote their health and well-being but there is no person responsible available or willing to make that decision for the patient.
- There is a dispute or uncertainty between the practitioner, *person responsible* and/or the patient about whether or not to proceed with the treatment.
- The proposed treatment involves a significant risk.

The GAAT does not provide any guidance on what might constitute a 'significant risk'. It is unclear whether participation in a research project (for example, an early phase clinical trial) could be interpreted as involving a 'significant risk' to a person.

Consent given by *person responsible*

A *person responsible* for a person who is incapable of giving consent to the carrying out of medical or dental treatment may consent to the carrying out of *medical or dental treatment* if he or she is satisfied of all of the following:

- The relevant person is incapable of giving consent.
- The medical or dental treatment would be in the best interests of that person, having regard to the following matters:
 - the wishes of that person, so far as they can be ascertained
 - the consequences to that person if the proposed treatment is not carried out
 - any alternative treatment available to that person
 - the nature and degree of any significant risks associated with the proposed treatment or any alternative treatment, and

- that the treatment is to be carried out only to promote and maintain the health and wellbeing of that person.

For the purposes of the GAAT, a *person responsible* for another person is:

- where the other person is under the age of 18 years and has a spouse, the spouse
- where the other person is under the age of 18 years and has no spouse, his or her parent
- where the other person is of or over the age of 18 years, one of the following persons, in order of priority:
 - his or her guardian
 - his or her spouse
 - the person having the care of the other person, or
 - a close friend or relative of the other person.
- If a person is under the guardianship of the Secretary of the Department administering the *Children, Young Persons and their Families Act 1997* pursuant to a care and protection order made under that Act, the Secretary of that Department is taken to be the person responsible for the person.
- For an *intimate or non-intimate forensic procedure*, the person responsible is the Public Guardian.

Urgent medical or dental treatment

Section 40 of the GAAT allows a medical practitioner or dentist to carry out *medical or dental treatment* on a person who is incapable of giving consent without the requirement to obtain consent. The medical practitioner or dentist may carry out or supervise the treatment if he or she considers the treatment is necessary, as a matter of urgency to:

- to save the person's life
- prevent serious damage to the person's health, or
- prevent the person from suffering or continuing to suffer significant pain or distress.

To the extent that a patient's participation in a research project (and more specifically, a clinical trial) might involve the provision of *medical or dental treatment* that satisfies the requirements of section 40, a medical practitioner or dentist might be able to rely on these provisions to include the patient in the research without the requirement to obtain consent. Of course, as identified elsewhere in this report, research is typically conducted to ascertain the effectiveness of a particular treatment and to determine (or prove) whether the treatment can, in fact, save life or prevent damage or injury to health or prevent suffering. As such, there may be few circumstances in the research context where section 40 could apply.

Role of GABT

GABT does not have a specifically defined or direct role in relation to the approval of human research or a clinical trial - there is no requirement to submit a research project or a clinical trial to GABT for approval. Of course, to the extent the research activity constitutes *medical or dental treatment* or *special treatment*, the GABT may have a role in providing consent under section 39 of the GAAT.

GABT may also have a role in relation to the consideration and determination of issues related to guardianship and disputes under the GAAT.

Checklist of matters for an HREC to consider

- Does the research involve participants who lack the capacity to provide informed consent?
- Does the research involve the provision of *medical or dental treatment* or *special treatment* as defined in the GAAT?
- Does the proposal clearly document how the researcher will seek consent from any substitute decision maker, including the GABT or the *person responsible*?
- Has the HREC approval been given subject to the research being conducted in accordance with all relevant legal requirements regarding 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?

Victoria

Note 2: As of 3 March 2017, Victoria has not provided its advice on the accuracy of the following information.

Legislation

Guardianship and Administration Act 1986 (Vic) (**GAAV**)

Applicable requirements

Outline of requirements

- The GAAV applies to the carrying out of a *medical research procedure* on a person who is at least 18 years of age and who lacks the capacity to provide informed consent.
- The GAAV prescribes a four step process for authorising the carrying out of a *medical research procedure* on an adult patient who lacks the capacity to provide informed consent. The process consists of the following, sequential steps:
 - The approval of the research by a *human research ethics committee* (as defined in the GAAV).
 - An assessment of whether the person is likely to recover capacity to consent within a reasonable period of time.
 - The giving of consent by the patient's *person responsible*.
 - The performance of the research on the basis of procedural authorisation.
- The Victorian Civil and Administrative Tribunal (**VCAT**) has a limited role in this process. It is not necessary to submit a research proposal to VCAT for approval.
- Section 42A of the GAA allows for the carrying out of a *medical research procedure* on an impaired capacity patient without the requirement to obtain consent or procedural authorisation in limited circumstances.

Definition of person who is incapable of giving consent

Part 4A of the GAAV applies to a 'person with a disability' who is 18 years of age or older and who is *incapable of giving consent* to the carrying out of a *medical research procedure*. Part 4A refer to such a person as a 'patient'. The provisions of Part 4A apply whether or not there is a guardianship or administration order in place in relation to the person.

Section 36 of the GAAV provides that a person is *incapable of giving consent* to the carrying out of a *medical research procedure* if the person:

- is incapable of understanding the general nature and effect of the proposed procedure or treatment, or
- is incapable of indicating whether or not he or she consents or does not consent to the carrying out of the proposed procedure or treatment.

The conduct of a *medical research procedure*

Part 4A of the GAAV sets out the requirements regarding the carrying out of a *medical research procedure* on an adult who lacks the capacity to provide informed consent. For the purposes of Part 4A, an adult is a person who is 18 years old or more.

The GAAV defines *medical research procedure* as:

- a procedure carried out for the purposes of medical research, including, as part of a clinical trial, the administration of medication or the use of equipment or a device, or
- a procedure that is prescribed by the regulations to be a medical research procedure for the purposes of the GAAV.

However, a *medical research procedure* does not include:

- any non-intrusive examination (including a visual examination of the mouth, throat, nasal cavity, eyes or ears or the measuring of a person's height, weight or vision)
- observing a person's activities
- undertaking a survey
- collecting or using information, including *personal information* (within the meaning of the *Privacy and Data Protection Act 2014* (Vic)) or *health information* (within the meaning of the *Health Records Act 2001* (Vic)), or
- any other procedure that is prescribed by the regulations not to be a medical research procedure for the purposes of the GAAV.

Prescribed four step process

Part 4A of the GAAV prescribes a four step process for authorising the carrying out of a *medical research procedure* on an adult patient who *lacks the capacity* to provide informed consent.

1. Approval by relevant human research ethics committee (section 42Q)

The first step is to determine whether the relevant research project is approved by the relevant 'human research ethics committee'. A *medical research procedure* must not be carried out on a patient if the relevant research project has not been approved by the relevant 'human research ethics committee'.

Section 3(1) of the GAAV provides that 'the relevant human research ethics committee is the human research ethics committee responsible for approving the relevant research project'. Section 3(1) defines 'human research ethics committee' as:

- a human research ethics committee established in accordance with the requirements of the National Statement; or
- an ethics committee established under the by-laws of a public hospital, public health service, denominational hospital or multi-purpose service (within the meaning of the *Health Services Act 1988* (Vic)).

2. Is person likely to recover the capacity to consent? (section 42R)

The second step is to determine whether the patient is likely to recover the capacity to consent to the medical research procedure within a *reasonable time*.

The *reasonable time* is the time by which the *medical research procedure* would need to be performed on the patient, given the nature of the relevant research project and having regard to

- the medical or physical condition of the patient
- the stage of treatment or care, and
- other circumstances specific to the patient.

If the patient is likely to recover, a *registered practitioner* must not carry out, or supervise the carrying out of, a *medical research procedure* on the patient under section 42S or 42T of the GAA. In other words, the matter must not proceed to Step 3 or Step 4.

For the purposes of the GAAV, a *registered practitioner* is a person registered under the *Health Practitioner Regulation National Law* to practise in the medical profession (other than as a student) or a person registered under the *Health Practitioner Regulation National Law* to practise in the dental profession as a dentist (other than as a student).

3. Consent given by *person responsible* (section 42S)

The third step is to seek the consent of the *person responsible* for the patient, where permitted by section 42R of the GAA.

A *person responsible* is the first person listed below who is responsible for the patient and who, in the circumstances, is reasonably available and willing and able to make a decision under Part 4A of the GAA.

- A person appointed by the patient under section 5A of the *Medical Treatment Act 1988* (Vic).
- A person appointed by VCAT to make decisions in relation to the proposed procedure or treatment.
- A person appointed under a guardianship order with power to make decisions in relation to the proposed procedure or treatment.
- A person appointed by the patient (before the patient became incapable of giving consent) as an enduring guardian with power to make decisions in relation to the proposed procedure or treatment.
- A person appointed in writing by the patient (being the person appointed last in time before the patient became incapable of giving consent) to make decisions in relation to *medical research procedures* that include the proposed procedure or medical or dental treatment which includes the proposed treatment.
- The patient's spouse or domestic partner.
- The patient's primary carer.
- The patient's nearest relative. The patient's nearest relative for the purposes of the GAA is the spouse or domestic partner of that person or, if that person does not have a spouse or domestic partner, the relative of that person listed first below who is at least 18 years of age:
 - Son or daughter
 - Father or mother.
 - Brother or sister.
 - Grandfather or grandmother.
 - Grandson or granddaughter.
 - Uncle or aunt.
 - Nephew or niece.

The *person responsible* may only consent to the carrying out of the procedure if he or she believes that the carrying out of the procedure would not be contrary to the *best interests of the patient*.

Section 42U provides that in determining whether a medical research procedure would or would not be contrary to the *best interests of a patient*, the following matters must be taken into account:

- The wishes of the patient, so far as they can be ascertained.
- The wishes of any nearest relative or any other family members of the patient.
- The nature and degree of any benefits, discomforts and risks for the patient in having or not having the procedure.
- Any other consequences to the patient if the procedure is or is not carried out.

4. Procedural Authorisation (section 42T)

A *registered practitioner* may carry out, or supervise the carrying out of, a *medical research procedure* on a patient pursuant to procedural authorisation only if the *person responsible* cannot be ascertained or contacted.

Further, in order to carry out, or supervise the carrying out of, a *medical research procedure* on a patient pursuant to procedural authorisation, the *registered practitioner* must ensure all of the following requirements are satisfied:

- The patient is not likely to be capable, within a reasonable time as determined in accordance with section 42R of giving consent to the carrying out of the procedure.
- It has not been possible to ascertain whether there is a *person responsible*, or who that person is; or, if a *person responsible* is ascertained, to contact that person to seek his or her consent to the proposed procedure under section 42S, after taking steps that are reasonable in the circumstances to have been taken:
- The *registered practitioner* believes on reasonable grounds that inclusion of the patient in the relevant research project would not be contrary to the *best interests of the patient*.
- The *registered practitioner* does not have any reason to believe that the carrying out of the procedure would be against the patient's wishes.
- The *registered practitioner* believes on reasonable grounds that the relevant *human research ethics committee* has approved the research project in the knowledge that a patient may participate in the project without the prior consent of the patient or the *person responsible*.
- The *registered practitioner* believes on reasonable grounds that:
 - one of the purposes of the relevant research project is to assess the effectiveness of the therapy being researched, and
 - the *medical research procedure* poses no more of a risk to the patient than the risk that is inherent in the patient's condition and alternative treatment.
- The *registered practitioner* believes on reasonable grounds that the relevant research project is based on valid scientific hypotheses that support a reasonable possibility of benefit for the patient as compared with standard treatment.

It is uncertain whether this requirement would be satisfied in relation to certain research projects. For example, in relation to an early phase clinical trial of a novel compound, it may be difficult for a practitioner to form a reasonable belief that there is a reasonable possibility of benefit for the patient given that the safety and effectiveness of the compound may be unknown and unproven. In all cases, the onus is on the registered practitioner who relies on section 42T to be able to demonstrate that the research project satisfies all of the requirements of the section.

If a *registered practitioner* carries out or supervises the carrying out of a *medical research procedure* pursuant to procedural authorisation, the *registered practitioner* must also do the following:

- Before, or as soon as practicable after, the *medical research procedure* is carried out, the *registered practitioner* must sign a certificate certifying each of the matters listed above and stating that the *person responsible* (if any) or the patient (if the patient gains or regains capacity) will be informed.
- The *registered practitioner* must inform the *person responsible* (if any) or the patient (if the patient gains or regains capacity) as soon as reasonably practicable of:
 - the patient's inclusion in the relevant research project, and

- the option to refuse consent for the procedure to be continued and withdraw the patient from future participation in the project without compromising the patient's ability to receive any available alternative treatment or care.
- The *registered practitioner* must forward a copy of the relevant certificate to the Public Advocate of Victoria and the relevant *human research ethics committee* as soon as practicable (and in any event within 2 working days) after supervising the carrying out of, or carrying out, the procedure and ensure that the certificate is kept in the patient's clinical records.
- Steps that are reasonable in the circumstances must continue to be taken:
 - to ascertain whether there is a *person responsible* and, if so, who that person is, and
 - if the *person responsible* is ascertained, to contact that person to seek his or her consent to the proposed procedure.

The conduct of a medical research procedure in the emergency context

Section 42A of the GAAV may apply in relation to a *medical research procedure* that is to be performed in the emergency context.

Section 42A provides that a *registered practitioner* may carry out, or supervise the carrying out of, a *medical research procedure* on a patient without consent or without authorisation under section 42T if the practitioner believes on reasonable grounds that the procedure or treatment is necessary, as a matter of urgency:

- to save the patient's life
- to prevent serious damage to the patient's health, or
- to prevent the patient from suffering or continuing to suffer significant pain or distress.

The onus will be on the *registered practitioner* relying on section 42A to demonstrate that the above grounds apply. Given that a *medical research procedure* is typically conducted to ascertain the effectiveness of a particular treatment and to determine (or prove) whether the treatment can, in fact, save life or prevent damage or injury to health or prevent suffering, there may be few circumstances where section 42A can actually be applied.

Role of Victorian Civil and Administrative Tribunal

VCAT does not have a role in relation to the approval of a *medical research procedure*, unlike some other jurisdictions. VCAT has a role, albeit limited, in relation to issues arising under Part 4A of GAA which includes the following:

- VCAT will hear an application made to it in relation to any matter, question or dispute under Part 4A relating to the *best interests of a patient*.
- The *person responsible* for a patient may apply to VCAT for directions or an advisory opinion on any matter or question relating to the scope or exercise of his or her authority to consent to a medical research procedure on behalf of the patient.
- VCAT hears and determines issues relating to guardianship.

In exercising any power under the GAA, VCAT will also have regard to any relevant human rights as set out in the *Charter of Human Rights and Responsibilities Act 2006* (Vic). This principle is reinforced in *ZEH (Guardianship)* [2015] VCAT 2051 (30 December 2015), where the VCAT Member ruled that in

interpreting the principles of the GAA, VCAT is generally bound to act compatibly with any relevant human rights set out in the *Charter of Human Rights and Responsibilities Act 2006* (Vic).

While *ZEH (Guardianship)* concerned an application regarding whether an impaired capacity person should be required to undergo sterilisation, the principle is applicable to issues regarding the conduct of a medical research procedure pursuant to the GAA.

Checklist of matters for HRECs to consider

- Does the research involve participants aged 18 years or older who lack the capacity to provide informed consent?
- Does the research constitute a *medical research procedure* as defined in the GAAV?
- Does the consent model for the research project properly consider the four step process in Part 4A of the GAA?
- Will the circumstances of the conduct of the research generally allow a patient's person responsible to be identified in time?
- If the researcher contemplates that the research might be conducted under procedural authorisation, does the research satisfy all the relevant requirements for it to proceed under procedural authorization?
- Has the researcher prepared participant information sheet and consent forms that adequately deal with the proposed model to obtain consent?
- Has the HREC approval been given subject to the research being conducted in accordance with all relevant legal requirements regarding 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?

Western Australia

Note: This section describes the legislation in Western Australia regarding the giving of consent for the provision of **medical treatment** to a person who lacks the capacity to provide informed consent; it does so because there is no Western Australian legislation that specifically refers to or directly deals with the giving of consent for an adult who lacks the capacity to provide consent to participate in a human research project or a clinical trial.

This section should be read subject to the comments set out in paragraph 2.2 of section A (page 5) of this report.

In the absence of any express provision in Western Australian legislation to the contrary, it is arguable that the principles for the making of decisions for impaired capacity adults generally under Western Australian legislation also apply to the making of consent decisions for an impaired capacity person to participate in human research. In the context of medical research (and clinical trials in particular) the principles concerning substitute decision making for the provision of health care or treatment will be most relevant. Those legislative provisions are discussed below. However, it can only be extrapolated that those principles apply to decisions regarding research given that the legislation discussed below makes no specific reference to human research or clinical trials.

Legislation

Guardianship and Administration Act 1990 (WA) (GAAWA)

Applicable requirements

Outline of requirements

- There is no legislation in Western Australia that deals specifically with the giving of consent for a person with impaired capacity to participate in human research or a clinical trial.
- In the absence of an express provision to the contrary, it is arguable that the requirements for consent regarding the participation in research of an impaired capacity adult may fall within the general legal requirements regarding the making of other decisions for that person, including decisions regarding the giving of consent for the provision of *medical treatment* to such person (to the extent the research involves the provision of *medical treatment*).
- The GAAWA provides that a *treatment* decision for an impaired capacity person may be made by the first person in a list set out in the GAAWA which include an enduring guardian, a guardian, and a *person responsible*.
- There is no requirement for any tribunal or court to give approval to the research project or to otherwise give the requisite consent for a person who lacks the capacity to provide consent to participate in the research project.

Consent for treatment

The GAAWA prescribes requirements regarding who may make a *treatment decision* for a person who 'is unable to make reasonable judgments in respect of any treatment proposed to be provided to them'. These requirements generally apply to persons who have reached 18 years of age. The relevant procedures for the making of such a decision are set out in Part 9D of the GAAWA.

In the GAAWA, a *treatment decision* is defined as a 'decision to consent or refuse consent to the commencement or continuation of any *treatment* of the person'. *Treatment* is defined as:

- medical or surgical treatment, including a life sustaining measure and palliative care
- dental treatment, or
- other health care.

Does treatment include participation in human research or a clinical trial?

The GAAWA does not specifically refer to research, medical research or clinical trials. There is no other legislation in Western Australia which specifically refers to the giving of consent for patients who lack the capacity to provide consent to participate in research, medical research or a clinical trial.

To the extent that medical research involves medical or surgical *treatment*, or could be characterised as *treatment*, then research, including clinical trials, might fall within the definition of *treatment*. If it does, then the process described in Part 9 would arguably apply to the giving of consent for an impaired capacity person to participate in that research. Of course, as the Western Australian legislation does not specifically state that the conduct of research or a clinical trial constitutes *treatment* and does not specify who may make *treatment decisions* for a person with impaired capacity with respect to their participation in such research (unlike, for example, the legislation in Victoria, New South Wales and Queensland), the legislative position in Western Australia in this respect is uncertain and these assumptions regarding the operation of the GAAWA could potentially be challenged.

Furthermore, it is even more uncertain that these provisions would apply to human research that does not involve *treatment* as defined in the GAAWA. As is the case with the legislation in South Australia and Tasmania, while it might be argued that the conduct of a clinical trial constitutes or involves the giving of *treatment*, it may be more difficult to make such a case with other types of human research that are not a clinical trial. In those cases, it is questionable whether the procedures for giving consent for medical or dental treatment for an impaired capacity adult will apply in the same manner.

Depending on the research, it may be necessary to rely upon the substitute decision making principles that relate to matters other than the provision of medical treatment for an impaired capacity person.

Who may give consent for treatment decisions?

If a patient is unable to make reasonable judgments in respect of any *treatment* proposed to be provided to the patient, section 110ZJ of the GAAWA provides that the order of priority of persons who may make a *treatment decision* in relation to the patient is the following:

- If the patient has made an advance health directive containing a *treatment decision* in respect of the *treatment*, whether or not the *treatment* is provided to the patient must be decided in accordance with the *treatment decision*.
- An enduring guardian (appointed under the GAAWA) who is authorised to make a *treatment decision* in respect of the *treatment*, reasonably available, and willing to make a *treatment decision* in respect of the *treatment*.
- A guardian (appointed under the GAAWA) who is authorised to make a *treatment decision* in respect of the *treatment*, reasonably available, and willing to make a *treatment decision* in respect of the *treatment*.
- A *person responsible* for the patient.

The *person responsible* for the patient is the first in order of the below listed persons who is of full legal capacity, reasonably available, and willing to make a *treatment decision* in respect of the *treatment*:

- The patient's spouse or de facto partner if that person has reached 18 years of age and is living with the patient.
- The patient's nearest relative who maintains a close personal relationship with the patient, being the first in order of priority of the following relatives who has reached 18 years of age:
 - The spouse or de facto partner
 - A child
 - A parent
 - A sibling.
- The person who has reached 18 years of age and is the primary provider of care and support (including emotional support) to the patient, but is not paid for providing that care and support.
- Any other person who has reached 18 years of age and maintains a close personal relationship with the patient. A person maintains a close personal relationship with the patient only if the person has frequent contact of a personal (as opposed to a business or professional) nature with the patient and takes a genuine interest in the patient's welfare.

When making a *treatment decision* for the patient, the *person responsible* for the patient must act according to the person's opinion of the *best interests of the patient*.

The GAAWA does not contain any specific provisions that set out the factors that a person responsible should take into account in determining what might be in the patient's best interests when making a *treatment decision*. However, section 51(2) of the GAAWA contains provisions relating to what constitutes the best interests of a represented person in the context of the exercise of a guardian's powers. Section 51(2) provides that a guardian acts in the best interest of a represented person if he or she acts as far as possible:

- as an advocate for the represented person
- in such a way as to encourage the represented person to live in the general community and participate as much as possible in the life of the community
- in such a way as to encourage and assist the represented person to become capable of caring for himself and of making reasonable judgments in respect of matters relating to his person
- in such a way as to protect the represented person from neglect, abuse or exploitation
- in consultation with the represented person, taking into account, as far as possible, the wishes of that person as expressed, in whatever manner, or as gathered from the person's previous actions
- in the manner that is least restrictive of the rights, while consistent with the proper protection, of the represented person
- in such a way as to maintain any supportive relationships the represented person has, and
- in such a way as to maintain the represented person's familiar cultural, linguistic and religious environment.

These principles could, to the extent applicable to the exercise of any authority by a person responsible, guide a person responsible in relation to what constitutes the best interests of the represented person in relation to a *treatment decision*.

Urgent or emergency treatment

The GAAWA permits a health professional to provide *urgent treatment* to a patient in the absence of a *treatment decision* (as defined in the GAAWA) in relation to the patient. *Urgent treatment* is defined as ‘treatment urgently needed by a patient to save the patient’s life, to prevent serious damage to the patient’s health or to prevent the patient from suffering or continuing to suffer significant pain or distress’.

Section 110ZI states that *urgent treatment* may be provided without a *treatment decision* if the following conditions are satisfied:

- The patient needs *urgent treatment*.
- The patient is unable to make reasonable judgments in respect of the treatment.
- It is not practicable for the health professional who proposes to provide the treatment to determine whether or not the patient has made an advance health directive containing a *treatment decision* that is inconsistent with providing the treatment.
- It is not practicable for the health professional to obtain a *treatment decision* in respect of the treatment from the patient’s guardian, enduring guardian or *person responsible*.

To the extent that a patient’s participation in a research project (and more specifically, a clinical trial) might involve the provision of *urgent treatment* and satisfy the requirements of section 110ZI, a health professional might be able to rely on these provisions to include the patient in the research without a *treatment decision* made in relation to the patient. Of course research is typically conducted to ascertain the effectiveness of a particular treatment and to determine (or prove) whether the treatment can, in fact, save life or prevent damage or injury to health or prevent suffering; there may therefore be few circumstances in the research context where section 110ZI could apply.

Role of State Administrative Tribunal of Western Australia

The State Administrative Tribunal (**SAT**) of Western Australia does not have a specifically defined or direct role in relation to the approval of human research or a clinical trial or the giving of consent for an impaired capacity person to participate in human research or a clinical trial. In particular, there is no requirement to submit a research project or a clinical trial to the SAT for approval.

The SAT may have an indirect role in relation to issues concerning the conduct of research to the extent that it has certain powers regarding the making of *treatment decisions* in relation to a person who lacks the capacity to provide informed consent. For example, the SAT can determine issues regarding advanced health directives and can make declarations regarding who may make *treatment decisions* for an impaired capacity person. Further, in a 2013 Position Statement, the Office of the Public Advocate of WA advised that an application for a guardianship order should be made to the SAT when ‘an ethically contentious treatment or procedure is proposed, for example, clinical drug trials’.

Checklist of matters for an HREC to consider

- Does the research involve participants who lack the capacity to provide informed consent?
- Does the clinical trial involve the provision of *treatment* as defined in the GAAWA to an impaired capacity person?
- Does the proposal clearly document how the researcher will seek consent from any substitute decision maker?
- Has the HREC approval been given subject to the research being conducted in accordance with all relevant legal requirements regarding 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?

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This report has been prepared by Rallis Legal for the NHMRC.



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