2015

LEGISLATIVE ASSEMBLY FOR THE

AUSTRALIAN CAPITAL TERRITORY

POWERS OF ATTORNEY AMENDMENT BILL 2015

EXPLANATORY STATEMENT

Presented by
Simon Corbell MLA
Attorney-General

Authorised by the ACT Parliamentary Counsel—also accessible at www.legislation.act.gov.au

Introduction

This explanatory statement relates to the *Powers of Attorney Amendment Bill 2015* as presented to the Legislative Assembly. It has been prepared in order to assist the reader of the bill and to help inform debate on it. It does not form part of the bill and has not been endorsed by the Assembly.

The Statement must to be read in conjunction with the bill. It is not, and is not meant to be, a comprehensive description of the bill. What is said about a provision is not to be taken as an authoritative guide to the meaning of a provision, this being a task for the courts.

Overview

Purpose

The policy objective of the amendments is to remove barriers to people with impaired decision-making capacity participating in medical research. Removing these barriers may allow these people to receive beneficial treatment not otherwise available to them and will assist health researchers to develop innovative treatments which may benefit a class of people with a certain condition.

The amendments are also aimed at making the process for deciding about a person's participation in medical research consistent for all substitute decision-makers.

The *Powers of Attorney Amendment Bill 2015* (the Bill) will:

a) amend the *Powers of Attorney Act 2006* to:

i) allow a person (the principal) to authorise their attorney to make decisions about medical research matters involving ethically-approved research;

ii) allow enduring attorneys to make decisions about medical research matters involving ethically-approved research when the power of attorney does not include medical research matters but permits the attorney to make decisions about health care matters;

iii) introduce safeguards by way of a two-tiered process which must be followed by an enduring attorney making a decision about medical research matters; and

iv) empower the ACT Civil and Administrative Tribunal (ACAT) to:

(A) assist the attorney to make a decision about medical research matters; and

Authorised by the ACT Parliamentary Counsel—also accessible at www.legislation.act.gov.au

(B) review an attorney's decision about medical research matters;

b) amend the *Guardianship and Management of Property Act 1991* to:

i) introduce the same tiered process for decisions about medical research matters made by a guardian;

ii) prohibit health attorneys from making decisions about medical research matters other than decisions involving low-risk research; and

c) amend the *Medical Treatment (Health Directions) Act 2006* to require all substitute decision-makers (enduring attorneys, guardians and health attorneys) to act consistently with a health direction, including one that limits or refuses participation in medical research.

This approach to achieving the objectives of the policy is reasonable because it strikes an appropriate balance between removing barriers to participation in medical research and protecting a person's right to not be involved in medical research. The approach achieves this balance by:

a) providing a mechanism for people to decide whether they wish to be involved in medical research before they become incapacitated;

b) providing equality under the law by introducing a mechanism for a substitute decision-maker to consent to a person participating in medical research despite the person not making a specific direction about medical research participation;

c) introducing safeguards to protect the participant when a substitute decision-maker is considering a person's participation in medical research; and

d) providing avenues for the ACAT to:

i) assist the substitute decision-maker to make a decision about a person's participation in medical research; and

ii) review a substitute decision-maker's decision to provide or refuse consent to a person participating in medical research.

This approach requires the substitute decision-maker to decide about a person's participation in medical research with only limited involvement by the ACAT. An alternative approach would have been to require the ACAT to decide about person's participation in medical research. This approach was not taken as it would have:

a) adversely impacted on the ACAT's workload, which is unjustified when a properly appointed decision-maker, often with a personal proximity to the principal, is available to make these decisions;

Authorised by the ACT Parliamentary Counsel—also accessible at www.legislation.act.gov.au

b) had the potentially perverse outcome of replacing the appointed decision-maker with an unknown person or panel of people; and

c) potentially undermined the aim of facilitating human involvement in ethically-approved and potentially beneficial medical research, as it may have had the effect of dissuading decision-makers from pursuing medical research matters if they were required to apply to ACAT for the consent.

This approach was formulated in consultation with stakeholders over several months, with all suggestions considered during the drafting of the policy and the Bill.

Consistency with other jurisdictions

This approach is a hybrid of the regimes for medical research participation by people with impaired decision-making capacity operating in New South Wales, Victoria and Queensland.

This approach requires ethical approval of all research projects, which is a requirement under the *Guardianship Act 1987* (NSW), the *Guardianship and Administration Act 1986* (Vic) and the *Guardianship and Administration Act 2000* (Qld).

Like Victoria, this approach includes processes to be followed by the decision-maker and a doctor when considering medical research matters. These processes include considerations which are drawn from both the Victorian and Queensland Guardianship and Administration Acts.

Costs and benefits

The Bill is expected to benefit the ACT financially, because:

a) researchers in the ACT who have previously considered relocating their studies due to restrictions on involving people with impaired capacity are likely to continue operating in the ACT; and

b) researchers who have not operated in the ACT due to restrictions on involving people with impaired capacity may commence studies in the ACT.

Human rights considerations

This Bill achieves the policy objective of advancing medical research about people with impaired decision-making capacity while carefully balancing the human rights of those people.

The Bill supports section 8 of the *Human Rights Act 2004* (HR Act) – Recognition and equality before the law. It also engages section 10 – Protection from torture and cruel, inhuman or degrading treatment - as it relates to participation in medical research without consent (s 10 (2)).

Authorised by the ACT Parliamentary Counsel—also accessible at www.legislation.act.gov.au

Section 8 - Recognition and equality before the law

The Powers of Attorney Act prohibits people from authorising their enduring attorney to make decisions on their behalf about participating in medical research. If people with a power of attorney become incapacitated at a time when they have not already consented to medical research, they are prevented from participating in medical research altogether. People who do not have an enduring attorney may be able to participate in medical research if their guardian or health attorney consents.

The Bill promotes recognition and equality before the law by allowing people to authorise their enduring attorney to make decisions on their behalf about participation in medical research. Where a power of attorney does not authorise their enduring attorney to consent, an enduring attorney can still consent to a person participating in medical research, provided they follow the conditions set out in the Bill.

The Bill also applies the same conditions to guardians who are making decisions about medical research matters, providing recognition and equality before the law to all people with impaired decision-making capacity, regardless of whether they appoint an enduring attorney prior to becoming incapacitated.

Section 10 (2) - Freedom from medical experimentation without consent

Section 10 (2) of the HR Act provides that "no-one may be subjected to medical or scientific experimentation or treatment without [their] free consent". The Bill supports as well as limits this right.

The Bill supports this right by providing people the opportunity to appoint an enduring attorney for medical research matters before becoming incapacitated. The Bill also makes it clear that any health direction previously made by the person with impaired decision-making capacity must be followed, including a direction to not participate in medical research.

Limitation on the right

a. Nature of the right affected

The Bill limits a person's right to consent to medical treatment under section 10(2) by allowing an enduring attorney or guardian (and in limited circumstances, a health attorney) to make a decision about a person with impaired decision-making capacity participating in medical research.

b. Importance of the purpose of the limitation

Allowing an enduring attorney, health attorney or guardian to consent to participation in medical research including experimental care may allow a person to receive beneficial treatment that would otherwise not be available to them. The amendments in this Bill will also assist health researchers to develop new treatments for the benefit of a class of people

Authorised by the ACT Parliamentary Counsel—also accessible at www.legislation.act.gov.au

with a certain condition. This is particularly significant in conditions, such as dementia, where the majority of participants are like to have impaired capacity to consent.

c. Nature and extent of the limitation

The Bill limits this right to the extent that an enduring attorney or guardian is able to consent to participation in medical research, with or without the person's previous consent. The extent is constrained by a number of factors, including:

- the medical research must be approved a by a human research ethics committee in accordance with the *National Statement on Ethical Conduct in Human Research* (National Health and Medical Research Council, 2007);
- a person's wishes, as far as can be worked out, must be given effect to unless it would significantly adversely affect their interests;
- the person's life must be interfered with the smallest extent possible;
- the decision-maker must consult with the person's carers unless it would adversely affect the person's interests;
- the decision-maker must not consent if the person is likely to regain decision-making capacity before they can meaningfully participate in the research;
- the research must have the potential to result in a benefit to the person or others with the condition and the potential benefit of participating in the research must outweigh any potential risk or adverse impact on the person's quality of life;
- participating in the research must not unduly interfere with the person's privacy; and
- in the case of a health attorney, the treatment must be low-risk.

Any limitation is also constrained by the ability of an attorney to seek an opinion or advice from the ACAT. In addition, an interested person (defined broadly in section 74 of the Powers of Attorney Act) may apply to ACAT for a review of an attorney's decision to consent.

d. Relationship between the limitation and its purpose

The purpose of this Bill is to allow a substitute decision-maker to consent to a person with impaired decision-making capacity participating in potentially beneficial medical research. Such consent requires a limitation on the right in section 10 (2) as there is no way the person could validly consent on their own behalf.

Authorised by the ACT Parliamentary Counsel—also accessible at www.legislation.act.gov.au

e. Any less restrictive means available to achieve the purpose

There is no other less restrictive means available to achieve the purpose of the Bill. People with impaired decision-making abilities cannot provide consent to participate in medical research on their own behalf, so a substitute decision-maker is required.

The Bill introduces a clear set of processes that must be followed and conditions that must be met before a substitute decision-maker may consent to medical research. The decision-maker must have regard to the best interests (including giving effect to a person's express wishes) and privacy of the person about whom the decision is made and there are processes for independent review of a decision. These factors mean that the limit on the right to protection from medical research without consent is the least restrictive possible and is reasonable and proportionate.

Authorised by the ACT Parliamentary Counsel—also accessible at www.legislation.act.gov.au

Powers of Attorney Amendment Bill 2015

Detail

Powers of Attorney Act 2006

Clause 1 — Name of Act

This is a technical clause that names the short title of the Act as the *Powers of Attorney Amendment Act 2015*.

Clause 2 — Commencement

This clause provides that the Act will commence on a day fixed by the Minister by written notice. This allows time to advise the community about the amendments prior to commencement.

Clause 3 — Legislation amended

This clause explains that the Bill amends the *Powers of Attorney Act 2006* (PoA Act), the *Guardianship and Management of Property Act 1991* (Guardianship Act), and the *Medical Treatment (Health Directions) Act 2006* (Health Directions Act).

Clause 4 — What is an *enduring power of attorney?* Section 8, note

This clause amends the note to clarify that a general power of attorney operates in relation to property matters, as set out in section 31(2).

Clause 5 – Meaning of *personal care matter,* Section 11, definition of *personal care matter*

This clause has the effect of inserting into section 11 ‘medical research matter’ so that it is excluded from the definition of personal care matter.

Clause 6 — Meaning of *health care matter,* Section 12, definition of *health care matter*

This clause inserts into section 12 ‘or medical research matter’ so that medical research matters are excluded from the definition of health care matter.

Clause 7 — New section 12A

This clause inserts a new section that defines *medical research matter* to mean ‘low-risk research’ and ‘medical research’, which are defined in section 41A.

The note links section12A with part 4.3A because an enduring attorney must exercise a power about medical research matters in accordance with part 4.3A.

Authorised by the ACT Parliamentary Counsel—also accessible at www.legislation.act.gov.au

Clauses 8 to 10 — Section 13(2) and section 14(2) and (3) – Limit on s 13 power to appoint attorneys – enduring powers of attorney

These clauses insert 'medical research matter' into sections 13 and 14:

(a) so that a person (the principal) may appoint one or more enduring attorneys for medical research matters, in addition to property matters, personal care matters and health care matters; and

(b) to clarify that a principal must not appoint a corporation for medical research matters or the public advocate for a matter other than a personal care matter, a health care matter or a medical research matter.

Clause 9 omits a note from section 13(2) which is duplicated in section 13(1).

Clause 11 — Others acting for attorney, Section 33(2)

This clause is a technical amendment to ensure consistency of language in the legislation. It replaces 'decision-making ability' (not used elsewhere in the Act) with 'decision-making capacity'.

The Guardianship Act uses both terms, decision-making ability generally, and 'decision-making capacity' for the sections relevant to the PoA Act. This appears to be a deliberate distinction in the Guardianship Act which does not require amendment.

Clause 12 — Special health care matters, Section 37 (1) (d)

'Participation in medical research or experimental health care' is excluded from health care matters by section 37(1) (d). This clause removes that exclusion. However clause 6 continues to exclude participation in both medical research and experimental health care from health care matters, as these concepts are included in medical research matters (see s 12A in cl 7).

Clause 13 — New part 4.3A

This clause inserts a new part 4.3A (Medical research matters), which sets out the process for enduring attorneys authorised for medical research matters to consider the principal's participation in low-risk research and medical research.

<u>New section 41A: Definitions – pt 4.3A</u>

This section defines 'approved', 'low-risk research', 'medical research', 'medical research power of attorney', 'experimental health care', 'NHMRC', 'personal information' and 'personal health information'.

Authorised by the ACT Parliamentary Counsel—also accessible at www.legislation.act.gov.au

The Bill includes 'low-risk research' to cover research projects involving minor and uncontroversial treatment. Low-risk research may be offered in relatively urgent situations such as the emergency department and the intensive care unit, where health attorneys are asked to consent to treatment. Due to the minor and uncontroversial and sometimes urgent nature of the treatment, it is not considered appropriate to apply the decision-making process set out in section 41D (or section 34 of the Guardianship Act). However in order to protect the interests of the principal, the research must be approved by a human research ethics committee and the decision-maker must follow the decision-making principles.

'Medical research' is all research which is not low-risk research and includes experimental health care. 'Experimental health care' is all research into health care, but may or may not be medical in nature. This is intended to capture matters that may be considered health care, but which, because of their experimental nature, require the decision-maker to go through the decision-making process set out in section 41D (or section 34 of the Guardianship Act). This is intended to avoid situations like the experimentation in nursing homes in Victoria in 2000 using kerosene baths to treat scabies.[1]

A 'medical research power of attorney' is an enduring power of attorney which authorises the attorney for medical research matters. It is also an enduring attorney which authorises the attorney for health matters so long as the enduring attorney was made before these amendments commence. In this case it is considered appropriate to extend the trust provided to the enduring attorney to make decisions about health care matters for the principal to medical research matters, in order allow those people who do not or cannot make a power of attorney for medical research matters access to potentially beneficial medical research. Protections for people who do not want to be involved in medical research are provided by the Health Directions Act, which allows a person to refuse or withdraw from medical treatment, including medical research. The Bill elevates the status of health directions by requiring all substitute decision-makers to follow a health direction, where appropriate, when making decisions about medical treatment and research.

This section also refers to the definitions of 'personal information' under section 8 of the *Information Privacy Act 2014* and 'personal health information' in the dictionary of the *Health Records (Privacy and Access) Act 1997*, importing them into the PoA Act.

<u>New section 41B: Attorney must follow decision-making principles</u>

This section requires an enduring attorney who is authorised for medical research matters to make decisions about medical research matters in accordance with the decision-making principles.

These decision-making principles are based on the principal's wishes and come from the Guardianship Act. However, in addition, clause 13 inserts section 41B(3), which is a presumption that the principal wishes to continue participating in research that he or she was

[1] "Outrage over nursing home treatment", *7.30 Report,* 2000, abc.net.au.

Authorised by the ACT Parliamentary Counsel—also accessible at www.legislation.act.gov.au

participating in before losing capacity. The Bill also inserts this presumption into the Guardianship Act (see cl [1.13] and [1.24]).

Authorised by the ACT Parliamentary Counsel—also accessible at www.legislation.act.gov.au

New section 41C: Attorney may consent to principal's participation in low-risk research

This section allows an enduring attorney authorised for medical research matters to consent to the principal participating in low-risk research if the research is approved by a human research ethics committee constituted in accordance with, and acting in compliance with, the *National Statement on Ethical Conduct in Human Research* (2007), as amended.

This section works in conjunction with section 41B, requiring the enduring attorney to make the decision about approved low-risk research in accordance with the decision-making principles.

The note links section 41C to the Health Directions Act, because an enduring attorney must also comply with a health direction of the principal, which is relevant to and consistent with the enduring attorney's appointment for medical research matters. Where an inconsistency between the health direction and the enduring power of attorney exists, the most recent document prevails.

The enduring attorney may seek the assistance of the ACAT to make a decision about the principal's participation in low-risk research (s 41C (3)).

New section 41D: Attorney may consent to principal's participation in medical research

This section provides the process when an enduring attorney is considering the principal's participation in medical research.

This process involves a prerequisite, followed by two steps, one which is the responsibility of an independent doctor and the other which must be carried out by the enduring attorney (who may seek assistance, including from the independent doctor).

The term 'independent doctor' is defined in section 41F (3). Requiring the doctor to be independent of the research is intended to avoid criticisms which are made of other jurisdictions' regimes, where the assessing doctor may be the researcher or connected in some other way to the research and is therefore potentially susceptible to being influenced by the interests of the research project rather than the best interests of the principal. A financial benefit is not referred to in this definition, as it is not the intention to prevent the doctor receiving a fee as the treating doctor, and accepting a fee to make a decision favourable to the payer – which is not permitted – amounts to conduct which is already prohibited under criminal laws and ethical codes of conduct.

The prerequisite to this process is that all medical research be approved by a human research ethics committee constituted in accordance with, and acting in compliance with, the *National Statement on Ethical Conduct in Human Research* (2007), as amended (see s 41D(2)(a)).

Authorised by the ACT Parliamentary Counsel—also accessible at www.legislation.act.gov.au

Step one in section 41D (2) (b) requires the independent doctor to assess the possibility of the principal regaining capacity before the latest time that the principal may meaningfully participate in the research. This is intended to:

(a) avoid the principal being involved in research which is unnecessary, because the principal is ultimately likely to regain capacity; and

(b) provide the principal with the maximum possible time to regain capacity while accounting for the timeline of the research.

When making this assessment, the independent doctor must consider the factors in section 41F, such as the severity of the principal's condition and any other circumstances relevant to the principal. This section is based on section 42R (2) of the *Guardianship and Administration Act 1986* (Vic).

After making the section 41D (2) (b) assessment, the independent doctor must provide a written statement of belief with reasons (see s 41F (2)). If the independent doctor believes the principal is *not likely* to be capable of providing consent to participate in the research, the enduring attorney may consider whether to consent to the principal participating in accordance with section 41D(2)(c). This section is based on section 72(2) of the *Guardianship and Administration Act 2000* (Qld) and is intended to provide the principal the opportunity to participate in potentially beneficial research while being safeguarded against participating in inappropriate and potentially dangerous research.

This section works in conjunction with section 41B, requiring the enduring attorney to make the decision about medical research in accordance with the decision-making principles. The note in section 41D (2) (c) refers to the Health Directions Act, because an enduring attorney must also comply with any health direction of the principal which is relevant to and consistent with the enduring attorney's appointment for medical research matters. Where an inconsistency between the health direction and the enduring power of attorney exists, the most recent document prevails.

Section 41D (3) allows the enduring attorney to seek the assistance of the ACAT when making a decision about the principal's participation in medical research.

<u>New section 41E: Attorney must not benefit from attorney's decision</u>

This section prohibits an enduring attorney from receiving a benefit, directly or indirectly, as a result of making a decision about a medical research matter, or being involved in or connected to the research. This is intended to avoid the enduring attorney being influenced in his or her decision by anything other than the wellbeing of the principal. However, this section, recognising that the relationship between the principal and the enduring attorney may be personal, allows the enduring attorney to receive a personal benefit resulting from the principal's health improving as a result of participating in the research.

Authorised by the ACT Parliamentary Counsel—also accessible at www.legislation.act.gov.au

New section 41F: Assessment of likelihood of principal regaining decision-making capacity

This section is discussed with section 41D above.

New section 41G: Interested person may apply to ACAT for review of attorney's decision

This section allows an interested person to apply to the ACAT for a review of the enduring attorney's decision about the principal's participation in low-risk research or medical research.

The list of interested people in section 74 is used for this purpose, and includes the principal. This is intended to give a principal who regains capacity, or whose capacity is intermittent, power to seek review of their enduring attorney's decision about a medical research matter. There may also be circumstances where a principal is considered to be lacking capacity but nonetheless wishes to seek review of a decision about a medical research matter and is not able to seek the assistance of an interested person to apply for the review. In this circumstance it is intended that the principal will be able to rely on his or her personal right to seek the review.

The Bill inserts a regulatory power to add to the list of interested people. This is intended to introduce flexibility to this definition, which will apply to all uses of the term 'interested person', including the PoA Act and part 3 of the Guardianship Act.

Clause 14 — Obligations on health care facilities in relation to powers of attorney, Section 49 (a)

This clause inserts 'medical research matter' into section 49(a) so that a person in charge of a health care facility has certain obligations relating to enduring powers of attorney for medical research matters.

Clause 15 — Meaning of *interested person*—ch7, Section 74, definition of *interested person*, new paragraph (h)

This section is discussed with section 41G above.

Clauses 16 to 19 — Section 85 and schedule 1, section 1.11

These clauses include 'medical research matters' into section 85 and section 1.11 of schedule 1, requiring:

(a) a relevant person to inform the public advocate about a medical research matter decision which is not in the best interests of the principal; and

(b) an enduring attorney to make a decision about medical research matters in a way which is consistent with section 1.11 of schedule 1.

Authorised by the ACT Parliamentary Counsel—also accessible at www.legislation.act.gov.au

Clause 20 — Dictionary, new definitions

This clause refers to definitions of 'approved', 'decision-making principles', 'low-risk research', 'medical research', 'medical research matter' and 'medical research power of attorney', as defined throughout the Bill.

Schedule 1 – Other amendments

Schedule 1 amends the Guardianship Act and the Health Directions Act.

Part 1.1 – Guardianship and Management of Property Act 1991

Clauses [1.1] and [1.2] – **Section 7 (3) (e)**

This clause amends the powers given to a guardian in relation to consent for a medical procedure or other treatment to clarify that it includes medical research or low-risk research.

The note in this clause links section 7(3) (e) to part 2B because a guardian must only provide a consent for medical research or low-risk research in accordance with part 2B.

Clause [1.3] – Section 8B (1) (a)

This clause inserts 'or medical research matters' into section 8B (1) (a) to require a guardian who has the power to consent to medical treatment for a person to consider that person's enduring power of attorney about medical research matters or health care matters following the ACAT revoking all or part of the enduring power of attorney.

Clause 1.4 – Section 8B (2)

This amendment inserts 'medical research or low-risk research' to clarify the scope of the power.

Clause [1.5] – New section 8B (3)

This clause inserts the definitions of 'health care matter' and 'medical research matter' into section 8B by referring to the definitions in the PoA Act.

Clauses [1.6] to [1.23] – Part 2A Consent without formal representation

These clauses amend part 2A of the Guardianship Act by expanding the power of health attorneys to make decisions about low-risk research.

Clause [1.6] – Section 32A, definition of medical treatment, par (b)

This clause inserts 'a prescribed medical procedure', 'medical research' and 'low-risk research' into section 32A(b) so that these terms are excluded from the definition of medical treatment. Health attorneys are able to consent to medical treatment; excluding these terms

Authorised by the ACT Parliamentary Counsel—also accessible at www.legislation.act.gov.au

from medical treatment allows the Bill to prohibit health attorneys from consenting to medical research and places conditions on health attorneys consenting to low-risk research (cl [1.5]-[1.6]).

Clauses [1.7] to [1.11] – Section 32D: health attorneys may consent to low-risk research

These clauses include low-risk research in section 32D to authorise health attorneys to consent to low-risk research, in addition to medical treatment.

Clause [1.9] links section 32D to the Health Directions Act because health attorneys must make a decision about medical treatment and low-risk research in accordance with a health direction (cl [1.30]).

Clause [1.10] includes a prerequisite to the health attorney consenting to low-risk research that the research must be approved by a human research ethics committee constituted in accordance with, and acting in compliance with, the *National Statement on Ethical Conduct in Human Research* (2007), as amended.

Clauses [1.12] and [1.13] – Section 32E: decision-making principles

These clauses insert 'low-risk research' into section 32E to clarify that a health attorney must make a decision about low-risk research in accordance with the decision-making principles in section 4.

Clauses [1.14] to [1.16] – Sections 32F and 32G: health professional's obligations etc

These clauses insert 'low-risk research' into sections 32F and 32G to extend a health professional's obligations, rights and protections relating to a health attorney's decision to include a decision about a person's participation in low-risk research.

Authorised by the ACT Parliamentary Counsel—also accessible at www.legislation.act.gov.au

Clauses [1.17] and [1.18] – Sections 32H and 32I: referral to the public advocate

Sections 32H and 32I require a health professional to refer a health attorney's decision about medical treatment to the public advocate in certain circumstances. As this Bill introduces a new requirement for health attorneys to make decisions about medical treatment in accordance with a health direction, the amendments clarify that a health professional must refer a health attorney's decision about medical treatment to the public advocate if:

(a) the health professional believes the health attorney's decision is inconsistent with a health direction; or

(b) there is a dispute between two or more health attorneys and the health professional is unaware of a health direction that supports one side of the dispute.

This provides further protection for a person who has expressed his or her preferences in a health direction. It is also intended to result in fewer referrals to the public advocate resulting from disputes between health attorneys, as a health professional may follow the direction which is consistent with a health direction, rather than refer the dispute to the public advocate.

It was not considered appropriate to include a requirement for a health professional to refer a matter relating to low-risk research to the public advocate. This is because low-risk research, while potentially beneficial, is unlikely to be crucial to the patient, as is the case with some medical treatment. Where a health attorney does refuse to consent to low-risk research, the health professional will instead be able to seek consent from the health attorney to medical treatment generally. Further, as an interested person is able to seek a review of a health attorney's decision by the ACAT (cl [1.20], extending the public advocate's jurisdiction to include low-risk research decisions may have resulted in multiple reviews being carried out by two different bodies over the one decision.

Clauses [1.19] and [1.20] – Sections 32J and 32JA: review of health attorney's decision

These clauses are intended to provide additional protections for a person who is subject to decisions being made by a health attorney.

Clause [1.19] requires a health professional to provide information to the public advocate when a health attorney's decision to consent to a person participating in low-risk research results in the person participating in the research for six months or more.

Clause [1.20] allows an interested person to apply to the ACAT for a review of a health attorney's decision. The discussion about new section 41G of the PoA Act above discusses the ACAT review process further.

Authorised by the ACT Parliamentary Counsel—also accessible at www.legislation.act.gov.au

Clauses [1.21] and [1.22] – Section 32M: preservation of health professional's liability

Section 32M preserves, under certain circumstances, a health professional's liability in relation to providing medical treatment. Clauses [1. 21] and [1.22] extend this to carrying out low-risk research.

Clause [1.23] – Sections 32O and 32P

This clause inserts new sections 32O and 32P.

Section 32O provides that a health attorney's decision to consent to a protected person participating in low-risk research can be withdrawn by an interested person. 'Interested person' for this section is defined in section 32O (4) to be the protected person's guardian and enduring attorney and the protected person. The guardian and enduring attorney are included despite the definition of protected person in section 32A, which provides that a protected person does not have an enduring attorney or a guardian. This is aimed at situations where a doctor seeks consent from a health attorney without knowing that the protected person has a guardian or an enduring attorney. This is intended to protect the protected person's interests by empowering the officially-appointed decision-maker with ultimate decision-making responsibility about the protected person's care.

The protected person was included here to accommodate circumstances such as where the person regains capacity or where the person's capacity is intermittent. There may also be circumstances where a protected person is considered to be lacking capacity but nonetheless expresses a clear wish to not be involved in the research. In this circumstance it is intended that the protected person will be able to withdraw from the research.

It is also intended that a health attorney with higher priority than the decision-maker will be able to withdraw the decision-maker's decision. This is provided in section 32B which sets out a priority order for health attorneys.

If a health attorney's decision is withdrawn, any data or bodily tissue collected as a result of the person participating in the research must be removed from the research unless the person agrees otherwise in writing.

Section 32P prohibits a health attorney from receiving a benefit, directly or indirectly, as a result of making a decision about low-risk research, or being involved in or connected to the research. This is intended to avoid the health attorney being influenced in his or her decision by anything other than the wellbeing of the protected person. However, this section, recognising the personal relationship between the protected person and the health attorney, allows the health attorney to receive a personal benefit resulting from the protected person's health improving as a result of participating in the research.

Authorised by the ACT Parliamentary Counsel—also accessible at www.legislation.act.gov.au

Clause [1.24] – New part 2B: Medical research and low-risk research

This clause inserts a new part 2B, which sets out the process for guardians, if authorised to provide a consent required for a medical procedure or other treatment, to consider the protected person's participation in low-risk research and medical research.

New section 33: Guardian may consent to principal's participation in low-risk research

This section allows a guardian, if authorised, to consent to the protected person participating in low-risk research if the research is approved by a human research ethics committee constituted in accordance with, and acting in compliance with, the *National Statement on Ethical Conduct in Human Research* (2007), as amended. This section works in conjunction with section 4, requiring the guardian to make the decision about approved low-risk research in accordance with the decision-making principles.

The note links section 33 to the Health Directions Act, because a guardian must also comply with health direction of the protected person.

The guardian may seek the assistance of the ACAT to make a decision about the protected person's participation in low-risk research (s 33(3)).

New section 34: Guardian may consent to principal's participation in medical research

This section provides the process for a guardian, if authorised to provide a consent required for a medical procedure or other treatment, to consider the protected person's participation in medical research.

This process involves a prerequisite, followed by two steps, one which is the responsibility of an independent doctor and the other which must be carried out by the guardian (who may seek assistance, including from the independent doctor).

The term 'independent doctor' is defined in section 36(3). Requiring the doctor to be independent of the research is intended to avoid criticisms which are made of other jurisdictions' regimes, where the assessing doctor may be the researcher or connected in some other way to the research and is therefore potentially susceptible to being influenced by the interests of the research project rather than the best interests of the protected person. A financial benefit is not referred to in this definition, as it is not the intention to prevent the doctor receiving a fee as the treating doctor, and accepting a fee to make a decision favourable to the payer amounts to conduct which is already prohibited under criminal laws and ethical codes of conduct.

The prerequisite to this process is that all medical research be approved by a human research ethics committee constituted in accordance with, and acting in compliance with, the *National Statement on Ethical Conduct in Human Research* (2007), as amended (see s 34(2)(a)).

Authorised by the ACT Parliamentary Counsel—also accessible at www.legislation.act.gov.au

Step one in section 34(2)(b) requires the independent doctor to assess the possibility of the protected person regaining capacity before the latest time that the protected person may meaningfully participate in the research. This is intended to:

(a) avoid the protected person being involved in research which is unnecessary, because the protected person is ultimately likely to regain capacity; and

(b) provide the protected person with the maximum possible time to regain capacity while accounting for the timeline of the research.

When making this assessment, the independent doctor must consider the factors in section 36, such as the severity of the protected person's condition and any other circumstances relevant to the protected person. This section is based on section 42R (2) of the *Guardianship and Administration Act 1986* (Vic).

After making the section 34(2) (b) assessment, the independent doctor must provide a written statement of belief with reasons (see s 36(2)). If the independent doctor believes the protected person is *not likely* to be capable of providing consent to participate in the research, the guardian may consider whether to consent to the protected person participating in accordance with section 34(2) (c). This section is based on section 72(2) of the *Guardianship and Administration Act 2000* (Qld) and is intended to provide the protected person the opportunity to participate in potentially beneficial research while being safeguarded against participating in inappropriate and potentially dangerous research.

Note 1 in section 34(2) (c) refers to the Health Directions Act, because a guardian must also comply with any health direction of the protected person. Note 2 links section 34 to section 4, requiring the enduring attorney to make the decision about medical research in accordance with the decision-making principles. In addition, section 34(3) inserts a presumption that the protected person wishes to continue participating in research that he or she was participating in before losing capacity.

Section 34(4) allows the guardian to seek the assistance of the ACAT when making a decision about the protected person's participation in medical research.

<u>New section 35: Guardian must not benefit from guardian's decision</u>

This section prohibits a guardian from receiving a benefit, directly or indirectly, as a result of making a decision about a medical research matter, or being involved in or connected to the research. This is intended to avoid the guardian being influenced in his or her decision by anything other than the wellbeing of the protected person. However, this section, recognising that the relationship between the protected person and the guardian may be personal, allows the guardian to receive a personal benefit resulting from the protected person's health improving as a result of participating in the research.

Authorised by the ACT Parliamentary Counsel—also accessible at www.legislation.act.gov.au

New section 36: Assessment of likelihood of principal regaining decision-making capacity

This section is discussed with section 34 above.

New section 37: Interested person may apply to ACAT for review of guardian's decision

This section allows an interested person to apply to the ACAT for a review of the guardian's decision about the protected person's participation in low-risk research or medical research.

For more information about the list of interested people, see the discussion about the PoA Act's new section 41G, above.

Clauses [1.25] and [1.26] – Section 65: Declaration about decision-making capacity

Clause [1.25] inserts 'medical research matter' into section 65(2) so that in addition to property matters, personal care matters and health care matters, the ACAT may make a declaration relating to medical research matters that a principal for an enduring power of attorney has decision-making capacity or impaired decision-making capacity.

Clause [1.26] refers to the definitions of 'health care matter', 'medical research matter', 'personal care matter' and 'property matter' in the PoA Act, importing them into the Guardianship Act.

Clauses [1.27] Section 69 (1) (a) Capacity to consent

Clause [1.27] amends section 69 to clarify that that this provision also applies to capacity to consent to medical research.

Clause [1.28] – New section 72D

This clause inserts new section 72D, which is based on section 87 of the PoA Act and provides that a doctor's certificate of capacity or incapacity about a person is evidence of that fact. It is intended that guardians and health attorneys relying on a doctor's certificate about a protected person's capacity or incapacity may rely on this section when making decisions about low-risk research and medical research.

Authorised by the ACT Parliamentary Counsel—also accessible at www.legislation.act.gov.au

Clause [1.29] – Dictionary, new definitions

This clause refers to the definitions of 'approved', 'low-risk research' and 'medical research' in the PoA Act, importing them into the Guardianship Act. For more information about these definitions, see the discussion about the PoA Act's new section 41A above.

Part 1.2 – Medical Treatment (Health Directions) Act 1991

Clause [1.30]

Section 18: Effect of health directions on later guardian or health attorney

This clause substitutes section 18 to require health attorneys, in addition to guardians, to make decisions regarding a protected person's medical treatment or participation in low-risk research in accordance with a health direction of the protected person.

The health attorney, however, must only comply with a health direction where it is reasonable to do so (s 18(3)). The examples indicate that it would not be reasonable to expect a health attorney to consider a health direction where an urgent decision is required, or where the attorney is unaware, after making reasonable enquiries, that a health direction exists.

It was not considered appropriate to apply this same caveat to the guardians' obligation to comply with a health direction. This is because health attorneys are asked to consent to medical treatments in relatively urgent circumstances. A guardian, on the other hand, is court-appointed, and so in most cases will be able to determine if the protected person has made a health direction before a decision must be made. Further, any risk associated with a health attorney not following a health direction is mitigated in part by the minor nature of a health attorney's decision (for example, low-risk research) and their decision is always subject to the decision of any decision-maker with more authority, such as a guardian or enduring attorney.

Clause [1.30] also refers to the definitions of 'low-risk research' and 'medical research' in the PoA Act, importing them into the Health Directions Act.

Section 19: Relationship between health directions and enduring powers of attorney

Clause [1.30] substitutes section 19 to require an enduring attorney to comply with a health direction of the principal, even where the health direction is made after the enduring power of attorney. However, because the principal is able to make directions about health matters in both documents, this may result in an inconsistency between the two documents. In that case, the enduring attorney must follow the direction in the most recent document.

The enduring attorney may apply to the ACAT for assistance to determine the consistency of the two documents (s 19(4)).

Authorised by the ACT Parliamentary Counsel—also accessible at www.legislation.act.gov.au

This clause also refers to the definitions of ‘attorney, ‘health care matter’, ‘medical research matter’ and ‘principal’ in the PoA Act, importing them into the Health Directions Act. For more information about these definitions, see the discussion about the PoA Act’s new section 41A above.

Authorised by the ACT Parliamentary Counsel—also accessible at www.legislation.act.gov.au