GUARDIANSHIP AND ADMINISTRATION AMENDMENT (MEDICAL RESEARCH) BILL 2020

EXPLANATORY MEMORANDUM

Overview of the Bill

The Guardianship and Administration Amendment (Medical Research) Bill 2020 amends the *Guardianship and Administration Act 1990* to provide the authorisation and appropriate safeguards to enable enduring guardians, guardians and next of kin to consent to medical research for people under legal incapacity.

Alternatively, where the situation is urgent and it is not practicable to obtain consent within an appropriate timeframe, the Guardianship and Administration Amendment (Medical Research) Bill 2020 permits a researcher to carry out research approved by a Human Research Ethics Committee (HREC) where an independent medical practitioner has determined that a person is incapable of making reasonable judgements about this for themselves; and where an independent medical practitioner has determined that the research is in the best interests of the person or not adverse to the interests of the person by increasing his or her medical risks.

1 Short Title
Clause 1 provides that the Bill, once enacted, will be known as the *Guardianship and Administration Amendment (Medical Research) Act 2020*.

2 Commencement
Clause 2 provides that Part 1 of the Act will come into operation on Royal Assent, and the rest of the Act will come into operation on the day after Royal Assent.

3 Act amended
Clause 3 provides that this Act amends the *Guardianship and Administration Act 1990*.

4 Section 3 amended

Subclause (1) deletes the definitions of treatment and treatment decision.

Subclause (2) inserts a number of definitions into section 3 of the *Guardianship and Administration Act 1990.*

Electroconvulsive therapy has the meaning given in the *Mental Health Act 2014* section 192.

Medical research is given the meaning set out in new section 3AA.

Personal information is defined in accordance with the definition in the *Freedom of Information Act 1992*, Glossary, clause 1.

Placebo means a substance not containing an active agent under study administered to some individuals to compare the effects of the active agent administered to other individuals.

Research candidate means an individual –

(a) whose participation is sought in medical research; or

(b) in respect of whom consent to participate in medical research has been given under Part 9E.

Research decision, in relation to a research candidate, means a decision to consent or refuse to consent to the candidate's participation in medical research.

Research decision-maker, for a research candidate, has the meaning given in new section 110ZP.

A new definition of **treatment** is inserted, and means medical or surgical treatment, including a life sustaining measure or palliative care; or dental treatment; or other health care; and in Parts 9B and 9E, includes medical research. If Parts 9B and 9E do not apply, then treatment does not include medical research.

A new definition of **treatment decision** is inserted, and means in relation to a person, a decision to consent or refuse consent to the commencement or continuation of any treatment of the person. In Part 9B, treatment decision includes a decision to consent or refuse consent to the commencement or continuation of the person's participation in medical research.

Subclause (3) adds that a decision made under new Part 9E Division 5, by the State Administrative Tribunal, is a **determination.**

5 Section 3AA inserted

Clause 5 inserts new section 3AA, which defines, for the purposes of the *Guardianship and Administration Act,* what medical research is and what medical research may include.

Medical research means research conducted with or about individuals, or their data or tissue, in the field of medicine or health; and includes an activity undertaken for the purposes of that research.

Subsection (2) sets out a list of types of research that constitute medical research but is not intended to be limited to this list. Subsection (2)(l) provides that any other types of medical research must be prescribed in regulations.

The types of medical research included in subsection (2) are modelled on the definition of *medical research procedure* in the *Medical Treatment Planning and Decisions Act 2016* (Vic) section 3(1).

Types of medical research in subsection (2) are:

(a) the administration of pharmaceuticals or placebos;

(b) the use of equipment or a device;
(c) health care that has not yet gained the support of a substantial number of practitioners in that field of health care;
(d) providing health care to which paragraph (c) does not apply to carry out a comparative assessment referred to in paragraph (e);
(e) carrying out a comparative assessment of the health care provided under paragraphs (c) and (d);
(f) taking samples from an individual, including taking a blood sample; or a sample of tissue or fluid from the body, including the mouth, throat, nasal cavity, eyes or ears;
(g) any non-intrusive examination including a visual examination of the mouth, throat, nasal cavity, eyes or ears; or the measuring of an individual's height, weight or vision;
(h) observing an individual;
(i) undertaking a survey, interview or focus group;
(j) collecting, using or disclosing information, including personal information;
(k) considering or evaluating samples or information taken under an activity listed in this subsection;
(l) any other activity prescribed by the regulations to be medical research.

Subsection (3) provides that medical research does not include research conducted about individuals, or their data or tissue, in the field of medicine or health that only involves analysing data about the individuals; and does not result in the disclosure or publication of personal information; and does not include any other activity prescribed by the regulations not to be medical research.

6 Section 13 amended

Clause 6 amends section 13 to expand the jurisdiction of the State Administrative Tribunal to ensure that the Tribunal has jurisdiction over matters in the new Part 9E.

7 Section 45 amended

Clause 7 inserts a new function that a plenary guardian may have under section 45 of the *Guardianship and Administration Act*.

The effect of new subsection (2)(i) is that a represented person's plenary guardian may make a research decision in relation to the represented person, if they are a research decision-maker.

The function of being a research decision-maker is subject to sections 110ZR and 110ZT, as well as section 45(4A)(a) as inserted by this Bill.

This means that all of the conditions set out in new section 110ZR must be met. These conditions govern how a person may be approved to be a research candidate with consent of a research decision-maker (see clause 12).

It also means that a plenary guardian who is a research decision-maker is bound by new section 110ZT; that is, they cannot provide consent to medical research for the purpose of sterilisation of the represented person (see clause 12).

In subsection (4A), new paragraph (a) is inserted to make it clear that a plenary guardian cannot consent to the sterilisation of the represented person for the purpose of medical research, or to electroconvulsive therapy being performed on the research candidate.

Subsection (4A)(b) makes clear that a plenary guardian cannot consent to the sterilisation of the represented person for any other purposes, except in accordance with Division 3.

8 Section 51 amended

Section 51 currently sets out that a guardian is to act in the best interests of a represented person.

Section 51, subsection (1) is amended to replace the term 'shall' with the term 'must', and to replace 'his' opinion with 'the guardian's' opinion.

'Must' replaces 'shall' in order to strengthen the obligation of the guardian to act in the best interests of the represented person, subject to any direction of the State Administrative Tribunal.

The term 'the guardian' replaces 'his' in order to replace outdated gendered language.

In subsection (2), gendered language is also replaced with gender-neutral terms.

New subsection (2A) is inserted under section 51, to provide that a guardian acts in the best interests of a represented person in making a research decision if the guardian acts in accordance with sections 110ZR and 110ZT.

[New section 110ZR, which is provided in clause 12, sets out how a research decision-maker may make a research decision in relation to the candidate's participation in the medial research].

9 Section 55A amended

New subsection (1A) is inserted into section 55A to provide that where a guardianship order relates to making a research decision in relation to a represented person, the appointed guardian must make the decision about medical research only where the guardian is the research decision-maker.

10 Section 110G amended

Section 110G sets out the general functions of an enduring guardian. Clause 10 adds further limitations on an enduring guardian's function to the existing limitations under subsection (1).

These added limitations are the functions under new sections 110ZR and 110ZT.

[New section 110ZR, which is provided in clause 12, sets out how a research decision-maker may make a research decision in relation to the candidate's participation in the medial research.]

[New section 110ZT provides that a research decision-maker cannot consent to medical research for the purpose of sterilisation of the represented person or for electroconvulsive therapy to be performed on the candidate (see clause 12).]

11 Section 110I amended

New subsection (1A) is inserted into section 110I to provide that to the extent an enduring power of guardianship relates to the making of a research decision in relation to the appointor, the power may only be exercised by the enduring guardian if the enduring guardian is the research decision-maker for the appointor.

12 Part 9E inserted

Clause 12 inserts new Part 9E - Medical research, after section 110ZN.

Division 1 – Preliminary

New section 110ZO introduces a number of terms used in new Part 9E.

Health Minister means the minister administering the *Health Services Act 2016*.

HREC means a human research ethics committee established in accordance with the National Statement.

Independent medical practitioner is defined in relation to medical research, and means a medical practitioner who:

(a) is not involved in providing treatment under Part 9E to the research candidate whose participation is sought in the research; and
(b) is not involved in, or connected to, the research, other than having a professional interest in the area of the research; and
(c) is not the spouse, de facto partner, parent, grandparent, sibling, child or grandchild of the research candidate whose participation is sought in the medical research; and
(d) is not a member of the HREC that approved the research.

Lead researcher, in relation to medical research, means a medical practitioner who has sole or joint overall responsibility for conducting the research.

Medical practitioner means a person registered under the *Health Practitioner Regulation National Law (WA)* in the medical profession (other than a student).

National Statement means the National Statement on Ethical Conduct in Human Research (2007), as modified or replaced from time to time, issued under the *National Health and Medical Research Council Act 1992* (Cth) section 7(1)(a).

Researcher means a lead researcher or an individual who conducts, or assists with the conduct of, medical research.

Review application means an application for review made under section 110ZZ.

Reviewed decision means a decision made under this Part that is the subject of a review application.

Urgent medical research decision means a decision to conduct medical research under section 110ZS(1).

New section 110ZP

New section 110ZP sets out who is a research decision-maker for a research candidate, by providing a hierarchy of relationships or roles between a person and a research candidate.

Subsection (1) provides that a person is a research decision-maker if a research candidate is unable to make reasonable judgments in respect of their participation in medical research. It then sets out that priority will be given to the person first in the order of priority set out in the following subsections. If there is no one who fulfils the criteria set out under the first priority, then a person who fulfils the criteria set out under next level of priority will be considered, and so on. This cascading hierarchy is set out in subsections (2) to (4).

Subsection (2) sets out that that if the research candidate has an enduring guardian, and the enduring guardian is authorised to make a research decision for the candidate, and the enduring guardian is reasonably available and willing to make a research decision for the candidate, that the enduring guardian will be the research decision-maker.

Subsection (3) operates if subsection (2) is not satisfied, and sets out that if the research candidate has a guardian, who is authorised to make a research decision for the candidate, and the guardian is reasonably available and willing to make a research decision for the candidate, that the guardian will be the research decision-maker.

Subsection (4) would operate where neither subsections (2) or (3) apply nor there is a substitute decision-maker. New section 110ZQ sets out who is a substitute decision-maker.

Subsection (5) sets out who will make a research decision in the event that there are two or more research decision-makers for a research candidate (of the same level of priority).

Paragraph (a) states that if there are two or more research decision-makers, they will be joint research decision-makers for the candidate.

Paragraph (b) states that if the two or more research decision-makers cannot agree on the research decision about the research candidate's participation in the medical research, then the person who is next in order of priority under section 110ZP will be the research decision-maker.

New section 110ZQ

This section sets out what is referred to in section 110ZP(4) as a substitute decision-maker for a research candidate, and the order of priority that will be applied in determining who is a substitute decision-maker.

Subsection (1) states that a person must be of full legal capacity, be reasonably available and be willing to make a research decision in relation to a research candidate in order to be a substitute decision-maker. They must also be the first in order of priority of the persons listed in subsection (2).

Subsection (2)(a) provides that the research candidate's spouse or de facto partner will be given the highest priority to fulfil the role of substitute decision-maker, provided that they are an adult and are either living with the research candidate or they maintain a close personal relationship with the candidate.

Subsection (2)(b) provides that 1) a child; 2) a parent; 3) a sibling (in that order), will be a substitute decision-maker, provided that the person is an adult and maintains a close personal relationship with the research candidate.

Subsection (2)(c) provides that next priority will be given to a primary provider of care and support (including emotional support) to the research candidate, provided that this person is not remunerated for providing that care and support. This person must also be an adult. Subsection (4) later clarifies that receiving a carer payment or other benefit from the Commonwealth or a State or Territory for providing home care for the candidate does not constitute remuneration for purposes of subsection (2)(c).

Subsection (2)(d) provides that next priority is given to any other person who maintains a close personal relationship to the research candidate. The person must be an adult.

Subsection (3) defines how a 'close personal relationship' is demonstrated for purposes of subsection (2)(a)(ii), (b) and (d)(ii). It is demonstrated by the person having frequent contact of a personal nature with the research candidate and by taking a genuine interest in the welfare of the candidate. A business or professional relationship will not be deemed to be a 'close personal relationship'.

Subsection (5) provides that where there may be two or more persons who are substitute decision-makers of the same level of priority, they will be deemed joint substitute decision-makers for the candidate. However, if the persons cannot agree on the research decision, the person next in priority under section 110ZQ will be the substitute decision-maker.

Division 2 – Decisions about medical research

Division 2 sets out how decisions about a research candidate's participation in medical research are made, including what must be taken into account and what procedures must be followed. The Division sets out two circumstances involving decisions about whether a research candidate should participate in medical research:

- medical research with consent of a research decision-maker; and
- urgent medical research without consent.

Division 2 also provides that a research decision-maker is not authorised to make a decision about a research candidate's participation in medical research for the purposes of sterilisation or electroconvulsive therapy.

New section 110ZR

New section 110ZR authorises a research decision-maker to make a research decision for a research candidate in relation to a candidate's participation in medical research, provided certain conditions are satisfied.

Subsection (1) sets out the preconditions required before a research decision-maker can consider giving this consent. These are:

(a) the medical research has been approved by an HREC; and
(b) a research candidate is unable to make reasonable judgments in respect of their participation in the medical research; and
(c) in an independent medical practitioner's opinion, subject to section 110ZV, the research candidate is not likely to be able to make such judgments within the timeframe approved by the HREC.

Subsection (2) provides that a research decision-maker must not provide consent for a research candidate's participation in the medical research unless the research decision-maker:

- receives the determination of an independent medical practitioner about whether the research candidate's participation will be in the best interests of the candidate or not adverse to the interests of the candidate;
- determines, having regard to the assessment of an independent medical practitioner, that the candidate's participation will be in the candidate's best interests or will not be adverse to the candidate's interests; and
- determines, having regard to the independent medical practitioner's determination that either the candidate's participation:
    - will only involve observing the candidate, or carrying out a non-invasive examination, treatment or procedure; or
    - will not involve any known substantial risks to the candidate; or
    - where there is an existing treatment, the medical research will not involve any known substantial risks to the candidate greater than the risks associated with the treatment; or
    - will not involve substantial risks to the candidate greater than if the candidate did not participate in the research.

Subsection (3) sets out that an independent medical practitioner must determine whether the research candidate's participation is in the best interests of the candidate or will not be adverse to the interests of the candidate. An independent medical practitioner must also determine the matters in subsection (2)(c), in accordance with section 110ZW.

[Section 110ZW sets out that this means that an independent medical practitioner must take into account whether the candidate's participation in the medical research will involve any known substantial risks to the candidate and whether there is an existing treatment available to the candidate. If there is an existing treatment available to the candidate, the independent medical practitioner must determine whether there are substantial risks to the candidate involved with the existing treatment, and if there are substantial risks, whether those risks are greater than the risks involved in participating in the medical research. If there is no existing treatment available, the independent medical practitioner must determine whether the risks involved in participating in the research are greater than not participating in the research. The independent medical practitioner must inform the research decision-maker or the researcher of his or her determination of these matters, and his or her reasons for this determination before the medical research commences in writing (if practicable). If this is not practicable, then orally prior to the medical research commencing. If this is not practicable, then in writing after the medical research commences.]

Subsection (4) provides that a research decision maker cannot make a research decision to consent to the candidate's participation in the proposed research where participation would be inconsistent with any advance health directive in operation in respect of the candidate.

Subsection (5) is intended to make clear that a research decision made by a research decision-maker under section 110ZR has the effect of providing consent to participate in the medical research as if the decision had been made by the research candidate and as if the research candidate were of full legal capacity.

Subsection (6) enables a research decision-maker to revoke consent for a research candidate that the research decision-maker had previously provided consent for.

Subsection (7) provides that if the research candidate regains the ability to make reasonable judgments about his or her participation in medical research, or if a research decision-maker revokes consent for the candidate's participation, then the previous decision to participate ceases to have effect. The lead researcher must ensure that the research is discontinued as soon as is practicable. The medical research cannot be recommenced unless a new research decision is made. This will be by the candidate themselves, in the case that he or she regained the ability to make a research decision. In the case that a research decision-maker had revoked consent, this decision to recommence could be provided by the research decision-maker.

New section 110ZS

New section 110ZS authorises urgent medical research without consent of a research decision-maker in certain limited circumstances.

Subsection (1), paragraphs (a) to (i) list the nine criteria that must all be satisfied in order for medical research to be conducted in relation to the candidate in the absence of a research decision by a research decision-maker.

These criteria include five specific circumstances that must occur, and four safeguard measures designed to ensure high ethical standards and protection of the research candidate's rights.

The specific circumstances that must all occur in order for urgent medical research to be considered without consent are:

Paragraph (b) – a research candidate requires urgent treatment as defined in section 110ZH.

Paragraph (c) – the research candidate is unable to make reasonable judgments in respect of their participation in the medical research.

Paragraph (d) – there is no research decision in relation to the candidate in respect of their participation in the research.

Paragraph (e) – it is not practicable for the researcher to obtain a research decision in relation to the candidate from the research decision-maker for the candidate.

Paragraph (f) – it is unlikely that it will be practicable for the researcher to obtain a research decision from the research decision-maker within the timeframe approved by the HREC.

The safeguards that must all be complied with for urgent medical research to be conducted are:

Paragraph (a) – the medical research has been approved by an HREC.

Paragraph (g) – the researcher receives an independent medical practitioner's determination (in accordance with section 110ZV) that the candidate is not likely to be able to make reasonable judgments about participation in the research within the timeframe for the research as set out by the HREC.

Paragraph (h) – the researcher receives an independent medical practitioner's determination that the candidate's participation is in the best interests of the candidate or is not adverse to the interests of the candidate.

Paragraph (i) – the researcher receives an independent medical practitioner's determination that the candidate's participation will only involve observing the candidate, or carrying out a non-invasive examination, treatment or procedure; or will not involve any known substantial risks to the candidate; or where there is an existing treatment, the medical research will not involve any known substantial risks to the candidate greater than the risks associated with the treatment; or will not involve substantial risks to the candidate greater than if the candidate did not participate in the research.

Subsection (2) provides that a researcher must not conduct medical research in respect of the candidate in accordance with an urgent medical research decision if the researcher is aware, or ought reasonably be aware, the research is inconsistent with any advance health directive in operation in respect of the candidate.

Subsection (3) provides an obligation for the lead researcher to continue to take reasonable steps throughout the duration of the medical research to obtain a research decision under section 110ZR in relation to the research candidate's participation in the research, from the research decision-maker.

Subsection (4) provides that subsection (5) will apply if a researcher conducts medical research in relation to a research candidate in accordance with an urgent medical research decision, and either the candidate regains the ability to make reasonable judgments in respect of medical research, or the research decision-maker makes a decision to refuse consent for the candidate's participation under section 110ZR.

Subsection (5) states that under these two circumstances (in subsection (4)) the lead researcher must ensure the research is discontinued as soon as is safely practicable and is not recommenced unless the the research candidate or research decision-maker consents to continue in the research.

New section 110ZT

The substance of section 110ZT, subsections (2) and (3) is that under no circumstances can consent be given for a research candidate to participate in medical research that is a procedure for sterilisation of the research candidate or for electroconvulsive therapy to be performed on the candidate.

Subsection (3) provides that a contravention of subsections (1) and (2) will be an offence punishable by imprisonment for 2 years or a fine of $10 000.

Division 3 – Provisions about research decisions and urgent medical research decisions

Division 3 sets out the role of an independent medical practitioner in providing a safeguard in decisions made about a research candidate's participation in medical research.

New section 110ZU

This section sets out what an independent medical practitioner must assess if required to make an assessment of a research candidate's best interests in relation to carrying out medical research with consent of a research decision-maker, or medical research without consent.

Subsection (1) provides that the paramount consideration in determining best interests is the wishes of the research candidate, to the extent they can be ascertained. The independent medical practitioner must also take into account the likely effects of the candidate's participation, including the existence, likelihood and severity of any potential risks to the candidate, and whether those risks are justified by any likely

benefits of the research to the candidate or to the broader community. The independent medical practitioner must consider any consequences for the candidate if the candidate was not to participate in the research, and whether there are any alternative treatments available to the candidate. Subsection (1) also provides that the independent medical practitioner will be required to consider any other prescribed matters.

Subsection (2) relates to the giving of placebos. It provides that where the medical research may involve the giving of placebos, this does not prevent the independent medical practitioner or a research decision-maker from being satisfied that participation in the research is in the candidate's best interests, or is not adverse to the interests of the research candidate.

Subsection (3) sets out that an independent medical practitioner must inform a research decision-maker, or researcher, of his or her determination of the matters in section 110ZU, and his or her reasons for the determination. These reasons must be set out in writing before the medical research commences, if practicable, or if this is not practicable, orally before the research commences. If the determination is made orally, the determination and reasons must be provided in writing after the medical research commences.

New section 110ZV

This section sets out what an independent medical practitioner must consider when required to make a determination about whether a person is likely to regain the ability to make reasonable judgments within the timeframe for the research approved by the HREC. This determination is used to inform medical research with consent of a research decision-maker, or medical research without consent.

Subsection (1) provides that an independent medical practitioner must take into account the research candidate's medical, mental and physical condition; the severity of the candidate's condition and the prognosis for the candidate; the current stage of treatment and care required for the candidate; and any other circumstances relevant to the research candidate. The independent medical practitioner must also take into account the nature of, and timeframe approved by the HREC for the proposed medical research.

Subsection (2) provides that an independent medical practitioner must inform a research decision-maker, or researcher, of his or her determination of the matters in section 110ZV, and his or her reasons for the determination in writing before the research commences, if practicable, or if this is not practicable, orally before the research commences. If the determination is made orally, the determination and reasons must be provided in writing after the medical research commences.

New section 110ZW

This section sets out what an independent medical practitioner must assess if required to make a determination about risks to the research candidate if the research candidate participates in the medical research, in relation to carrying out medical

research with consent of a research decision-maker, or medical research without consent.

Subsection (1) provides that an independent medical practitioner must make a determination about whether the candidate's participation in the medical research will involve any known substantial risks to the candidate and whether there is an existing treatment available to the candidate.

If there is an existing treatment available to the candidate, the independent medical practitioner must determine whether there are substantial risks to the candidate involved with the existing treatment, and if there are substantial risks, whether those risks are greater than the risks involved in participating in the medical research.

If there is no existing treatment available, the independent medical practitioner must determine whether the risks involved in participating in the research are greater than not participating in the research.

Subsection (2) provides that the independent medical practitioner must inform the research decision-maker or the researcher of his or her determination of these matters, and his or her reasons for this determination before the medical research commences in writing (if practicable). If the determination is made orally, the determination and reasons must be provided in writing after the medical research commences.

Division 4 – Effect of research decisions and urgent medical research decisions

Division 4 sets out provisions about what reliance a researcher may have on research decisions and urgent research decisions, and about the validity of certain research decisions and urgent research decisions.

New section 110ZX

The term **take research action** is introduced in this section and means to commence or continue any medical research in relation to a research candidate, or to not commence or to discontinue medical research in relation to a research candidate.

New subsections (2) and (4) together provide that:

- A researcher will be taken for all purposes to take research action in accordance with a research decision or urgent research decision, as if the decision were made by the research candidate; that the research action had the research candidate's consent; and the research candidate was of full legal capacity, where the researcher reasonably believed the candidate was unable to make reasonable judgments in respect of the research action, and the researcher has relied in good faith on the research decision made by the research decision-maker.

- A researcher will be taken for all purposes to take research action in accordance with a research decision, as if the decision were made by the research candidate; that the research action had the research candidate's

consent; and the research candidate was of full legal capacity, where the researcher has relied upon another researcher obtaining the research decision from a research decision-maker.

- A researcher will be taken for all purposes to take research action in accordance with an urgent research decision, as if the decision were made by the research candidate; that the research action had the research candidate's consent; and the research candidate was of full legal capacity, where the researcher has relied in good faith on what is an urgent medical research decision.

- A researcher will be taken for all purposes to take research action in accordance with an urgent research decision, as if the decision were made by the research candidate; that the research action had the research candidate's consent; and the research candidate was of full legal capacity, where the researcher has relied upon another researcher ascertaining that the research action is in accordance with an urgent medical research decision.

Subsection (5) explains that a researcher is taken to have acted in 'good faith' for purposes of relying on a research decision or an urgent medical research decision if, after considering whether or not to rely on it, the researcher acted honestly in relying on it.

Subsection (6) provides that whether or not an assumption made by a researcher that another researcher had ascertained the research action was in accordance with a research decision or an urgent research decision, is a reasonable assumption, will be determined by whether the researcher sighted written evidence that another researcher had ascertained that a research decision was made in accordance with a research decision or an urgent research decision, or anything else relevant to the determination.

New section 110ZY

Subsection (1) provides that if a researcher does not carry out medical research in relation to a research candidate, in accordance with a research decision or urgent research decision, and the result is such that the candidate's condition worsens in severity or worsens the prognosis for the candidate, the researcher is take to have acted in accordance with a valid decision.

Subsection (2) provides that a researcher will not have acted in accordance with a valid decision where the action in inconsistent with:

- Section 110ZR(4) or (7)(b) or 110ZS(2) or (5); or
- Section 110ZT; or
- Any decision made under Division 5, which is a decision made by the State Administrative Tribunal.

Division 5 – Jurisdiction of State Administrative Tribunal

Division 5 sets out the jurisdiction of the State Administrative Tribunal over matters in new Part 9E of the *Guardianship and Administration Act 1990*.

New section 110ZZ

This section provides that if the State Administrative Tribunal is of the opinion that a person has an interest in a decision made under Part 9E, the person may apply to the State Administrative Tribunal for a review of a decision.

New section 110ZZA

This section provides that the review process will engage the various powers of the State Administrative Tribunal contained in the *State Administrative Tribunal Act 2004*, and will not engage some parts of the *State Administrative Tribunal Act 2004,* including section 20; subject to subsection (4) — sections 21, 22 and 23; sections 26(e) and 31; section 29(3)(c)(ii); section 29(5)(b).

The State Administrative Tribunal may review a decision about whether research is in the best interests of a candidate, or whether a candidate is able to make reasonable judgments about undertaking the research. If the Tribunal considers that a review is warranted, it may effectively set aside a decision made by a research decision-maker or a researcher.

The effect of subsection (3) is that an interested person who makes a review application may request the independent medical practitioner's written reports under Division 3 made in relation to the reviewed decision from the research decision-maker or researcher who made the reviewed decision; or the independent medical practitioner who made the report.

The effect of subsection (4) is that if the person who is requested to provide the written reports fails to provide the written reports requested under subsection (3), the interested person can apply to the Tribunal for an order that the written records are provided to the interested person.

New section 110ZZB

Subsection (1) provides that a decision of the State Administrative Tribunal takes effect on the day that the decision is made, therefore any decision will only have prospective effect.

Subsection (2) provides that where the State Administrative Tribunal sets aside a decision, it will not affect the validity of anything done by a researcher in reliance upon the decision prior to the Tribunal's decision.

This protects the researcher acting upon the basis of a research decision, however allows the prospect of the Tribunal intervening to correct research decisions.

Division 6 – Reporting

Division 6 sets out a requirement for researchers to report medical research conducted under new Part 9E of the *Guardianship and Administration Act 1990* to the Health Minister, and for the Health Minister to report to Parliament on medical research carried out under new Part 9E.

New section 110ZZC

This section sets out the requirement for researchers to report to the Health Minister. A written notice must be in an approved written form, stating that the researcher is conducting medical research in relation to the research candidate, and whether the research is medical research with consent of a research decision-maker or urgent medical research without consent. It must also set out the type of medical research being conducted, the purpose of the medical research, and any other information required by the approved form.

New section 110ZZD

This section sets out the requirement for the Health Minister to report to Parliament on medical research carried out under new Part 9E.

It provides that the Health Minister must report annually to Parliament. The report must contain information on the number of research candidates who have participated in medical research under Part 9E; whether the medical research is medical research with consent of a research decision-maker or urgent medical research without consent; the type of medical research the researcher is conducting in relation to the candidate; the purpose of the medical research; and any other matter relating to the operation of Part 9E that the Health Minister considers appropriate.

Lastly, the report to Parliament may contain statistics or other general information derived from written notices to the Health Minister from researchers made under section 110ZZC, but must not contain personal information.

Division 7 – Reviews

Division 7 contains a review clause (new section 110ZZE) that provides that the operation and effectiveness of Part 9E must be reviewed as soon as practicable after one year from the date that Part 9E comes into operation. After the first one-year review, the operation and effectiveness of Part 9E must be reviewed every three years.

It is also provided that the Minister must table the report before each House of Parliament as soon as practicable after the report is prepared, but the report cannot be tabled later than 12 months after the initial one year period, or than the three-year periods thereafter.

13 Section 119 amended

Clause 13 is a minor amendment replacing subsection (1) to add medical research as a matter not included under section 119.