Western Australia

Guardianship and Administration Amendment (Medical Research) Act 2020

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Contents

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No. 14 of 2020

An Act to amend the *Guardianship and Administration Act 1990*.

[Assented to 6 April 2020]

The Parliament of Western Australia enacts as follows:

1. Short title

This is the *Guardianship and Administration Amendment (Medical Research) Act 2020*.

2. Commencement

This Act comes into operation as follows —

(a) sections 1 and 2 — on the day on which this Act receives the Royal Assent (***assent day***);

(b) sections 13 and 15 — on the day after the period of 4 years beginning on the day after assent day;

(c) the rest of the Act — on the day after assent day.

3. Act amended

This Act amends the *Guardianship and Administration Act 1990*.

4. Section 3 amended

(1) In section 3(1) delete the definitions of:

treatment

treatment decision

(2) In section 3(1) insert in alphabetical order:

electroconvulsive therapy has the meaning given in the *Mental Health Act 2014* section 192;

medical research has the meaning given in section 3AA;

personal information has the meaning given 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 medical research is conducted under Part 9E;

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

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

treatment —

(a) means —

(i) medical or surgical treatment, including a life sustaining measure or palliative care; or

(ii) dental treatment; or

(iii) other health care;

and

(b) in Parts 9B and 9E — includes medical research; and

(c) if paragraph (b) does not apply — does not include medical research;

treatment decision, in relation to a person —

(a) means a decision to consent or refuse consent to the commencement or continuation of any treatment of the person; and

(b) in Part 9B — includes a decision to consent or refuse consent to the commencement or continuation of the person's participation in medical research.

(3) In section 3(1) in the definition of ***determination***:

(a) in paragraph (g) delete "declaration; and" and insert:

declaration; or

(b) in paragraph (h) delete "112(4);" and insert:

112(4); or

(c) after paragraph (h) insert:

(i) a decision made under Part 9E Division 5;

(d) after each of paragraphs (a) to (f) insert:

or

5. Section 3AA inserted

After section 3 insert:

3AA. Term used: medical research

(1) For the purposes of this Act, ***medical research*** —

(a) means research conducted with or about individuals, or their data or tissue, in the field of medicine or health; and

(b) includes an activity undertaken for the purposes of that research.

(2) Without limiting subsection (1), ***medical research*** includes the following —

(a) the administration of pharmaceuticals or placebos;

(b) the use of equipment or a device;

(c) providing 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 —

(i) a blood sample; or

(ii) a sample of tissue or fluid from the body, including the mouth, throat, nasal cavity, eyes or ears;

(g) any non-intrusive examination, including —

(i) a visual examination of the mouth, throat, nasal cavity, eyes or ears; or

(ii) 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.

(3) Despite subsections (1) and (2), ***medical research*** does not include —

(a) research conducted about individuals, or their data or tissue, in the field of medicine or health that —

(i) only involves analysing data about the individuals; and

(ii) does not result in the disclosure or publication of personal information;

and

(b) any other activity prescribed by the regulations not to be medical research.

6. Section 13 amended

In section 13:

(a) in paragraph (g) delete "administration." and insert:

administration; and

(b) after paragraph (g) insert:

(h) jurisdiction otherwise conferred on the Tribunal under this Act.

(c) after each of paragraphs (a) to (e) insert:

and

7. Section 45 amended

(1) In section 45(2):

(a) in paragraph (h) delete "person." and insert:

person;

(b) after paragraph (h) insert:

(i) if the plenary guardian is a research decision-maker for the represented person — subject to subsection (4A)(a) and sections 110ZR and 110ZT, make research decisions in relation to the represented person.

(2) Delete section 45(4A) and insert:

(4A) A plenary guardian —

(a) cannot consent, for the purposes of medical research, to —

(i) the sterilisation of the represented person; or

(ii) electroconvulsive therapy being performed on a research candidate;

and

(b) cannot consent to the sterilisation of the represented person for any other purposes, except in accordance with Division 3.

8. Section 51 amended

(1) In section 51(1) delete "shall act according to his" and insert:

must act according to the guardian's

(2) In section 51(2):

(a) delete "he" and insert:

the guardian

(b) in paragraph (c) delete "himself and of making reasonable judgments in respect of matters relating to his" and insert:

themself and of making reasonable judgments in respect of matters relating to their

(3) After section 51(2) insert:

(2A) Without limiting the generality of subsection (1), a guardian acts in the best interests of a represented person in making a research decision in relation to the represented person if the guardian acts in accordance with sections 110ZR and 110ZT.

(4) In section 51(3) delete "shall" and insert:

is to

9. Section 55A amended

After section 55A(1) insert:

(1A) To the extent a guardianship order relates to the making of a research decision in relation to the represented person, a guardian appointed under the order may make the decision only if the guardian is the research decision-maker for the person the subject of the guardianship order.

10. Section 110G amended

In section 110G(1) delete "section 45(3), (4A) and (4)," and insert:

sections 45(3), (4A) and (4), 110ZR and 110ZT,

11. Section 110I amended

After section 110I(1) insert:

(1A) To the extent an enduring power of guardianship relates to the making of a research decision in relation to the appointor, the power may be exercised only if the enduring guardian is the research decision-maker for the appointor.

12. Part 9E inserted

After section 110ZN insert:

Part 9E — Medical research

Division 1 — Preliminary

110ZO. Terms used

In this Part —

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, in relation to medical research, means a medical practitioner who —

(a) is not involved in providing treatment under this Part to the research candidate whose participation is sought in the research; and

(b) is not involved in, nor 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 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 (Western Australia)* in the medical profession (other than as 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* (Commonwealth) section 7(1)(a);

researcher means —

(a) a lead researcher; or

(b) 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).

110ZP. Term used: research decision-maker

(1) A person is a ***research decision-maker*** for a research candidate if —

(a) the candidate is unable to make reasonable judgments in respect of their participation in medical research; and

(b) the person is first in order of the following persons —

(i) a person to whom subsection (2) applies;

(ii) if there is no person to whom subsection (2) applies — a person to whom subsection (3) applies;

(iii) if there is no person to whom either subsection (2) or (3) applies — a person to whom subsection (4) applies.

(2) This subsection applies to a person who is —

(a) an enduring guardian for the research candidate; and

(b) authorised to make a research decision in relation to the candidate; and

(c) reasonably available; and

(d) willing to make a research decision in relation to the candidate.

(3) This subsection applies to a person who is —

(a) a guardian for the research candidate; and

(b) authorised to make a research decision in relation to the candidate; and

(c) reasonably available; and

(d) willing to make a research decision in relation to the candidate.

(4) This subsection applies to a person who is a substitute decision-maker for the research candidate under section 110ZQ.

(5) If there are 2 or more persons who are the research decision-makers for a research candidate under this section —

(a) the persons are jointly the research decision-maker for the candidate; and

(b) if the persons cannot agree on a research decision for the candidate — the person next in order of priority under this section is the research decision-maker for the candidate.

110ZQ. Substitute decision-maker for a research candidate

(1) For the purposes of section 110ZP(4), a person is a substitute decision-maker for a research candidate if the person is the first in order of the persons listed in subsection (2) who is —

(a) of full legal capacity; and

(b) reasonably available; and

(c) willing to make a research decision in relation to the candidate.

(2) For subsection (1), the persons are the following —

(a) the research candidate's spouse or de facto partner if that person —

(i) has reached 18 years of age; and

(ii) is living with the candidate or maintains a close personal relationship with the candidate;

(b) the person who is first in the following order of priority of relatives of the research candidate who has reached 18 years of age and maintains a close personal relationship with the candidate —

(i) a child;

(ii) a parent;

(iii) a sibling;

(c) the person who —

(i) has reached 18 years of age; and

(ii) is the primary provider of care and support (including emotional support) to the research candidate, but is not remunerated for providing that care and support;

(d) any other person who —

(i) has reached 18 years of age; and

(ii) maintains a close personal relationship with the research candidate.

(3) For subsection (2)(a)(ii), (b) and (d)(ii), a person maintains a close personal relationship with a research candidate only if the person —

(a) has frequent contact of a personal (as opposed to a business or professional) nature with the candidate; and

(b) takes a genuine interest in the candidate's welfare.

(4) For subsection (2)(c)(ii), a person is not remunerated for providing care and support to a research candidate only because the person receives a carer payment or other benefit from the Commonwealth or a State or Territory for providing home care for the candidate.

(5) If there are 2 or more persons who are the substitute decision-makers for a research candidate under this section —

(a) the persons are jointly the substitute decision-maker for the candidate; and

(b) if the persons cannot agree on a research decision for the candidate — the person next in order of priority under this section is the substitute decision-maker for the candidate.

Division 2 — Decisions about medical research

110ZR. Medical research with consent of research decision-maker

(1) The research decision-maker for a research candidate may make a research decision in relation to the candidate's participation in medical research if —

(a) the research has been approved by an HREC; and

(b) the candidate is unable to make reasonable judgments in relation to participating in the research; and

(c) an independent medical practitioner determines in accordance with section 110ZV that the candidate is not likely to be able to make reasonable judgments within the timeframe for the research approved by the HREC.

(2) The research decision-maker for a research candidate must not consent to the candidate's participation in medical research unless the research decision-maker —

(a) receives the determination of an independent medical practitioner under subsection (3); and

(b) determines, having regard to the independent medical practitioner's determination under subsection (3)(a), that the candidate's participation in the research is in the best interests of the candidate or is not adverse to the interests of the candidate; and

(c) determines, having regard to the independent medical practitioner's determination under subsection (3)(b), that the candidate's participation —

(i) will only involve observing the candidate or carrying out another

non-invasive examination, treatment or procedure; or

(ii) if subparagraph (i) does not apply — will not involve any known substantial risks to the candidate; or

(iii) if subparagraphs (i) and (ii) do not apply and there is an existing treatment available to the candidate — will not involve any known substantial risks to the candidate greater than the risks associated with that treatment; or

(iv) if subparagraphs (i) to (iii) do not apply — will not involve substantial risks to the candidate greater than if the candidate did not participate in the research.

(3) An independent medical practitioner must determine —

(a) whether the research candidate's participation will be in the best interests of the candidate or will not be adverse to the interests of the candidate in accordance with section 110ZU; and

(b) the matters stated in subsection (2)(c) in accordance with section 110ZW.

(4) A research decision-maker for a research candidate cannot make a research decision under this section to consent to the candidate's participation in the medical research if the participation is inconsistent with any advance health directive in operation in respect of the candidate.

(5) A research decision made under this section has effect as if —

(a) it were made by the research candidate or with the candidate's consent; and

(b) the research candidate were of full legal capacity.

(6) If a research decision-maker for a research candidate has made a research decision to consent to the candidate's participation in the medical research under subsection (1), a research decision-maker for the candidate may decide that, contrary to the research decision, the candidate will no longer participate in the research.

(7) If a research candidate regains the ability to make reasonable judgments in respect of medical research while the candidate participates in the research or a research decision-maker makes a decision under subsection (6) —

(a) the research decision made under subsection (1) ceases to have further effect; and

(b) the lead researcher in relation to the research must ensure that —

(i) the research is discontinued as soon as is safely practicable; and

(ii) the research is not recommenced unless a research decision is made by the candidate, or by the research decision-maker under subsection (1), to consent to continue to participate in the research.

110ZS. Urgent medical research without consent

(1) A researcher may conduct medical research in relation to a research candidate if —

(a) the research has been approved by an HREC; and

(b) the candidate requires urgent treatment as defined in section 110ZH; and

(c) the candidate is unable to make reasonable judgments in respect of their participation in the research; and

(d) there is no research decision in relation to the candidate in respect of their participation in the research; and

(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; and

(f) it is unlikely that it will be practicable for the researcher to obtain a research decision in relation to the candidate from the research decision-maker for the candidate within the timeframe for the research approved by the HREC; and

(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 in respect of their participation in the research within the timeframe for the research approved by the HREC; and

(h) the researcher receives an independent medical practitioner's determination in accordance with section 110ZU that the candidate's participation

is in the best interests of the candidate or is not adverse to the interests of the candidate; and

(i) the researcher receives an independent medical practitioner's determination in accordance with section 110ZW that the candidate's participation in the research —

(i) will only involve observing the candidate or carrying out another non-invasive examination, treatment or procedure; or

(ii) if subparagraph (i) does not apply — will not involve any known substantial risks to the candidate; or

(iii) if subparagraphs (i) and (ii) do not apply and there is an existing treatment available to the candidate — will not involve any known substantial risks to the candidate greater than the risks associated with that treatment; or

(iv) if subparagraphs (i) to (iii) do not apply — will not involve substantial risks to the candidate greater than if the candidate did not participate in the research.

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

(3) While a researcher conducts medical research in relation to a research candidate in accordance with an urgent medical research decision, the lead researcher in relation to the research must continue to take

reasonable steps to obtain a research decision under section 110ZR in relation to the research candidate from the research decision-maker for the candidate.

(4) Subsection (5) applies if —

(a) a researcher conducts medical research in relation to a research candidate in accordance with an urgent medical research decision; and

(b) either —

(i) the research candidate regains the ability to make reasonable judgments in respect of the medical research; or

(ii) a research decision-maker makes a research decision under section 110ZR to refuse consent to the candidate's participation in the research.

(5) The lead researcher in relation to the medical research must ensure that —

(a) the research is discontinued as soon as is safely practicable; and

(b) the research is not recommenced unless the research candidate or research decision-maker consents to continue to participate in the research.

110ZT. Particular medical research not permitted

(1) In this section —

procedure for the sterilisation has the meaning given in section 56.

(2) A research decision-maker for a research candidate cannot consent under this Part to —

(a) a procedure for the sterilisation of the candidate; or

(b) electroconvulsive therapy being performed on the candidate.

(3) A person must not, for the purposes of medical research, carry out or take part in —

(a) a procedure for the sterilisation of a research candidate; or

(b) electroconvulsive therapy being performed on a research candidate.

Penalty for this subsection: imprisonment for 2 years or a fine of $10 000.

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

110ZU. Assessment by independent medical practitioner of research candidate's best interests

(1) An independent medical practitioner must take into account the following in making a determination under section 110ZR(3)(a) or 110ZS(1)(h) —

(a) the wishes of the research candidate (to the extent they can be ascertained) as the paramount consideration;

(b) the likely effects of the research candidate's participation, including —

(i) the existence, likelihood and severity of any potential risks to the candidate; and

(ii) whether those risks are justified by any likely benefits of the research to the candidate or to the broader community;

(c) any consequences for the research candidate if they are not involved in the research;

(d) any alternative treatments available to the research candidate;

(e) any other prescribed matters.

(2) The fact that medical research may involve the giving of placebos does not prevent a research decision-maker or an independent medical practitioner from being satisfied that it is in the best interests of a research candidate or is not adverse to the interests of the candidate that they participate in the research.

(3) The independent medical practitioner must inform a research decision-maker or researcher of the practitioner's determination, and the reasons for the determination —

(a) if practicable before the medical research commences — in writing; or

(b) if paragraph (a) does not apply —

(i) orally before the medical research commences; and

(ii) in writing after the research candidate commences participation in the medical research.

110ZV. Assessment by independent medical practitioner of likelihood of research candidate regaining ability to consent

(1) An independent medical practitioner must take into account the following when making a determination under section 110ZR(1)(c) or 110ZS(1)(g) —

(a) the research candidate's medical, mental and physical condition;

(b) the severity of the research candidate's condition and the prognosis for the candidate;

(c) the current stage of treatment and care required for the research candidate;

(d) any other circumstances relevant to the research candidate;

(e) the nature of, and the timeframe approved by the HREC for, the medical research in which the research candidate is to participate.

(2) The independent medical practitioner must inform a research decision-maker or researcher of the practitioner's determination, and the reasons for the determination —

(a) if practicable before the medical research commences — in writing; or

(b) if paragraph (a) does not apply —

(i) orally before the medical research commences; and

(ii) in writing after the research candidate commences participation in the medical research.

110ZW. Assessment by independent medical practitioner of risks

(1) An independent medical practitioner must take into account the following in making a determination under section 110ZR(3)(b) or 110ZS(1)(i) —

(a) whether the research candidate's participation in medical research will involve any known substantial risks to the candidate;

(b) whether there is an existing treatment available to the research candidate;

(c) if there is an existing treatment available to the research candidate —

(i) whether there are substantial risks to the candidate involved in the existing treatment available to the candidate; and

(ii) if there are substantial risks involved in the existing treatment — whether those risks are greater than the risks involved in participating in the medical research;

(d) if there is no existing treatment available — whether the risks involved in participating in the medical research are greater than not participating in the research.

(2) The independent medical practitioner must inform the research decision-maker or researcher of the practitioner's determination, and the reasons for the determination —

(a) if practicable before the medical research commences — in writing; or

(b) if paragraph (a) does not apply —

(i) orally before the medical research commences; and

(ii) in writing after the research candidate commences participation in the medical research.

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

110ZX. Reliance by researcher on research decision or urgent medical research decision

(1) In this section —

take research action means —

(a) to commence or continue any medical research in relation to a research candidate; or

(b) to not commence or to discontinue any medical research in relation to a research candidate.

(2) This section applies if a researcher —

(a) takes research action —

(i) reasonably believing that a research candidate is unable to make reasonable judgments in respect of the research action; and

(ii) relying in good faith on what is purportedly a research decision made by the research decision-maker for the research candidate under section 110ZR;

or

(b) takes research action —

(i) in circumstances where it is reasonable for the researcher to rely on another researcher having ascertained whether the research action is in accordance with a research decision by the research decision-maker for the research candidate under section 110ZR; and

(ii) reasonably assuming that another researcher has ascertained that the research action is in accordance with a research decision by the research decision-maker for the research candidate under section 110ZR;

or

(c) takes research action —

(i) reasonably believing that the research candidate is unable to make reasonable judgments in respect of the research action; and

(ii) relying in good faith on what is purportedly an urgent medical research decision made by a researcher;

or

(d) takes research action —

(i) in circumstances where it is reasonable for the researcher to rely on another researcher having ascertained whether the research action is in accordance with an urgent medical research decision; and

(ii) reasonably assuming that another researcher has ascertained that the research action is in accordance with an urgent medical research decision.

(3) However, this section does not apply to the extent that a researcher takes research action inconsistent with —

(a) section 110ZR(4) or (7)(b) or 110ZS(2) or (5); or

(b) section 110ZT; or

(c) a decision made under Division 5.

(4) If this section applies, the researcher is taken for all purposes to take the research action in accordance with a research decision or urgent medical research decision that has effect as if —

(a) the decision were made by the research candidate; and

(b) the research action is taken with the research candidate's consent; and

(c) the research candidate were of full legal capacity.

(5) For the purposes of subsection (2)(a)(ii) and (c)(ii), a researcher is taken to have relied in good faith on what was purportedly a research decision or urgent medical research decision if, after considering whether or not to rely on it, the researcher acted honestly in relying on it.

(6) For the purposes of determining under subsection (2)(b)(ii) and (d)(ii) whether the researcher's assumption was reasonable, the following matters must be taken into account —

(a) whether the researcher sighted any written evidence that another researcher had ascertained that the research action was in accordance with a research decision or urgent medical research decision;

(b) anything else relevant to the determination.

110ZY. Validity of certain research decisions or urgent medical research decisions

(1) If a researcher does not commence or discontinues medical research in relation to a research candidate in accordance with a research decision or urgent medical research decision, the researcher is taken for all purposes to have done so in accordance with a valid decision, even if an effect of doing so is to worsen the severity of the candidate's condition or the prognosis for the candidate.

(2) However, subsection (1) does not apply to the extent that an act or omission of a researcher is inconsistent with —

(a) section 110ZR(4) or (7)(b) or 110ZS(2) or (5); or

(b) section 110ZT; or

(c) a decision made under Division 5.

Division 5 — Jurisdiction of State Administrative Tribunal

110ZZ. Applying for review of decision made under this Part

A person who, in the opinion of the State Administrative Tribunal, is interested in a decision made under this Part may apply for a review of a decision.

110ZZA. Procedure on review

(1) The following provisions of the *State Administrative Tribunal Act 2004* do not apply in relation to a review application —

(a) section 20;

(b) subject to subsection (4) — sections 21, 22 and 23;

(c) sections 26(e) and 31;

(d) section 29(3)(c)(ii);

(e) section 29(5)(b).

(2) For the purposes of the *State Administrative Tribunal Act 2004* section 26(c), a reviewed decision may be varied or ceased by the person making the decision.

(3) A person who makes a review application may request (a ***report request***) the independent medical practitioner's written reports under Division 3 made in relation to the reviewed decision from —

(a) the research decision-maker or researcher who made the reviewed decision; or

(b) the independent medical practitioner who made the report.

(4) The *State Administrative Tribunal Act 2004* sections 21(3) to (5), 22 and 23 apply to a report request as if —

(a) the report request were a request made under section 21(1) or 22(1) of that Act; and

(b) the person to whom the report request is made were the decision-maker.

110ZZB. Effect of State Administrative Tribunal's decision under this Division

(1) A decision of the State Administrative Tribunal on a review application takes effect on the day on which the Tribunal's decision is made.

(2) If the State Administrative Tribunal sets aside a reviewed decision, the Tribunal's decision does not affect the operation of sections 110ZX and 110ZY in relation to actions or omissions of a researcher before the day the Tribunal's decision takes effect under subsection (1).

Division 6 — Reporting

110ZZC. Researcher to report medical research conducted under this Part to Health Minister

If a researcher conducts medical research in relation to a research candidate under this Part, the researcher must give the Health Minister a written notice, in the form approved by the Health Minister, stating the following —

(a) that the researcher is conducting medical research in relation to the candidate;

(b) whether the medical research is carried out pursuant to —

(i) a research decision by the research decision-maker for the candidate under section 110ZR; or

(ii) an urgent medical research decision;

(c) the type of medical research the researcher is conducting in relation to the candidate;

(d) the purpose of the medical research;

(e) any other information required by the approved form.

110ZZD. Health Minister to report to Parliament on medical research carried out under this Part

(1) The Health Minister must, as soon as practicable after each anniversary of the day on which the *Guardianship and Administration Amendment (Medical Research) Act 2020* section 12 comes into operation, report to Parliament on the following in relation to the year to which the report relates —

(a) the number of research candidates who have participated in medical research under this Part;

(b) whether the medical research is carried out pursuant to —

(i) a research decision by the research decision-maker for the candidate under section 110ZR; or

(ii) an urgent medical research decision;

(c) the type of medical research the researcher is conducting in relation to the candidate;

(d) the purpose of the medical research;

(e) any other matter relating to the operation of this Part that the Health Minister considers appropriate.

(2) The report under subsection (1) —

(a) may include statistics or other general information derived from a written notice the Health Minister receives under section 110ZZC; but

(b) must not include personal information.

Division 7 — Reviews

110ZZE. Review of this Part

(1) The Minister must review the operation and effectiveness of this Part and prepare a report based on the review —

(a) as soon as practicable after the 1st anniversary of the day on which the *Guardianship and Administration Amendment (Medical Research) Act 2020* section 12 comes into operation; and

(b) after that, at intervals of not more than 3 years.

(2) The Minister must cause the report to be laid before each House of Parliament as soon as practicable after it is prepared, but not later than 12 months after the 1st anniversary or the expiry of the period of 3 years, as the case may be.

13. Section 110ZS deleted

Delete section 110ZS.

14. Section 119 amended

Delete section 119(1) and insert:

(1) This section applies if a person is unable to make reasonable judgments in respect of a matter relating to their person other than —

(a) treatment proposed to be provided to the person; or

(b) medical research proposed to be conducted in relation to the person.

15. Schedule 5 Division 3 inserted

At the end of Schedule 5 insert:

Division 3 — Transitional provision in relation to *Guardianship and Administration Amendment (Medical Research) Act 2020*

8. Effect of repealed s. 110ZS on continuing urgent medical research after repeal day

(1) In this clause —

amending Act means the *Guardianship and Administration Amendment (Medical Research) Act 2020*;

continuing urgent medical research means medical research in relation to a research candidate that —

(a) commenced before repeal day pursuant to an urgent medical research decision; and

(b) continues on and after repeal day;

repeal day means the day on which section 13 of the amending Act comes into operation;

repealed section 110ZS means section 110ZS as repealed by section 13 of the amending Act;

urgent medical research decision means a decision before repeal day to conduct medical research in relation to a research candidate under repealed section 110ZS(1).

(2) Until continuing urgent medical research is completed in relation to a research candidate —

(a) the urgent medical research decision pursuant to which the research is conducted continues to have effect as if repealed section 110ZS were not repealed; and

(b) Part 9E and repealed section 110ZS continue to apply to the research and urgent medical research decision as if repealed section 110ZS were not repealed.

By Authority: KEVIN J. McRAE, Government Printer