

Guardianship and Administration Amendment (Medical Research) Bill 2020

Contents

1.	Short title	2
2.	Commencement	2
3.	Act amended	2
4.	Section 3 amended	2
5.	Section 3AA inserted	4
	3AA. Term used: medical research	4
6.	Section 13 amended	6
7.	Section 45 amended	7
8.	Section 51 amended	8
9.	Section 55A amended	9
10.	Section 110G amended	9
11.	Section 110I amended	9
12.	Part 9E inserted	10
	Part 9E — Medical research	
	Division 1 — Preliminary	
	110ZO. Terms used	10
	110ZP. Term used: research decision-maker	11
	110ZQ. Substitute decision-maker for a research candidate	13
	Division 2 — Decisions about medical research	
	110ZR. Medical research with consent of research decision-maker	15
	110ZS. Urgent medical research without consent	18
	110ZT. Particular medical research not permitted	20
	Division 3 — Provisions about research decisions and urgent medical research decisions	
	110ZU. Assessment by independent medical practitioner of research candidate's best interests	21

Contents

	110ZV. Assessment by independent medical practitioner of likelihood of research candidate regaining ability to consent	22	
	110ZW. Assessment by independent medical practitioner of risks	23	
	Division 4 — Effect of research decisions and urgent medical research decisions		
	110ZX. Reliance by researcher on research decision or urgent medical research decision	24	
	110ZY. Validity of certain research decisions or urgent medical research decisions	27	
	Division 5 — Jurisdiction of State Administrative Tribunal		
	110ZZ. Applying for review of decision made under this Part	28	
	110ZZA. Procedure on review	28	
	110ZZB. Effect of State Administrative Tribunal under this Division	29	
	Division 6 — Reporting		
	110ZZC. Researcher to report medical research conducted under this Part to Health Minister	29	
	110ZZD. Health Minister to report to Parliament on medical research carried out under this Part	30	
	Division 7 — Reviews		
	110ZZE. Review of this Part	31	
13.	Section 119 amended		32

Western Australia

LEGISLATIVE ASSEMBLY

**Guardianship and Administration Amendment
(Medical Research) Bill 2020**

A Bill for

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

The Parliament of Western Australia enacts as follows:

s. 1

1 **1. Short title**

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

4 **2. Commencement**

5 This Act comes into operation as follows —

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

8 (b) the rest of the Act — on the day after that day.

9 **3. Act amended**

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

12 **4. Section 3 amended**

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

14 *treatment*

15 *treatment decision*

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

17
18 *electroconvulsive therapy* has the meaning given in the
19 *Mental Health Act 2014* section 192;

20 *medical research* has the meaning given in
21 section 3AA;

22 *personal information* has the meaning given in the
23 *Freedom of Information Act 1992* Glossary clause 1;

24 *placebo* means a substance not containing an active
25 agent under study administered to some individuals to
26 compare the effects of the active agent administered to
27 other individuals;

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31

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.

s. 5

- 1 (3) In section 3(1) in the definition of *determination*:
- 2 (a) in paragraph (g) delete “declaration; and” and insert:
- 3
- 4 declaration; or
- 5
- 6 (b) in paragraph (h) delete “112(4);” and insert:
- 7
- 8 112(4); or
- 9
- 10 (c) after paragraph (h) insert:
- 11
- 12 (i) a decision made under Part 9E Division 5;
- 13
- 14 (d) after each of paragraphs (a) to (f) insert:
- 15
- 16 or
- 17
- 18 **5. Section 3AA inserted**
- 19 After section 3 insert:
- 20
- 21 **3AA. Term used: medical research**
- 22 (1) For the purposes of this Act, *medical research* —
- 23 (a) means research conducted with or about
- 24 individuals, or their data or tissue, in the field
- 25 of medicine or health; and
- 26 (b) includes an activity undertaken for the purposes
- 27 of that research.
- 28 (2) Without limiting subsection (1), *medical research*
- 29 includes the following —
- 30 (a) the administration of pharmaceuticals or
- 31 placebos;

- 1 (b) the use of equipment or a device;
- 2 (c) providing health care that has not yet gained the
3 support of a substantial number of practitioners
4 in that field of health care;
- 5 (d) providing health care to which paragraph (c)
6 does not apply to carry out a comparative
7 assessment referred to in paragraph (e);
- 8 (e) carrying out a comparative assessment of the
9 health care provided under paragraphs (c)
10 and (d);
- 11 (f) taking samples from an individual, including —
12 (i) a blood sample; or
13 (ii) a sample of tissue or fluid from the
14 body, including the mouth, throat, nasal
15 cavity, eyes or ears;
- 16 (g) any non-intrusive examination, including —
17 (i) a visual examination of the mouth,
18 throat, nasal cavity, eyes or ears; or
19 (ii) the measuring of an individual's height,
20 weight or vision;
- 21 (h) observing an individual;
- 22 (i) undertaking a survey, interview or focus group;
- 23 (j) collecting, using or disclosing information,
24 including personal information;
- 25 (k) considering or evaluating samples or
26 information taken under an activity listed in this
27 subsection;
- 28 (l) any other activity prescribed by the regulations
29 to be medical research.

s. 6

- 1 (3) Despite subsections (1) and (2), *medical research* does
2 not include —
- 3 (a) research conducted about individuals, or their
4 data or tissue, in the field of medicine or health
5 that —
- 6 (i) only involves analysing data about the
7 individuals; and
- 8 (ii) does not result in the disclosure or
9 publication of personal information;
- 10 and
- 11 (b) any other activity prescribed by the regulations
12 not to be medical research.
13

14 **6. Section 13 amended**

15 In section 13:

- 16 (a) in paragraph (g) delete “administration.” and insert:
17
18 administration; and
- 19
- 20 (b) after paragraph (g) insert:
21
- 22 (h) jurisdiction otherwise conferred on the Tribunal
23 under this Act.
24
- 25 (c) after each of paragraphs (a) to (e) insert:
26
27 and
28

1 **7. Section 45 amended**

2 (1) In section 45(2):

3 (a) in paragraph (h) delete “person.” and insert:

4

5 person;

6

7 (b) after paragraph (h) insert:

8

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

14

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

16

17 (4A) A plenary guardian —

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

20 (i) the sterilisation of the represented
21 person; or

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

24 and

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

28

s. 8

1 **8. Section 51 amended**

2 (1) In section 51(1) delete “shall act according to his” and insert:

3

4 must act according to the guardian’s

5

6 (2) In section 51(2):

7 (a) delete “he” and insert:

8

9 the guardian

10

11 (b) in paragraph (c) delete “himself and of making
12 reasonable judgments in respect of matters relating to
13 his” and insert:

14

15 themselves and of making reasonable judgments in respect
16 of matters relating to their

17

18 (3) After section 51(2) insert:

19

20 (2A) Without limiting the generality of subsection (1), a
21 guardian acts in the best interests of a represented
22 person in making a research decision in relation to the
23 represented person if the guardian acts in accordance
24 with sections 110ZR and 110ZT.

25

26 (4) In section 51(3) delete “shall” and insert:

27

28 is to

29

1 **9. Section 55A amended**

2 After section 55A(1) insert:

3

4 (1A) To the extent a guardianship order relates to the
5 making of a research decision in relation to the
6 represented person, a guardian appointed under the
7 order may make the decision only if the guardian is the
8 research decision-maker for the person the subject of
9 the guardianship order.

10

11 **10. Section 110G amended**

12 In section 110G(1) delete “section 45(3), (4A) and (4),” and
13 insert:

14

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

16

17 **11. Section 110I amended**

18 After section 110I(1) insert:

19

20 (1A) To the extent an enduring power of guardianship
21 relates to the making of a research decision in relation
22 to the appointor, the power may be exercised only if
23 the enduring guardian is the research decision-maker
24 for the appointor.

25

s. 12

1 **12. Part 9E inserted**

2 After section 110ZN insert:

3

4 **Part 9E — Medical research**

5 **Division 1 — Preliminary**

6 **110ZO. Terms used**

7 In this Part —

8 ***Health Minister*** means the Minister administering the
9 *Health Services Act 2016*;

10 ***HREC*** means a human research ethics committee
11 established in accordance with the National Statement;

12 ***independent medical practitioner***, in relation to
13 medical research, means a medical practitioner who —

- 14 (a) is not involved in providing treatment under
15 this Part to the research candidate whose
16 participation is sought in the research; and
- 17 (b) is not involved in, nor connected to, the
18 research, other than having a professional
19 interest in the area of the research; and
- 20 (c) is not the spouse, de facto partner, parent,
21 grandparent, sibling, child or grandchild of the
22 research candidate whose participation is
23 sought in the research; and
- 24 (d) is not a member of the HREC that approved the
25 research;

26 ***lead researcher***, in relation to medical research, means
27 a medical practitioner who has sole or joint overall
28 responsibility for conducting the research;

1 **medical practitioner** means a person registered under
2 the *Health Practitioner Regulation National Law*
3 (*Western Australia*) in the medical profession (other
4 than as a student);

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

10 **researcher** means —

- 11 (a) a lead researcher; or
12 (b) an individual who conducts, or assists with the
13 conduct of, medical research;

14 **review application** means an application for review
15 made under section 110ZZ;

16 **reviewed decision** means a decision made under this
17 Part that is the subject of a review application;

18 **urgent medical research decision** means a decision to
19 conduct medical research under section 110ZS(1).

20 **110ZP. Term used: research decision-maker**

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

- 23 (a) the candidate is unable to make reasonable
24 judgments in respect of their participation in
25 medical research; and
26 (b) the person is first in order of the following
27 persons —

- 28 (i) a person to whom subsection (2)
29 applies;
30 (ii) if there is no person to whom
31 subsection (2) applies — a person to
32 whom subsection (3) applies;

s. 12

- 1 (iii) if there is no person to whom either
2 subsection (2) or (3) applies — a person
3 to whom subsection (4) applies.
- 4 (2) This subsection applies to a person who is —
5 (a) an enduring guardian for the research
6 candidate; and
7 (b) authorised to make a research decision in
8 relation to the candidate; and
9 (c) reasonably available; and
10 (d) willing to make a research decision in relation
11 to the candidate.
- 12 (3) This subsection applies to a person who is —
13 (a) a guardian for the research candidate; and
14 (b) authorised to make a research decision in
15 relation to the candidate; and
16 (c) reasonably available; and
17 (d) willing to make a research decision in relation
18 to the candidate.
- 19 (4) This subsection applies to a person who is a substitute
20 decision-maker for the research candidate under
21 section 110ZQ.
- 22 (5) If there are 2 or more persons who are the research
23 decision-makers for a research candidate under this
24 section —
25 (a) the persons are jointly the research
26 decision-maker for the candidate; and
27 (b) if the persons cannot agree on a research
28 decision for the candidate — the person next in
29 order of priority under this section is the
30 research decision-maker for the candidate.

1 **110ZQ. Substitute decision-maker for a research candidate**

- 2 (1) For the purposes of section 110ZP(4), a person is a
3 substitute decision-maker for a research candidate if
4 the person is the first in order of the persons listed in
5 subsection (2) who is —
6 (a) of full legal capacity; and
7 (b) reasonably available; and
8 (c) willing to make a research decision in relation
9 to the candidate.
- 10 (2) For subsection (1), the persons are the following —
11 (a) the research candidate's spouse or de facto
12 partner if that person —
13 (i) has reached 18 years of age; and
14 (ii) is living with the candidate or maintains
15 a close personal relationship with the
16 candidate;
17 (b) the person who is first in the following order of
18 priority of relatives of the research candidate
19 who has reached 18 years of age and maintains
20 a close personal relationship with the
21 candidate —
22 (i) a child;
23 (ii) a parent;
24 (iii) a sibling;
25 (c) the person who —
26 (i) has reached 18 years of age; and
27 (ii) is the primary provider of care and
28 support (including emotional support) to
29 the research candidate, but is not
30 remunerated for providing that care and
31 support;

s. 12

- 1 (d) any other person who —
2 (i) has reached 18 years of age; and
3 (ii) maintains a close personal relationship
4 with the research candidate.
- 5 (3) For subsection (2)(a)(ii), (b) and (d)(ii), a person
6 maintains a close personal relationship with a research
7 candidate only if the person —
8 (a) has frequent contact of a personal (as opposed
9 to a business or professional) nature with the
10 candidate; and
11 (b) takes a genuine interest in the candidate's
12 welfare.
- 13 (4) For subsection (2)(c)(ii), a person is not remunerated
14 for providing care and support to a research candidate
15 only because the person receives a carer payment or
16 other benefit from the Commonwealth or a State or
17 Territory for providing home care for the candidate.
- 18 (5) If there are 2 or more persons who are the substitute
19 decision-makers for a research candidate under this
20 section —
21 (a) the persons are jointly the substitute
22 decision-maker for the candidate; and
23 (b) if the persons cannot agree on a research
24 decision for the candidate — the person next in
25 order of priority under this section is the
26 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

s. 12

- 1 non-invasive examination, treatment or
2 procedure; or
- 3 (ii) if subparagraph (i) does not apply —
4 will not involve any known substantial
5 risks to the candidate; or
- 6 (iii) if subparagraphs (i) and (ii) do not apply
7 and there is an existing treatment
8 available to the candidate — will not
9 involve any known substantial risks to
10 the candidate greater than the risks
11 associated with that treatment; or
- 12 (iv) if subparagraphs (i) to (iii) do not
13 apply — will not involve substantial
14 risks to the candidate greater than if the
15 candidate did not participate in the
16 research.
- 17 (3) An independent medical practitioner must
18 determine —
- 19 (a) whether the research candidate’s participation
20 will be in the best interests of the candidate or
21 will not be adverse to the interests of the
22 candidate in accordance with section 110ZU;
23 and
- 24 (b) the matters stated in subsection (2)(c) in
25 accordance with section 110ZW.
- 26 (4) A research decision-maker for a research candidate
27 cannot make a research decision under this section to
28 consent to the candidate’s participation in the medical
29 research if the participation is inconsistent with any
30 advance health directive in operation in respect of the
31 candidate.

- 1 (5) A research decision made under this section has effect
2 as if —
- 3 (a) it were made by the research candidate or with
4 the candidate's consent; and
- 5 (b) the research candidate were of full legal
6 capacity.
- 7 (6) If a research decision-maker for a research candidate
8 has made a research decision to consent to the
9 candidate's participation in the medical research under
10 subsection (1), a research decision-maker for the
11 candidate may decide that, contrary to the research
12 decision, the candidate will no longer participate in the
13 research.
- 14 (7) If a research candidate regains the ability to make
15 reasonable judgments in respect of medical research
16 while the candidate participates in the research or a
17 research decision-maker makes a decision under
18 subsection (6) —
- 19 (a) the research decision made under subsection (1)
20 ceases to have further effect; and
- 21 (b) the lead researcher in relation to the research
22 must ensure that —
- 23 (i) the research is discontinued as soon as
24 is safely practicable; and
- 25 (ii) the research is not recommenced unless
26 a research decision is made by the
27 candidate, or by the research
28 decision-maker under subsection (1), to
29 consent to continue to participate in the
30 research.

s. 12

- 1 **110ZS. Urgent medical research without consent**
- 2 (1) A researcher may conduct medical research in relation
- 3 to a research candidate if —
- 4 (a) the research has been approved by an HREC;
- 5 and
- 6 (b) the candidate requires urgent treatment as
- 7 defined in section 110ZH; and
- 8 (c) the candidate is unable to make reasonable
- 9 judgments in respect of their participation in the
- 10 research; and
- 11 (d) there is no research decision in relation to the
- 12 candidate in respect of their participation in the
- 13 research; and
- 14 (e) it is not practicable for the researcher to obtain
- 15 a research decision in relation to the candidate
- 16 from the research decision-maker for the
- 17 candidate; and
- 18 (f) it is unlikely that it will be practicable for the
- 19 researcher to obtain a research decision in
- 20 relation to the candidate from the research
- 21 decision-maker for the candidate within the
- 22 timeframe for the research approved by the
- 23 HREC; and
- 24 (g) the researcher receives an independent medical
- 25 practitioner’s determination in accordance with
- 26 section 110ZV that the candidate is not likely to
- 27 be able to make reasonable judgments in
- 28 respect of their participation in the research
- 29 within the timeframe for the research approved
- 30 by the HREC; and
- 31 (h) the researcher receives an independent medical
- 32 practitioner’s determination in accordance with
- 33 section 110ZU that the candidate’s participation

-
- 1 is in the best interests of the candidate or is not
2 adverse to the interests of the candidate; and
- 3 (i) the researcher receives an independent medical
4 practitioner's determination in accordance with
5 section 110ZW that the candidate's
6 participation in the research —
- 7 (i) will only involve observing the
8 candidate or carrying out another
9 non-invasive examination, treatment or
10 procedure; or
- 11 (ii) if subparagraph (i) does not apply —
12 will not involve any known substantial
13 risks to the candidate; or
- 14 (iii) if subparagraphs (i) and (ii) do not apply
15 and there is an existing treatment
16 available to the candidate — will not
17 involve any known substantial risks to
18 the candidate greater than the risks
19 associated with that treatment; or
- 20 (iv) if subparagraphs (i) to (iii) do not
21 apply — will not involve substantial
22 risks to the candidate greater than if the
23 candidate did not participate in the
24 research.
- 25 (2) A researcher must not conduct medical research in
26 relation to a research candidate in accordance with an
27 urgent medical research decision if the researcher is
28 aware, or ought reasonably to be aware, the research is
29 inconsistent with any advance health directive in
30 operation in respect of the candidate.
- 31 (3) While a researcher conducts medical research in
32 relation to a research candidate in accordance with an
33 urgent medical research decision, the lead researcher in
34 relation to the research must continue to take

s. 12

- 1 reasonable steps to obtain a research decision under
2 section 110ZR in relation to the research candidate
3 from the research decision-maker for the candidate.
- 4 (4) Subsection (5) applies if —
- 5 (a) a researcher conducts medical research in
6 relation to a research candidate in accordance
7 with an urgent medical research decision; and
- 8 (b) either —
- 9 (i) the research candidate regains the
10 ability to make reasonable judgments in
11 respect of the medical research; or
- 12 (ii) a research decision-maker makes a
13 research decision under section 110ZR
14 to refuse consent to the candidate's
15 participation in the research.
- 16 (5) The lead researcher in relation to the medical research
17 must ensure that —
- 18 (a) the research is discontinued as soon as is safely
19 practicable; and
- 20 (b) the research is not recommenced unless the
21 research candidate or research decision-maker
22 consents to continue to participate in the
23 research.

24 **110ZT. Particular medical research not permitted**

- 25 (1) In this section —
- 26 *procedure for the sterilisation* has the meaning given
27 in section 56.
- 28 (2) A research decision-maker for a research candidate
29 cannot consent under this Part to —
- 30 (a) a procedure for the sterilisation of the
31 candidate; or

- 1 (b) electroconvulsive therapy being performed on
2 the candidate.
- 3 (3) A person must not, for the purposes of medical
4 research, carry out or take part in —
- 5 (a) a procedure for the sterilisation of a research
6 candidate; or
- 7 (b) electroconvulsive therapy being performed on a
8 research candidate.
- 9 Penalty for this subsection: imprisonment for 2 years or
10 a fine of \$10 000.

11 **Division 3 — Provisions about research decisions and**
12 **urgent medical research decisions**

13 **110ZU. Assessment by independent medical practitioner of**
14 **research candidate's best interests**

- 15 (1) An independent medical practitioner must take into
16 account the following in making a determination under
17 section 110ZR(3)(a) or 110ZS(1)(h) —
- 18 (a) the wishes of the research candidate (to the
19 extent they can be ascertained) as the
20 paramount consideration;
- 21 (b) the likely effects of the research candidate's
22 participation, including —
- 23 (i) the existence, likelihood and severity of
24 any potential risks to the candidate; and
- 25 (ii) whether those risks are justified by any
26 likely benefits of the research to the
27 candidate or to the broader community;
- 28 (c) any consequences for the research candidate if
29 they are not involved in the research;
- 30 (d) any alternative treatments available to the
31 research candidate;

s. 12

- 1 (e) any other prescribed matters.
- 2 (2) The fact that medical research may involve the giving
3 of placebos does not prevent a research decision-maker
4 or an independent medical practitioner from being
5 satisfied that it is in the best interests of a research
6 candidate or is not adverse to the interests of the
7 candidate that they participate in the research.
- 8 (3) The independent medical practitioner must inform a
9 research decision-maker or researcher of the
10 practitioner's determination, and the reasons for the
11 determination —
- 12 (a) if practicable before the medical research
13 commences — in writing; or
- 14 (b) if paragraph (a) does not apply —
- 15 (i) orally before the medical research
16 commences; and
- 17 (ii) in writing after the research candidate
18 commences participation in the medical
19 research.

20 **110ZV. Assessment by independent medical practitioner of**
21 **likelihood of research candidate regaining ability to**
22 **consent**

- 23 (1) An independent medical practitioner must take into
24 account the following when making a determination
25 under section 110ZR(1)(c) or 110ZS(1)(g) —
- 26 (a) the research candidate's medical, mental and
27 physical condition;
- 28 (b) the severity of the research candidate's
29 condition and the prognosis for the candidate;
- 30 (c) the current stage of treatment and care required
31 for the research candidate;

-
- 1 (d) any other circumstances relevant to the research
2 candidate;
- 3 (e) the nature of, and the timeframe approved by
4 the HREC for, the medical research in which
5 the research candidate is to participate.
- 6 (2) The independent medical practitioner must inform a
7 research decision-maker or researcher of the
8 practitioner's determination, and the reasons for the
9 determination —
- 10 (a) if practicable before the medical research
11 commences — in writing; or
- 12 (b) if paragraph (a) does not apply —
- 13 (i) orally before the medical research
14 commences; and
- 15 (ii) in writing after the research candidate
16 commences participation in the medical
17 research.

18 **110ZW. Assessment by independent medical practitioner of**
19 **risks**

- 20 (1) An independent medical practitioner must take into
21 account the following in making a determination under
22 section 110ZR(3)(b) or 110ZS(1)(i) —
- 23 (a) whether the research candidate's participation
24 in medical research will involve any known
25 substantial risks to the candidate;
- 26 (b) whether there is an existing treatment available
27 to the research candidate;
- 28 (c) if there is an existing treatment available to the
29 research candidate —
- 30 (i) whether there are substantial risks to the
31 candidate involved in the existing
32 treatment available to the candidate; and

s. 12

- 1 (ii) if there are substantial risks involved in
2 the existing treatment — whether those
3 risks are greater than the risks involved
4 in participating in the medical research;
- 5 (d) if there is no existing treatment available —
6 whether the risks involved in participating in
7 the medical research are greater than not
8 participating in the research.
- 9 (2) The independent medical practitioner must inform the
10 research decision-maker or researcher of the
11 practitioner's determination, and the reasons for the
12 determination —
- 13 (a) if practicable before the medical research
14 commences — in writing; or
- 15 (b) if paragraph (a) does not apply —
- 16 (i) orally before the medical research
17 commences; and
- 18 (ii) in writing after the research candidate
19 commences participation in the medical
20 research.

21 **Division 4 — Effect of research decisions and urgent**
22 **medical research decisions**

23 **110ZX. Reliance by researcher on research decision or**
24 **urgent medical research decision**

- 25 (1) In this section —
- 26 ***take research action*** means —
- 27 (a) to commence or continue any medical research
28 in relation to a research candidate; or
- 29 (b) to not commence or to discontinue any medical
30 research in relation to a research candidate.

- 1 (2) This section applies if a researcher —
- 2 (a) takes research action —
- 3 (i) reasonably believing that a research
- 4 candidate is unable to make reasonable
- 5 judgments in respect of the research
- 6 action; and
- 7 (ii) relying in good faith on what is
- 8 purportedly a research decision made by
- 9 the research decision-maker for the
- 10 research candidate under
- 11 section 110ZR;
- 12 or
- 13 (b) takes research action —
- 14 (i) in circumstances where it is reasonable
- 15 for the researcher to rely on another
- 16 researcher having ascertained whether
- 17 the research action is in accordance with
- 18 a research decision by the research
- 19 decision-maker for the research
- 20 candidate under section 110ZR; and
- 21 (ii) reasonably assuming that another
- 22 researcher has ascertained that the
- 23 research action is in accordance with a
- 24 research decision by the research
- 25 decision-maker for the research
- 26 candidate under section 110ZR;
- 27 or
- 28 (c) takes research action —
- 29 (i) reasonably believing that the research
- 30 candidate is unable to make reasonable
- 31 judgments in respect of the research
- 32 action; and

s. 12

- 1 (ii) relying in good faith on what is
2 purportedly an urgent medical research
3 decision made by a researcher;
- 4 or
- 5 (d) takes research action —
- 6 (i) in circumstances where it is reasonable
7 for the researcher to rely on another
8 researcher having ascertained whether
9 the research action is in accordance with
10 an urgent medical research decision;
11 and
- 12 (ii) reasonably assuming that another
13 researcher has ascertained that the
14 research action is in accordance with an
15 urgent medical research decision.
- 16 (3) However, this section does not apply to the extent that
17 a researcher takes research action inconsistent with —
- 18 (a) section 110ZR(4) or (7)(b) or 110ZS(2) or (5);
19 or
- 20 (b) section 110ZT; or
- 21 (c) a decision made under Division 5.
- 22 (4) If this section applies, the researcher is taken for all
23 purposes to take the research action in accordance with
24 a research decision or urgent medical research decision
25 that has effect as if —
- 26 (a) the decision were made by the research
27 candidate; and
- 28 (b) the research action is taken with the research
29 candidate's consent; and
- 30 (c) the research candidate were of full legal
31 capacity.

-
- 1 (5) For the purposes of subsection (2)(a)(ii) and (c)(ii), a
2 researcher is taken to have relied in good faith on what
3 was purportedly a research decision or urgent medical
4 research decision if, after considering whether or not to
5 rely on it, the researcher acted honestly in relying on it.
- 6 (6) For the purposes of determining under
7 subsection (2)(b)(ii) and (d)(ii) whether the
8 researcher's assumption was reasonable, the following
9 matters must be taken into account —
- 10 (a) whether the researcher sighted any written
11 evidence that another researcher had
12 ascertained that the research action was in
13 accordance with a research decision or urgent
14 medical research decision;
- 15 (b) anything else relevant to the determination.

16 **110ZY. Validity of certain research decisions or urgent**
17 **medical research decisions**

- 18 (1) If a researcher does not commence or discontinues
19 medical research in relation to a research candidate in
20 accordance with a research decision or urgent medical
21 research decision, the researcher is taken for all
22 purposes to have done so in accordance with a valid
23 decision, even if an effect of doing so is to worsen the
24 severity of the candidate's condition or the prognosis
25 for the candidate.
- 26 (2) However, subsection (1) does not apply to the extent
27 that an act or omission of a researcher is inconsistent
28 with —
- 29 (a) section 110ZR(4) or (7)(b) or 110ZS(2) or (5);
30 or
- 31 (b) section 110ZT; or
- 32 (c) a decision made under Division 5.

1 **Division 5 — Jurisdiction of State Administrative**
2 **Tribunal**

3 **110ZZ. Applying for review of decision made under this**
4 **Part**

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

9 **110ZZA. Procedure on review**

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

- 13 (a) section 20;
14 (b) subject to subsection (4) — sections 21, 22 and
15 23;
16 (c) sections 26(e) and 31;
17 (d) section 29(3)(c)(ii);
18 (e) section 29(5)(b).

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

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

- 26 (a) the research decision-maker or researcher who
27 made the reviewed decision; or
28 (b) the independent medical practitioner who made
29 the report.

- 1 (4) The *State Administrative Tribunal Act 2004*
2 sections 21(3) to (5), 22 and 23 apply to a report
3 request as if —
4 (a) the report request were a request made under
5 section 21(1) or 22(1) of that Act; and
6 (b) the person to whom the report request is made
7 were the decision-maker.

8 **110ZZB. Effect of State Administrative Tribunal under this**
9 **Division**

- 10 (1) A decision of the State Administrative Tribunal on a
11 review application takes effect on the day on which the
12 Tribunal's decision is made.
13 (2) If the State Administrative Tribunal sets aside a
14 reviewed decision, the Tribunal's decision does not
15 affect the operation of sections 110ZX and 110ZY in
16 relation to actions or omissions of a researcher before
17 the day the Tribunal's decision takes effect under
18 subsection (1).

19 **Division 6 — Reporting**

20 **110ZZC. Researcher to report medical research conducted**
21 **under this Part to Health Minister**

- 22 If a researcher conducts medical research in relation to
23 a research candidate under this Part, the researcher
24 must give the Health Minister a written notice, in the
25 form approved by the Health Minister, stating the
26 following —
27 (a) that the researcher is conducting medical
28 research in relation to the candidate;

s. 12

- 1 (b) whether the medical research is carried out
2 pursuant to —
- 3 (i) a research decision by the research
4 decision-maker for the candidate under
5 section 110ZR; or
- 6 (ii) an urgent medical research decision;
- 7 (c) the type of medical research the researcher is
8 conducting in relation to the candidate;
- 9 (d) the purpose of the medical research;
- 10 (e) any other information required by the approved
11 form.

12 **110ZZD. Health Minister to report to Parliament on medical**
13 **research carried out under this Part**

- 14 (1) The Health Minister must, as soon as practicable after
15 each anniversary of the day on which the *Guardianship*
16 *and Administration Amendment (Medical Research)*
17 *Act 2020* section 12 comes into operation, report to
18 Parliament on the following in relation to the year to
19 which the report relates —
- 20 (a) the number of research candidates who have
21 participated in medical research under this Part;
- 22 (b) whether the medical research is carried out
23 pursuant to —
- 24 (i) a research decision by the research
25 decision-maker for the candidate under
26 section 110ZR; or
- 27 (ii) an urgent medical research decision;
- 28 (c) the type of medical research the researcher is
29 conducting in relation to the candidate;
- 30 (d) the purpose of the medical research;

- 1 (e) any other matter relating to the operation of this
2 Part that the Health Minister considers
3 appropriate.
- 4 (2) The report under subsection (1) —
- 5 (a) may include statistics or other general
6 information derived from a written notice the
7 Health Minister receives under
8 section 110ZZC; but
- 9 (b) must not include personal information.

10 **Division 7 — Reviews**

11 **110ZZE. Review of this Part**

- 12 (1) The Minister must review the operation and
13 effectiveness of this Part and prepare a report based on
14 the review —
- 15 (a) as soon as practicable after the 1st anniversary
16 of the day on which the *Guardianship and*
17 *Administration Amendment (Medical Research)*
18 *Act 2020* section 12 comes into operation; and
- 19 (b) after that, at intervals of not more than 3 years.
- 20 (2) The Minister must cause the report to be laid before
21 each House of Parliament as soon as practicable after it
22 is prepared, but not later than 12 months after the 1st
23 anniversary or the expiry of the period of 3 years, as
24 the case may be.
25

s. 13

1 **13. Section 119 amended**

2 Delete section 119(1) and insert:

3

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

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

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

11

12

=====