Government of Western Australia
Department of Health

Guidance Document:
Involving Incapacitated Adults in Health and Medical Research

Research and Innovation Office, Department of Health

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The information contained in this document is not to be relied upon as legal advice or a substitute for legal advice.

This guidance document provides general advice from the Department of Health. It does not cover the Act in its entirety and should not be read in isolation without consulting the Act.

1 Contents

2 List of Abbreviations

Act	*Guardianship and Administration Act 1990* (WA)
Amendment Act	*Guardianship and Administration Amendment (Medical Research) Act 2020*
HREC	Human Research Ethics Committee
IMP	Independent Medical Practitioner
RDM	Research Decision-Maker
WAHEAF	Western Australian Health Ethics Application Form
WASM	Western Australian Specific Module

3 Introduction

The *Guardianship and Administration Act 1990* (WA) (Act) recognises that there may be occasions when people who are highly dependent on medical care or those with a cognitive impairment may not be capable of making reasonable judgements for themselves and may require someone to make decisions on their behalf.

From 7 April 2020, the *Guardianship and Administration Amendment (Medical Research) Act 2020* (Amendment Act) amended the Act, providing pathways for the participation of adults who do not have the capacity to consent in health and medical research under Part 9E of the Act. These pathways are:

- Medical Research with consent of Research Decision-Maker; and
- Urgent Medical Research without consent.

As the system manager for public health services in WA, the Department of Health has developed this guidance document in consultation with Health Service Providers to assist:

- Researchers with implementing this legislation in a consistent manner; and
- health services reviewing and overseeing research conducted under this legislation at their institutions.

While the Department of Health makes best efforts to ensure that information provided in this document is accurate, it should be not be considered as legal advice and it is not a substitute for referring to the legislation.

The most recent version of this guidance document should be accessed from the Research Governance Service (RGS) website Document Templates page.

The Act can be found here (refer to Part 9E – Medical research). The Amendment Act can be found here. Note that Appendix A provides an extract of the most relevant sections of the Act and the Amendment Act.

Implementation of the Act for specific research projects is complex. All researchers developing projects that may require recruitment of incapacitated adults must consult the relevant research ethics and/or governance office as early as possible.

Feedback on this document including requests for additional content should be directed to:

Research and Innovation Office
Department of Health
Email RIO.DOH@health.wa.gov.au

4 Scope of Medical Research

The Act uses the term Medical Research. For the purposes of this Act, 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.

All research to which this Act applies must have been approved by a Human Research Ethics Committee (HREC) in accordance with the *National Statement on Ethical Conduct in Human Research 2007 (updated 2018)*.

4.1 Type of Research

The Medical Research definition includes research in the field of medicine or health and therefore covers research of a broad nature including nursing, allied health, health sciences and mental health as well as medical research. It should be noted that the Act requires Lead Researchers, who are responsible for the research, to be medical practitioners (see Roles and Responsibilities below).

Medical Research involving sterilisation procedures or electroconvulsive therapy is not permitted.

4.2 Research Activity

The Act defines a list of activities that are considered Medical Research for the purposes of the Act.

The list includes all interventional research and research involving personal information.

Medical Research for the purposes of the Act does not include research that –

- only involves analysing data about the individuals; and
- does not result in the disclosure or publication of personal information.

In other words, research that only involves non-personal information is not included in the definition of Medical Research for the purposes of this Act.

5 Roles and Responsibilities

The Act defines the roles and responsibilities of the parties involved in a Medical Research decision. A summary of the different parties is provided below.

5.1 Research Candidate

A Research Candidate is an individual:

- whose participation is sought in Medical Research; or
- in respect of who Medical Research is conducted under the Act Part 9E.

The points above recognise that the Act applies to persons for whom enrolment in Medical Research is being considered, as well as those who have been enrolled.

5.2 Research Decision-Maker

The Research Decision-Maker (RDM) is a person who may consent or refuse to provide consent on behalf of the Research Candidate for participation in Medical Research where the requirements set out in the Act are met.

The process for determining who may be a RDM is set out in Part 9E. Under the Act a RDM may be a guardian appointed under the Act, spouse, de facto partner, relative or those with a close personal relationship depending on the circumstances.

5.3 Independent Medical Practitioner

The Independent Medical Practitioner (IMP) must be a medical practitioner registered under the *Health Practitioner Regulation National Law (Western Australia)* in the medical profession (other than a student) and must meet the requirements for 'independence', including that they are not:

- currently involved in the treatment of the Research Candidate under Part 9E of the Act[1];
- involved in or connected to the Medical Research[2];
- a spouse, partner or family member of the person; or
- a member of the HREC that approved the research.

The IMP's role is to form a determination regarding the Research Candidate's participation in the Medical Research. The IMP's determination includes:

- the likelihood of the Research Candidate regaining the ability to make reasonable judgements within the timeframe for the research approved by a HREC[3];

[1] As the treatment in this context is confined to treatment under Part 9E (Medical Research), it does not relate to general treatment, for example treatment provided by the Research Candidate's GP, that does not relate to the Medical Research.

[2] The purpose of this requirement is to ensure impartiality of the IMP determination and this should therefore be considered in the context of whether there may be a conflict of interest as to whether the person is or is not enrolled in research. All investigators on the research project and persons who have vested interests that prevent them from providing an independent determination would not meet this requirement.

[3] The intent of this clause is to protect a person's rights by ensuring they are not enrolled in research when it is likely that they will be able to make a decision within the timeframe that is required for the validity of the research to be maintained. The 'timeframe' must be clearly stated by researchers within the research protocol, so this can be considered by the HREC. The timeframe may not necessarily be numerically defined (for example, minutes/hours/days) as in many circumstances it may be more appropriate to define the 'timeframe' as an event occurring, or milestone being reached (for example, the point at which the patient requires the treatment).

- whether the Research Candidate's participation in the research will be in accordance with the risk categories set out in the Act (refer below); and
- whether the Research Candidate's participation is in their best interests or not adverse to their interests[4].

The risk categories set out in the Act are as follows:

  - will only involve observing that person or carrying out another non-invasive examination, treatment or procedure; or
  - if the point above does not apply, will not involve any known substantial risks to the Research Candidate; or
  - if the points above do not apply and if there is an existing treatment available to the Research Candidate, will not involve any known substantial risks to the Research Candidate greater than the risks associated with that treatment; or
  - if the points above do not apply, will not involve substantial risks to the Research Candidate greater than if that Research Candidate did not participate in the research.

The IMP should be suitably informed about the Research Candidate and the research protocol to allow them to make their determinations.

The determination made by the IMP regarding the likelihood of the Research Candidate regaining the ability to consent determines whether it is possible for that person to be enrolled in research without their consent.

The RDM can only consent to research on behalf of a Research Candidate if they have received and considered the determinations from the IMP regarding risk and best interests.

A Researcher can only enrol a person in research without consent (urgent medical research) if an IMP has determined that the level of risk falls within the risk categories listed above and the research is in the Research Candidate's best interests or not adverse to their interests.

The IMP's determination must be recorded in writing using the GAA Medical Research Decision Form, if practicable before the Medical Research commences. If this is not practicable, the IMP can provide their determination orally before the Medical Research commences, and then in writing after the Research Candidate commences participation in the Medical Research.

5.4 Lead Researcher

The Lead Researcher is a medical practitioner who has sole or joint overall responsibility for conducting the Medical Research.

There must be a Lead Researcher at each site that the research is being undertaken at (i.e. the Principal Investigator for each site). As the Lead Researcher is required to be a medical practitioner, this role cannot be undertaken by allied health or nursing staff.

If a Research Candidate is enrolled in Medical Research in accordance with an Urgent Medical Research Decision, the Lead Researcher must continue to take reasonable steps to obtain a Research Decision from a RDM.

If a Research Candidate regains the ability to make reasonable judgments in respect to Medical Research while participating in the Medical Research, or a RDM refuses consent or decides that the Research Candidate will no longer participate in the Medical Research, the Lead Researcher is responsible for

[4] An assessment of the person's best interests includes consideration of whether participation in the research is not adverse to the person's best interests. This supports the use of placebos and recognises that there is always an element of uncertainty regarding the outcomes of research.

ensuring that the Medical Research is discontinued as soon as safely practicable and not recommenced unless a Research Decision is made by the Candidate, or the RDM consents to participation in the research.

5.5 Researcher

Researcher means -

a) a Lead Researcher; or
b) an individual who conducts, or assists with the conduct of, Medical Research.

The Researcher is responsible for fulfilling the Act's requirements for Researchers to report the details of participants who are enrolled under the Act to the Minister for Health. Refer to GAA Medical Research Decision Report of this document.

6 Enrolment Pathways

The Act provides two circumstances when a Research Candidate without the capacity to provide informed consent may be enrolled in Medical Research, and these are described below.

The pathways are also provided in a visual format in the following flowchart. Reference should be made to the relevant sections of the Act as identified in the flowchart.

6.1 Medical Research with consent of Research Decision-Maker

Under this pathway, a RDM for a Research Candidate may make a Research Decision in relation to the Candidate's participation in Medical Research. A Research Decision means a decision to consent or refuse to consent to the Candidate's participation in Medical Research.

It is expected that the majority of people enrolled into research under the Act will be enrolled via this pathway.

A RDM cannot make a Research Decision to consent to the Research Candidate's participation in the Medical Research if the participation is inconsistent with any advance health directive in operation in respect of the Candidate.

6.2 Urgent Medical Research without consent

An Urgent Medical Research Decision means a decision to conduct Medical Research under this pathway.

This pathway applies if the Research Candidate requires urgent treatment and it is not practicable for the Researcher to obtain a Research Decision in relation to the person from a RDM.

Urgent treatment is defined in the Act to mean treatment urgently needed to:

(a) to save the patient's life;
(b) to prevent serious damage to the patient's health; or
(c) to prevent the patient from suffering or continuing to suffer significant pain or distress.

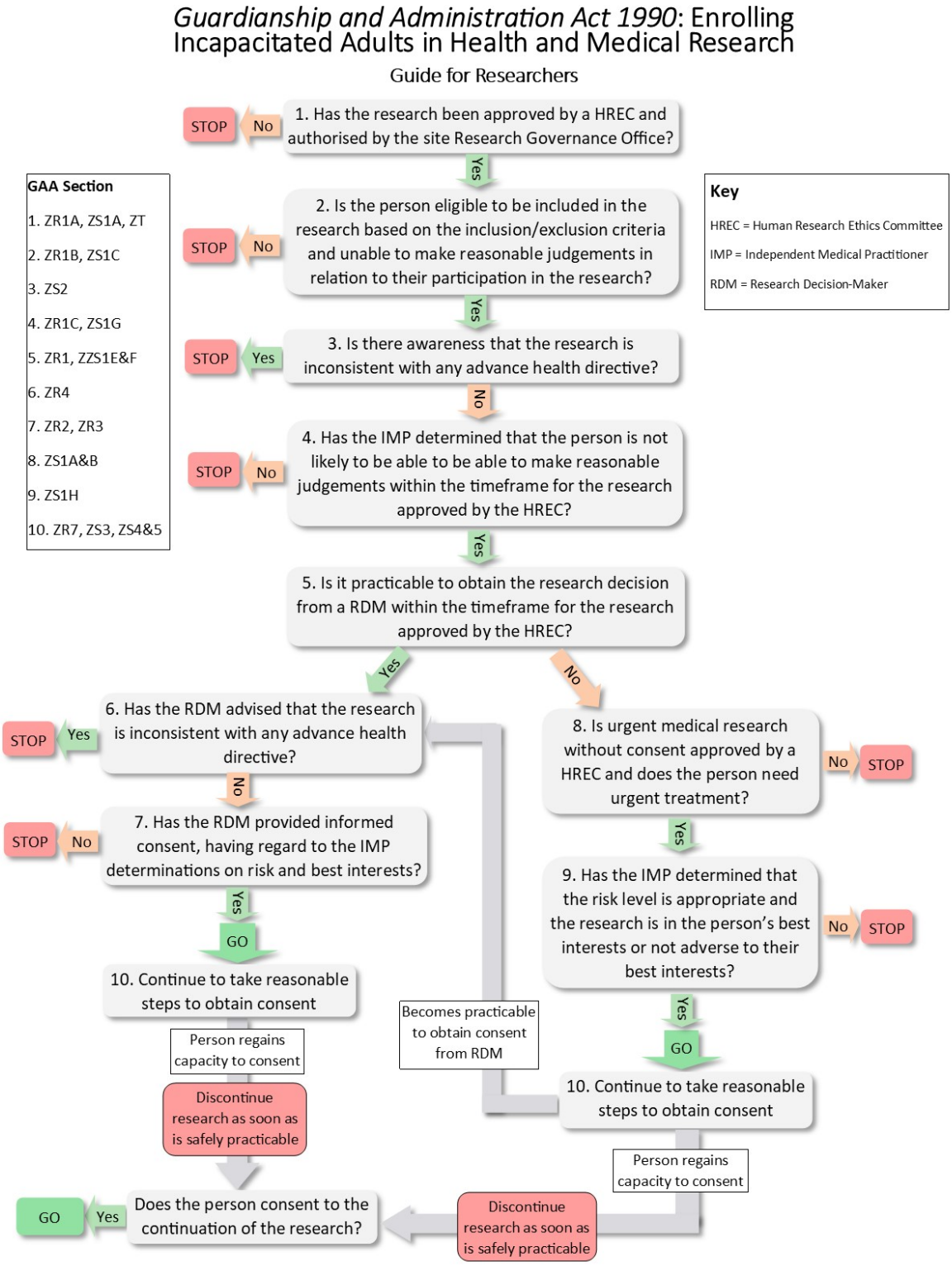
Urgent treatment does not include psychiatric treatment or sterilisation of the patient.

This pathway can only be used if the 'Medical Research with consent of Research Decision-Maker' pathway is not available. Note that it is necessary to seek a Research Decision from the RDM and/or the Research Candidate as soon as practicable.

A Researcher must not make an Urgent Medical Research Decision if the Researcher is aware that the participation is inconsistent with any advance health directive in operation in respect of the Candidate, or a RDM Research Decision already exists.

The Amendment Act includes a provision to repeal the 'Urgent Medical Research without consent' pathway after four years. A review of the Act will be undertaken prior to this date and retention or removal of this 'sunset clause' will form part of that review. While the 'sunset clause' is present in the Amendment Act this may affect the viability of research projects as funding and ethics approvals cannot be provided if the project is not considered feasible. If the 'Urgent Medical Research without consent' pathway is repealed, people already enrolled through this pathway may continue to be involved in the research as if the pathway had not been repealed.

6.3 Flowchart



7 Documentation Requirements

7.1 GAA Medical Research Decision Form

When incapacitated adults are enrolled into Medical Research, a GAA Medical Research Decision Form must be completed to document the decisions regarding the participation of the Research Candidate.

Two forms are available:

- GAA Medical Research Decision Form
    - For use when the HREC has only approved the 'Medical Research with consent of Research Decision-Maker' pathway.
- GAA Medical Research Decision Form – Urgent Treatment
    - For use when the HREC has approved both the 'Medical Research with consent of Research Decision-Maker' and 'Urgent Medical Research without consent' pathways.

The GAA Medical Research Decision Form templates can be downloaded from the WA Health Research Governance Service (RGS) website, on the Document Templates page.

Once completed, the Form should be retained within the study records.

7.2 GAA Medical Research Decision Report

All Medical Research conducted under Part 9E of the *Guardianship and Administration Act 1990* must be reported to the Minister for Health. The Department of Health has provided a report template to record data to enable the provision of this information to the Minister for Health. The report template can be downloaded from the WA Health Research Governance Service website, on the Document Templates page.

A report must be completed each time a Research Candidate is enrolled under Part 9E of the Act.

The Researcher is responsible for complying with the reporting process by completing and submitting the GAA Medical Research Decision Report to the Department of Health. Submissions should be made to RIO.DOH@health.wa.gov.au within 15 calendar days of enrolling the Research Candidate.

8 Appendix A: Extracts from the Act and Amendment Act

CONTENTS

A: Extracts - Guardianship and Administration Act 1990 (as at 07 April 2020)

Division 6 — Reporting

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

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

Division 7 — Reviews

110ZZE. Review of this Part

Extracts relevant to repeal of urgent medical research pathway - taken from the Guardianship and Administration Amendment (Medical Research) Act 2020

13. Section 110ZS deleted

15. Schedule 5 Division 3 inserted

A: Extracts - Guardianship and Administration Act 1990 (as at 07 April 2020)

PART 1 — PRELIMINARY

3. Terms used

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

3AA. Terms 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.

PART 5 – GUARDIANSHIP

Division 3 - Limitations on sterilisation of persons under guardianship or where application for guardianship made

56. Terms used

procedure for the sterilisation does not include a lawful procedure that is carried out for a lawful purpose other than sterilisation but that incidentally results or may result in sterilisation.

PART 9D – TREATMENT DECISIONS IN RELATION TO PATIENTS UNDER LEGAL CAPACITY

Division 1 – Preliminary matters

110ZH. Terms used

urgent treatment - means treatment urgently needed by a patient —

(a) to save the patient's life; or

(b) to prevent serious damage to the patient's health; or

(c) to prevent the patient from suffering or continuing to suffer significant pain or distress,

but does not include —

(d) psychiatric treatment, which is treatment as defined in the Mental Health Act 2014 section 4; or

(e) the sterilisation of the patient.

PART 9E – MEDICAL RESEARCH

Division 1 – Preliminary

110ZO. Terms used

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

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
  (a) reasonably available; and
  (b) 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 —

(ii) will only involve observing the candidate or carrying out another non-invasive examination, treatment or procedure; or
(iii) if subparagraph (i) does not apply — will not involve any known substantial risks to the candidate; or
(iv) 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
(v) 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.

B: Extracts relevant to repeal of urgent medical research pathway - taken from the Guardianship and Administration Amendment (Medical Research) Act 2020

13. Section 110ZS deleted

Delete section 110ZS.

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.