GOVERNMENT OF WESTERN AUSTRALIA

Department of Justice

Review of Part 9E *Guardianship and Administration Act 1990* (WA)

Discussion Paper

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Contents

1 Overview

The *Guardianship and Administration (Medical Research) Act 2020* (WA) (Amendment Act) commenced operation on 7 April 2020. The Amendment Act introduced a new Part 9E into the *Guardianship and Administration Act 1990* (WA) (GAA) to enable medical research to be carried out in respect of persons who do not have the ability to consent to it.

The GAA comes within the Attorney General's portfolio and the Department of Justice (Department) is the agency in the public sector principally assisting the Attorney General in its administration.

The Attorney General is required to carry out a statutory review of the operation and effectiveness of Part 9E of the GAA as soon as practicable after the first anniversary of the commencement of the Amendment Act. The first statutory review must therefore commence as soon as is practicable after 7 April 2021. Future reviews will be undertaken on a three-yearly basis.

The Department will assist the Attorney General to carry out the statutory review of the Amendment Act. A report will be prepared for the Attorney General. According to section 110ZZE(2) of the Amendment Act, the Attorney General must cause the report to be laid before each House of Parliament as soon as practicable after the report is prepared, but not later than 12 months after the first anniversary or the expiry of the period of three years, as the case may be.

1.1 Terms of Reference

The scope of the review is set out in section 110ZZE(1) of the GAA:

> *The Minister must review the operation and effectiveness of* [Part 9E] *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.*

A review of the Amendment Act's **operation** involves objective consideration of how the Amendment Act is being implemented and the consequences of that implementation in practice. This aspect of the review will examine data on the number of incapacitated persons enrolled in medical research since the Amendment Act commenced and the circumstances surrounding their participation. Individual case studies (if available) will also be considered to understand the practical effects on participants and/or their representatives of being enrolled in medical research without consent.

A review of the **effectiveness** of the Amendment Act involves examination of whether Part 9E has been meeting the desired policy objectives since it came into force in 2020. The policy behind the legislation was outlined in the Second Reading Speech when the legislation was introduced by the Minister for Health (see further, paragraph 3.2). One of the aims of the Amendment Act was to put into legislation those procedures which had been routine prior to the Department of Health receiving legal advice which put the lawfulness of those procedures in doubt. The measurement of the Amendment Act's effectiveness will therefore also involve consultation with stakeholders to consider the current process for medical research enrolment, compared to the process(es) that occurred prior to the suspension of medical research

activity involving incapacitated persons who were unable to provide consent (see paragraph 3.1).

Consideration of the Amendment Act's operation and effectiveness also presents a valuable opportunity for the Department to further consider the recommendations made by the Legislative Council's Standing Committee on Legislation (Standing Committee) which are summarised at paragraph 3.3.

1.2 Methodology

The review is being undertaken using mixed methods: mainly broad consultation with stakeholders, but also a brief review of previous relevant inquiries and a jurisdictional comparison. Some data analysis, where relevant and available, will also be undertaken during the review.

This Discussion Paper forms part of the consultation phase of the review.

In addition to seeking written submissions from stakeholders, the statutory review may give key stakeholders the opportunity for face-to-face meetings with the project management team to discuss the review.

2 Information for stakeholders

This Discussion Paper is provided to key stakeholders for consideration with an invitation to provide a submission to the review. Your feedback will be analysed to guide the review and the subsequent report on the review that will be presented to the Attorney General for tabling in Parliament.

Please note that only information that addresses the terms of reference can be used to inform the review.

This is an opportunity for you to provide your feedback and experience with Part 9E of the GAA only, not the entirety of the Act, nor other issues unrelated to the review.

2.1 Purpose of this document

The Department is seeking your comments to help guide its review into the Amendment Act, specifically to address the following two key questions:

1. What have been the consequences of the Amendment Act's **operation**?
2. Has the Amendment Act been **effective** in meeting its policy objectives?

To assist you when providing feedback to the review, this paper contains the following information:

- background information about the Amendment Act's origins and context;
- guided questions to help you address the review's terms of reference;
- a summary of key provisions in the Amendment Act;
- data about the number of research candidates enrolled in medical research using the powers in the Amendment Act; and
- information about how incapacitated persons are involved in medical research in other Australian and Commonwealth jurisdictions.

The information in this Discussion Paper is intended to help you understand the context in which the Amendment Act was introduced and the environment in which it currently operates.

2.2 Guided questions for stakeholders

These questions have been drafted to guide stakeholders through the issues that will be investigated as part of this review. They are not prescriptive and feedback may be provided in a different format if you prefer.

Your submission may address some, but not all, of the issues raised in the questions below. You may wish to use these guided questions as an ongoing reference during your consideration of the background information and data presented in this Discussion Paper.

No.	Question
1	What has been your experience, if any, with incapacitated persons being involved in medical research prior to the Amendment Act commencing in 2020?
2	What is your opinion on/experience with the current process for enrolling incapacitated persons in medical research, compared with the process prior to the suspension of medical research activity that involved patients who were unable to provide consent?[1]
3	Is the definition of 'medical research' in section 3AA of the Amendment Act appropriate, according to the intention and policy of the legislation? Have there been any unintended consequences as a result of the wording of the definition?
4	**For Researchers**: Has the Amendment Act created any difficulties for your medical research projects? **For Incapacitated Persons or their Decision-Makers**: Has the Amendment Act created any difficulties for you regarding your participation in medical research? **For Advocacy Groups**: Has the Amendment Act created any difficulties for your clients or the community on whose behalf you advocate? **For Regulators/Approvers of Research:** Has the Amendment Act created any difficulties for you in reviewing, approving and monitoring medical research projects? **For all:** Please provide specific examples or (deidentified) case studies for the above if possible.

[1] Note that the suspension of medical research activity occurred as a result of legal advice that was obtained by the Department of Health in 2018 regarding the legality of medical treatment provisions in the GAA being relied upon to enrol incapacitated persons in medical research. A copy of that legal advice is available as Appendix 4 to the Standing Committee on Legislation's report on the Amendment Act: see footnote 8 of this Discussion Paper for a link to the report.

5	What is your opinion on/experience with how the in-built safeguards in the Amendment Act are working in practice, including but not restricted to the: • requirement in sections 110ZR and 110ZS of the Amendment Act to obtain a determination from an independent medical practitioner before an incapacitated person may be enrolled in medical research; and • requirement for the lead researcher to be a medical practitioner.
6	Do you think there should be different procedures in place for enrolling an incapacitated person in medical research if their lack of capacity is temporary, rather than permanent? Why or why not?
7	Do you think there should be different procedures in place for enrolling a person in medical research, depending on the nature of their incapacity; for example, an unconscious person, a person with serious mental illness, a person with an intellectual disability or a person with dementia? Why or why not?
8	What is your opinion on/experience with the current prohibition on the use of electroconvulsive therapy as medical research in section 110ZT of the Amendment Act?
9	In other Australian jurisdictions, civil and administrative tribunals are significantly involved in the process of approving/assessing medical research where an incapacitated person is involved (see Chapter 5). Do you think it is desirable to give the State Administrative Tribunal a greater role in this way? Why or why not?
10	What is your experience with the process through which users are given assistance to navigate forms/processes in the practical implementation of the Amendment Act's operation?
11	Do you think that there should be statutory penalties for medical researchers who do not follow the procedures outlined in the Amendment Act (for example, Victoria's penalties at paragraph 5.7)? Why or why not?

2.3 How to make a submission

Send your written submission by email or post (email is preferred) to:

legpolicy@justice.wa.gov.au

Review of Part 9E *Guardianship and Administration Act 1990*
Strategic Reform
Department of Justice
GPO Box F317
PERTH WA 6841

The report on the review will be tabled in Parliament by the Attorney General and may contain references to submissions received during the consultation process, including submitter details or content.

Please clearly state in your submission if you would prefer for your submission (or parts thereof) to remain confidential.

2.4 Closing date for submissions

Submissions must be received not later than [8 weeks from date on letter].

2.5 Further information

If you have any queries or require further information about the submission process or the statutory review, please contact the Project Management Team at legpolicy@justice.wa.gov.au.

3 Background to the *Guardianship and Administration Amendment (Medical Research) Act 2020* (WA)

3.1 Review of the *Guardianship and Administration Act 1990* (WA) in 2015

A statutory review of the GAA commenced in 2013 and was tabled in Parliament in 2015 (2015 Review) under a previous State Government.[2] The issue of consent to medical research for people with decision-making difficulties emerged as a major issue in the 2015 Review and several recommendations were made to address the issue.

Prior to the 2015 Review, medical researchers often sought to enrol an incapacitated person in research by obtaining permission from a substitute decision-maker on the basis that the GAA authorised such decisions for them to participate in medical treatment.

The 2015 Review was clear that this process could not continue and the GAA required amendment to address this anomaly. Recommendation 6 of the 2015 Review provided that the GAA should be amended to permit a decision-maker to make decisions about an incapacitated person's involvement in medical research, in addition to making decisions about their medical treatment.

It would take several more years before the Bill for the Amendment Act was introduced into the Parliament and the process for enrolling incapacitated persons in medical research could be clarified. In 2018, the Department of Health sought legal advice from SSO regarding the legality of medical treatment provisions in the GAA still being relied upon to enrol incapacitated persons in medical research. The advice distributed to all Health Service Provider Chief Executives confirmed that 'consent to treatment by an authorised substitute decision-maker does not imply consent to participation in a research project' and 'a substitute decision-maker is not presently authorised by the [GAA] to consent to an incapacitated patient's full participation in a research project'.[3]

A consequence of the legal advice from SSO was that all existing research activity that involved patients who were unable to provide consent was suspended, with the Department of Health and SSO offering further advice on a case-by-case basis for affected medical research projects.[4]

These events confirm that, prior to the Amendment Act, Western Australia did not have legislation that specifically authorised incapacitated persons to be enrolled as candidates in medical research. Such participation was facilitated by relying on the provisions in the GAA that deal with medical treatment instead.

3.2 Urgent Bill introduced during the COVID-19 pandemic in 2020

In April 2020, the Minister for Health introduced the Guardianship and Administration Amendment (Medical Research) Bill 2020 (Bill) into Parliament, as the emerging COVID-19 emergency meant that the ability to conduct medical research trials had

[2] *Statutory Review of the Guardianship and Administration Act 1990 (November 2015)*, Legislative Council, Tabled Paper 3697, 2 December 2015.
[3] Department of Health WA, 'Research Involving Incapacitated Adults', 2018, available as Appendix 4 to Standing Committee on Legislation, *Guardianship and Administration Amendment (Medical Research) Bill 2020 and amendments made by the Guardianship and Administration Amendment (Medical Research) Act 2020*, Report 48, 25 November 2020.
[4] Department of Health WA, 'Research Involving Incapacitated Adults', 2018, p 2.

become crucial. The Bill introduced a new Part 9E into the GAA to enable medical research to be carried out in respect of persons who do not have the capacity to consent to it. The Bill also included a review clause that required the operation and effectiveness of Part 9E to be reviewed as soon as practicable after one year from the date that Part 9E commenced, followed by three-yearly reviews thereafter.[5]

The Bill passed the Legislative Assembly without amendment and was transmitted to the Legislative Council for consideration on the same day. During debate on the Bill in the Legislative Council, the Hon Michael Mischin MLC moved an amendment to insert a sunset clause into the Bill. The amendment to clause 2 of the Bill proposed to delete section 110ZS (see further, paragraph 3.4), to take effect four years after the day on which the legislation commenced: 8 April 2024.

The Government supported the insertion of the sunset clause and the amendment was passed by the Legislative Council. A transitional provision was also inserted in the Bill to ensure that those existing research decisions for individuals that would be affected by the operation of the sunset clause could continue, despite the research project not being able to proceed.[6]

The Bill passed both Houses of Parliament on 2 April 2020 and the Amendment Act commenced on 7 April 2020.

3.3 Recommendations of the Standing Committee on Legislation

The Legislative Council took the unusual step of passing the Amendment Act and referring it to its Standing Committee to inquire and report *after* the legislation had commenced.[7]

The Standing Committee reported to the Parliament on the Amendment Act on 25 November 2020 and made seven recommendations in its report: see **Appendix 1**.[8] Three of the Standing Committee's recommendations suggested that certain clauses of the Amendment Act be considered in the review: Recommendations 3, 4 and 6.

Recommendations 3 and 4 of the Standing Committee's report recommended that the review consider the requirements for 'independent medical practitioners' (IMP) in sections 110ZR and 110ZS of the Amendment Act. The review will consider these recommendations and one of the aims of this Discussion Paper is to seek stakeholder views on how the IMP requirements in the Amendment Act have been operating in practice.

During its inquiry, the Standing Committee heard evidence from the Department of Health and from medical witnesses on the prohibition of electroconvulsive therapy being used for medical research. The Standing Committee found that there is a 'strong

[5] A late drafting change to the Bill as a result of the Opposition's request changed the review period from its original 24 month period to 12 months: Hon Roger Cook MLA, Minister for Health, Legislative Assembly, Western Australia, *Parliamentary Debates (Hansard)*, 1 April 2020, p 2004.
[6] Section 15 of the Amendment Act will commence on the same day as the sunset clause (8 April 2024) and will insert a new clause 8 to Schedule 5 of the GAA: 'Effect of repealed s. 110ZS on continuing urgent medical research after repeal day.'
[7] After the Third Reading stage of the Bill, the Hon Michael Mischin MLC moved a motion without notice in the Legislative Council to refer the Bill to the Standing Committee on Legislation, which was supported by the Government and triggered the inquiry into the Amendment Act.
[8] The Standing Committee's report can be accessed via this link: Report 48.

body of expert opinion in favour of removing the prohibition on electroconvulsive therapy' and recommended that the review consider the issue, 'with a view to removing the prohibition' (Recommendation 6). This Discussion Paper is an opportunity for stakeholders to provide their views on this issue, including patient advocacy groups and representatives from the mental health, disability and aged care sectors.

3.4 Key provisions in the Amendment Act

The Amendment Act provides the authorisation and appropriate safeguards to enable an incapacitated person, through their representative, to provide consent for their participation in medical research. The provisions in Part 9E of the GAA are consistent with the existing laws for medical treatment of incapacitated persons in Western Australia.

There are two circumstances in the Amendment Act in which an incapacitated person may be enrolled in medical research, that is: with the consent of their decision-maker, and in urgent circumstances where that consent has not been obtained prior. The Amendment Act also inserted various safeguards to ensure that the process of enrolling that person in medical research was subject to independent oversight and ministerial reporting to the Parliament.

The following is a brief overview of key provisions in the Amendment Act:

- sections 3AA and 110ZO contain defined terms, including 'independent medical practitioner', 'lead researcher', 'medical research', 'research decision-maker' and 'urgent medical research decision';
- section 110ZR outlines the circumstances in which a research decision-maker may make a decision that a person who cannot provide consent will participate in medical research. This section is one of the key operational provisions in the Amendment Act, together with section 110ZS;
- section 110ZS provides for the urgent circumstances in which a researcher may conduct medical research without consent from either the participant or their research decision-maker. This section is subject to a sunset clause and will automatically expire four years after its commencement date;
- section 110ZT describes the types of medical research for which a research decision-maker cannot give their consent, namely procedures involving sterilisation of the candidate or electroconvulsive therapy;
- sections 110ZU-110ZW outline the role of the IMP and matters that they must take into account during their determinations according to sections 110ZR and 110ZS;
- sections 110ZX and 110ZY explain the effect of actions taken by a researcher with regard to medical research on a research candidate and the types of research actions that are deemed reasonable when undertaken by a researcher in good faith;
- sections 110ZZ-110ZZB establish the jurisdiction of the State Administrative Tribunal to review decisions made in accordance with the provisions of Part 9E;
- sections 110ZZC and 110ZZD set out the reporting requirements of researchers and of the Minister for Health; and
- section 110ZZE, which requires a review of the operation and effectiveness of Part 9E, as discussed at paragraph 1.1.

The wording used in section 110ZR of the Amendment Act is based on the approach in existing section 110ZD in Part 9C of the GAA, which deals with decisions about medical treatment. Similarly, section 110ZS is consistent with the provisions governing urgent medical treatment decisions in Division 2 of Part 9D of the GAA.

The Amendment Act also changed the definition of 'treatment' in section 3 of the GAA to extend it to include medical research in Part 9B Advance Health Directives (AHD) and Part 9E of the GAA. The effect of this broadening of the term is that a research decision-maker cannot make a decision about medical research that is contrary to a decision made in an AHD. If a person's AHD has already set out their decisions about participating in medical research, the decision-making hierarchies put in place by Part 9E of the GAA do not need to operate if/when they lose capacity.

4 Data

The following section presents data regarding the number of incapacitated persons who have been enrolled in medical research according to the provisions of Part 9E of the GAA.

The information in **Figure 1** is sourced from the Minister for Health's report to the Parliament pursuant to section 110ZZD of the GAA.[9]

Section 110ZZC of the GAA requires researchers to provide written notice to the Minister for Health of all medical research conducted according to the provisions in Part 9E. The written notice must include details regarding the manner in which the research candidate was enrolled (that is, with their decision-maker's consent or if it was urgent medical research without consent) and what the research entails.

Figure 1 is extracted from the Minister for Health's first section 110ZZD report, tabled in the Legislative Assembly on 19 October 2021.

Type of medical research	Purpose of medical research	Any other matter		
		NHMRC Broad Research Category	NHMRC Field of Research	Site
Research Candidates enrolled under 110ZR – Research Decision Maker (n = 8)				
Collection of samples from individuals (e.g. blood, tissues, fluids)	Diagnosis	Clinical Medicine and Science	110305 Emergency Medicine	Royal Perth Hospital
Procedure or practice (e.g. physiotherapy, mental health, surgical procedure)	Treatment	Clinical Medicine and Science	110317 Physiotherapy	Royal Perth Hospital
Comparative assessment of health care practices	Treatment	Clinical Medicine and Science	110321 Rehabilitation and Therapy (excl. Physiotherapy)	Royal Perth Hospital
Comparative assessment of health care practices	Treatment	Clinical Medicine and Science	110321 Rehabilitation and Therapy (excl. Physiotherapy)	Royal Perth Hospital
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110904 Neurology and Neuromuscular Diseases	Fiona Stanley Hospital
Survey, interview or focus group	Educational	Health Services Research	111703 Care for Disabled	Curtin University
Survey, interview or focus group	Educational	Health Services Research	111703 Care for Disabled	Curtin University
Survey, interview or focus group	Educational	Health Services Research	111703 Care for Disabled	Curtin University
Research Candidates enrolled under 110ZS – Urgent Medical Research (n = 1)				
Collection of samples from individuals (e.g. blood, tissues, fluids)	Diagnosis	Clinical Medicine and Science	110305 Emergency Medicine	Royal Perth Hospital
TOTAL RESEARCH CANDIDATES ENROLLED UNDER PART 9E OF THE ACT = 9				

Figure 1 – Research Candidates enrolled under Part 9E – Medical Research of the Guardianship and Administration Act 1990

[9] Western Australia, Legislative Assembly, Tabled Paper 722, *Medical Research Candidates recruited under Part 9E of the Act, Summary Report 7 April 2020 to 6 April 2021*.

5 Australian comparisons

Few Australian jurisdictions have legislation in place that specifically governs the involvement of incapacitated persons in medical research. All State and Territory guardianship laws have procedures for approving medical treatment for an incapacitated person with the consent of their decision-maker, but many extend these procedures to cover enrolment in medical research.

5.1 Australian Capital Territory

There are two Acts in the Australian Capital Territory that allow a decision-maker to provide consent for an incapacitated person to be enrolled in medical research. These are the:

- *Powers of Attorney Act 2006* (ACT); and
- *Guardianship and Management of Property Act 1991* (ACT).

The *Powers of Attorney Act 2006* (ACT) permits a 'medical research power of attorney' to be put in place by which a principal (the person who makes a power of attorney) allows their attorney (as the decision-maker) to exercise power in relation to participation in medical research.[10]

The medical research may include experimental health care or participation in a clinical trial. An attorney may also consent on behalf of a principal who has impaired decision-making ability to participate in approved medical research, provided they are satisfied on reasonable grounds of the matters outlined in the Act.[11] An independent doctor must assess the likelihood of the principal regaining their decision-making capacity and must provide their reasons in writing.[12]

An interested person may apply for review of an attorney's decision (or refusal) to enrol a principal in low-risk research to the ACT Civil and Administrative Tribunal (ACAT).[13]

The *Guardianship and Management of Property Act 1991* (ACT) empowers the ACAT to appoint a guardian to provide consent for a research candidate to be enrolled in approved medical research. The appointed guardian then has similar powers to provide consent for a protected person to participate in medical research as an attorney does, according to the *Powers of Attorney Act 2006* (ACT). This also includes a requirement for an independent doctor to make a written assessment as to the likelihood of a protected person regaining their decision-making capacity.[14]

A 'health attorney' may also be involved in the process of enrolling a protected person in low-risk approved medical research.[15] A person who is the protected person's partner, carer or close relative or friend is a health attorney for the purposes of the legislation.

[10] *Power of Attorney Act 2006* (ACT), ss 12A, 13 and 41A.
[11] *Power of Attorney Act 2006* (ACT), s 41D(2)(c): this includes being satisfied that the research relates to a condition that the principal already has been, or is at significant risk of being, exposed to, and that the potential benefit of the research outweighs the risk/inconvenience thereof.
[12] *Power of Attorney Act 2006* (ACT), s 41F.
[13] ibid., s 41G.
[14] *Guardianship and Management of Property Act 1991* (ACT), s 36.
[15] ibid., s 32D.

There is no explicit provision in ACT legislation that would allow an incapacitated person to be enrolled in urgent medical research without consent being obtained from a decision-maker.

5.2 New South Wales

According to the *Guardianship Act 1987* (NSW), an incapacitated person may only be enrolled in medical research with the approval of the New South Wales Civil and Administrative Tribunal (NSWCAT). This differs from the carrying out of medical or dental treatment on an incapacitated person: the Act permits a guardian to consent to this on an incapacitated person's behalf.[16]

Medical research is referred to in the Act as a 'clinical trial', a broad definition which involves 'drugs or techniques being tested … [and is] intended to cure or alleviate a particular condition from which the patients suffer'.[17] NSWCAT must be satisfied that the clinical trial meets the requirements in section 45AA(2) of the Act; if so, it may provide consent for the incapacitated person to participate, or may allow the person's guardian to provide consent.[18]

There is no explicit provision in the *Guardianship Act 1987* (NSW) to allow an incapacitated person to be enrolled in urgent medical research without consent being obtained from a decision-maker.

5.3 Northern Territory

The definition in the *Guardianship of Adults Act 2016* (NT) of 'restricted health care' includes health care that is provided for the purposes of medical research.[19] It does not, however, include: non-intrusive examination, observation of activities, collecting information from or about a person or health care prescribed by regulation as not being within the definition.[20]

A guardian cannot consent to an incapacitated person being subjected to restricted health care.[21]

An incapacitated person may be involved in medical research according to Northern Territory legislation via an advance consent decision made pursuant to the *Advance Personal Planning Act 2013* (NT). A person appointed in an advance personal plan may not make decisions about enrolling a person in 'restricted health matters' (this includes special medical research or experimental health care).[22]

There is no explicit provision in the *Guardianship of Adults Act 2016* (NT) to allow an incapacitated person to be enrolled in urgent medical research without consent being obtained from a decision-maker.

5.4 Queensland

The *Guardianship and Administration Act 2000* (Qld) (Qld Guardianship Act) uses the terms 'special medical research' and 'clinical research' to describe medical research

[16] *Guardianship Act 1987* (NSW), s 40.
[17] ibid., s 45AA(2)(a).
[18] ibid., s 45AB(1).
[19] *Guardianship of Adults Act 2016* (NT), s 8.
[20] ibid., s 8(4).
[21] *Guardianship of Adults Act 2016* (NT), s 23(2); *Advance Personal Planning Act 2013* (NT), s 25.
[22] *Advance Personal Planning Regulations 2014* (NT), r 4.

that an incapacitated person may be enrolled in according to that Act. Psychological research or approved clinical research are not included within that definition.

Only the Queensland Civil and Administrative Tribunal may consent to an incapacitated person participating in special medical research or 'experimental health care', if satisfied of various matters outlined in the Act.[23]

There is no explicit provision in the Qld Guardianship Act to allow an incapacitated person to be enrolled in urgent medical research without consent being obtained from a decision-maker.[24] Participation by an incapacitated person in approved clinical research can be approved by following the order of priority as set out in the Act for dealing with a health matter.[25]

5.5 South Australia

South Australia does not have specific legislation that permits an incapacitated person to be enrolled in medical research.

The *Guardianship and Administration Act 1993* (SA) permits decisions about medical treatment to be made by a decision-maker. The Act works in conjunction with the *Consent to Medical Treatment and Palliative Care Act 1995* (SA) to authorise a decision-maker to consent to medical treatment on behalf of an incapacitated person. In certain situations, emergency medical treatment may be administered to an incapacitated person without consent.[26]

In an emergency situation, the medical treatment can only be administered if another medical practitioner has personally examined the incapacitated person and prepares a written opinion in support of the treatment.[27]

5.6 Tasmania

The *Guardianship and Administration Act 1995* (Tas) contains no provision for an incapacitated person to be enrolled in medical research. The Act deals only with administering medical treatment for which a decision-maker may provide consent on behalf of an incapacitated person.[28]

There is, in fact, no reference at all to medical research in Tasmania's guardianship legislation.

5.7 Victoria

The *Medical Treatment Planning and Decisions Act 2016* (Vic) contains a definition of 'medical research procedure' that includes 'procedures carried out for the purposes of medical research'.[29] The decision-maker for an incapacitated person may consent to

[23] *Guardianship and Administration Act 2000* (Qld), s 72.
[24] See Qld Guardianship Act as made: Queensland Government, Queensland Legislation, https://www.legislation.qld.gov.au/view/pdf/asmade/act-2000-008. Viewed 28 October 2021.
[25] *Guardianship and Administration Act 2000* (Qld), s 66, referred to in the text of the Act as assented to on 20 April 2000 (No. 8 of 2000).
[26] *Consent to Medical Treatment and Palliative Care Act 1995* (SA), s 13.
[27] ibid., s 13(1), but note s 13(2): 'A supporting opinion is not necessary under subsection (1)(b) or (1a)(b) if in the circumstances of the case it is not practicable to obtain such an opinion.'
[28] *Guardianship and Administration Act 1995* (Tas), Part 6.
[29] *Medical Treatment Planning and Decisions Act 2016* (Vic), s 3. The definition excludes procedures such as visual examinations, measurements and observing a patient.

their participation in approved medical research, or the person themselves may consent.

An incapacitated person may be enrolled in approved medical research without consent if a health practitioner believes, on reasonable grounds, that the medical research is necessary as a matter of urgency.[30]

Part 5, Division 3 of the Act outlines the procedure that a medical practitioner must follow when administering medical research to an incapacitated person without consent. This includes the requirement for the medical practitioner to forward a signed certificate to the Victorian Public Advocate that confirms the procedure in the Act was correctly followed.[31]

The practitioner must also make reasonable efforts to ascertain if the incapacitated person to be enrolled in the research has an advance health directive or a person to make health decisions on their behalf. Failure to do so is deemed unprofessional conduct and the medical practitioner may be subject to financial penalties or regulatory action.[32]

The incapacitated person's decision-maker or person who has a 'special interest' (in the opinion of the Victorian Civil and Administrative Tribunal) may apply to the tribunal for a review of a medical research decision.[33]

[30] With various conditions applicable to the chosen procedure, such as it being necessary to save the person's life or prevent significant pain or distress: *Medical Treatment Planning and Decisions Act 2016* (Vic), s 53.
[31] ibid., s 81(3).
[32] According to the *Health Practitioner Regulation National Law (Victoria) Act 2009* (Vic).
[33] *Medical Treatment Planning and Decisions Act 2016* (Vic), s 82: an application for review may be in relation to a decision to administer a medical research procedure or to refuse such a procedure.

6 Commonwealth comparisons

6.1 New Zealand

The *Protection of Personal and Property Rights Act 1988* (NZ) is the main piece of legislation in New Zealand that governs the rights of people who may lack capacity, either temporarily or permanently.

The Act specifically provides that a 'welfare guardian' does not have the power to consent to an incapacitated person 'taking part in any medical experiment other than one to be conducted for the purpose of saving that person's life or of preventing serious damage to that person's health'.[34]

There is no reference at all to medical research in New Zealand's guardianship legislation.

6.2 Canada

Canadian guardianship legislation varies by province and each jurisdiction has its own guardianship system governed by either common law or statute.

Nova Scotia's *Guardianship Act 2002*, for example, deals with guardianship for children only and does not contain references to medical treatment decisions or medical research.

In British Columbia, however, there are several statutes that work together to govern how an incapacitated person may appoint a decision-maker and the decisions which may be made on an incapacitated person's behalf.[35]

The *Health Care (Consent) and Care Facility (Admission) Act [RSBC 1996]* includes approved medical research in its definition of 'health care' for the purposes of the Act.[36] A decision-maker may consent on behalf of an incapacitated person to participate in such medical research by following the procedure set out in the legislation.[37]

A health care provider may enrol an incapacitated person in urgent health care (including medical research) without consent being sought, if the criteria in section 12(1) of the Act are met:

- it is necessary to provide the health care without delay in order to preserve the adult's life, to prevent serious physical or mental harm or to alleviate severe pain;
- the adult is apparently impaired by drugs or alcohol or is unconscious or semi-unconscious for any reason or is, in the health care provider's opinion, otherwise incapable of giving or refusing consent;

[34] *Protection of Personal and Property Rights Act 1988* (NZ), s18(1)(f).
[35] These statutes are the: *Representation Agreement Act [RSBC 1996]*, *Power of Attorney Act [RSBC 1996]*, *Health Care (Consent) and Care Facility (Administration) Act [RSBC 1996]*, *Adult Guardianship Act [RSBC 1996]*, *Public Guardian and Trustee Act [RSBC 1996]* and *Patients Property Act [RSBC 1996]*.
[36] *Health Care (Consent) and Care Facility (Administration) Act [RSBC 1996]*, s 1.
[37] ibid., s 8.

- the adult does not have a personal guardian or representative who is authorised to consent to the health care, is capable of doing so and is available; and
- where practicable, a second health care provider confirms the first health care provider's opinion about the need for the health care and the incapability.[38]

6.3 United Kingdom

Legislation governing participation in clinical trials in the United Kingdom is complex and has been affected by legislative changes that were required as part of Brexit. Laws dealing with medical research also interact with the common law doctrine of 'Gillick competence' when a child under the age of 16 years is involved in a medical research decision.[39]

The Medicines for Human Use (Clinical Trials) Regulations 2004 (UK) (MHUCT Regulations) require clinical trials that involve incapacitated adults to comply with a series of conditions and principles, as set out in Schedule 1, Parts 1 through 5 of the regulations.[40] Clause 1(5) of Schedule 1, Part 1 of the MHUCT Regulations provides that an incapacitated adult who, prior to the onset of their incapacity, did not give informed consent (or explicitly refused consent) to take part in the clinical trial, cannot be included as a subject in that clinical trial.

Conditions specific to incapacitated adults being enrolled in a clinical trial are set out in Schedule 1, Part 5 of the MHUCT Regulations and include the following:

- The legal representative of an incapacitated person must have an interview with the investigator[41], or another member of the investigating team, and have the opportunity to understand the objectives, risks and inconveniences of the trial and the conditions under which the trial will be conducted.
- The legal representative has been informed of the right to withdraw the subject from the trial at any time.
- The incapacitated adult has received information regarding the trial's risks and benefits to a level suitable to their capacity to understand.
- There are grounds for expecting that the administration of the medicinal product being tested during the clinical trial will produce a benefit that outweighs the risks or produces no risk at all to the subject.
- The clinical trial must relate directly to a 'life-threatening or debilitating clinical condition' that the incapacitated adult suffers from.

[38] *Health Care (Consent) and Care Facility (Administration) Act [RSBC 1996]*, s 12.
[39] *Gillick v West Norfolk and Wisbech Area Health Authority* [1986] UKHL 7: where the House of Lords held that a child under the age of 16 years had the legal competence to consent to medical examination and treatment if they had sufficient maturity and intelligence to understand the nature and implications of that treatment.
[40] *The Medicines for Human Use (Clinical Trials) Regulations 2004* (UK), available from https://www.legislation.gov.uk/uksi/2004/1031/made. (Viewed 29 October 2021).
[41] 'Investigator' in relation to a clinical trial means 'the authorised health professional responsible for the conduct of that trial': *The Medicines for Human Use (Clinical Trials) Regulations 2004* (UK), r 2.

Regulation 30(1) MHUCT Regulations further provides that:

> *(1) The sponsor and investigator may take appropriate urgent safety measures in order to protect the subjects of a clinical trial against any immediate hazard to their health or safety.*
> *(2) If measures are taken pursuant to paragraph (1), the sponsor shall immediately, and in any event no later than 3 days from the date the measures are taken, give written notice to the licensing authority and the relevant ethics committee of the measures taken and the circumstances giving rise to those measures.*

The law regarding recruiting incapacitated adults in emergency situations without their consent being given varies across the United Kingdom.

In England and Wales, in an emergency situation, incapacitated adults may be enrolled in Clinical Trials of Investigational Medicinal Products (CTIMP) without prior consent if the following requirements are met:

- treatment needs to be given urgently;
- it is also necessary to take urgent action to administer the drug for the purposes of the trial;
- it is not reasonably practicable to obtain consent from a legal representative;
- the procedure is approved by a National Health Service Ethics Committee; and
- consent is sought from a legal representative as soon as possible.[42]

The same requirements above apply in Scotland and Northern Ireland for incapacitated adults who may be enrolled in CTIMP research in emergency situations without prior consent.

For 'other intrusive research' (that is, all research *other* than CTIMP) an incapacitated person may participate without prior advice from a decision-maker (called a 'consultee') in an emergency situation if:

- treatment must be given urgently;
- it is not reasonably practicable to seek advice from a decision-maker;
- the procedure is approved by a National Health Service Research Ethics Committee; and
- a decision-maker is consulted as soon as possible on the participant's likely views and feelings.[43]

The law in Northern Ireland also permits incapacitated adults to be recruited into intrusive research without prior consent by a decision-maker in emergency situations. The same procedure as applies in England and Wales (above) must be followed in these circumstances.[44]

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[42] Health Research Authority, *Consent and Participant Information Guidance*, 'Principles of consent: Emergency Research (England and Wales)', available from: http://www.hra-decisiontools.org.uk/consent/principles-emergency-EnglandandWales.html (viewed 8 Nov 2021).
[43] ibid.
[44] Health Research Authority, *Consent and Participant Information Guidance*, 'Principles of consent: Emergency Research (Northern Ireland)', available from: http://www.hra-decisiontools.org.uk/consent/principles-emergency-NIreland.html (viewed 8 Nov 2021).

In Scotland, the law differs for incapacitated adults who may be enrolled in research without consent *other than* CTIMP, even in emergency situations: there are no situations where this may occur. The consent of a decision-maker must be sought in every situation where an incapacitated person may participate in intrusive emergency research.[45]

[45] Health Research Authority, *Consent and Participant Information Guidance*, 'Principles of consent: Emergency Research (Scotland)', available from: http://www.hra-decisiontools.org.uk/consent/principles-emergency-Scotland.html (viewed 8 Nov 2021).

Appendix 1 – Recommendations of the Standing Committee on Legislation

Recommendation 1
The definition of 'independent medical practitioner' in s 110ZO of the *Guardianship and Administration Act 1990* be amended to provide clarity to stakeholders.
Recommendation 2
The definition of 'lead researcher' in s 110ZO of the *Guardianship and Administration Act 1990* be amended to allow nurses, psychiatrists, paramedics and allied health professionals to be lead researchers.
Recommendation 3
The requirement to obtain a determination from an independent medical practitioner for medical research conducted under s 110ZR of the *Guardianship and Administration Act 1990* be considered in the statutory review required by s 110ZZE(1)(a) of the Act after there has been an opportunity to review its implementation in practice.
Recommendation 4
The requirement to obtain a determination from an independent medical practitioner for urgent medical research conducted under s 110ZS of the *Guardianship and Administration Act 1990* be considered in the statutory review required by s 110ZZE(1)(a) of the Act after there has been an opportunity to review its implementation in practice
Recommendation 5
The four–year sunset clause on s 110ZS of the *Guardianship and Administration Act 1990* be repealed.
Recommendation 6
The prohibition on electroconvulsive therapy under s 110ZT of the *Guardianship and Administration Act 1990* be considered in the statutory review required by s 110ZZE(1)(a) of the Act with a view to removing the prohibition.
Recommendation 7
The Minister for Health advise if the use of telehealth is an option to overcome the problems of rural and regional communities complying with the obligation to obtain a determination from an independent medical practitioner under the *Guardianship and Administration Act 1990*.