40TH PARLIAMENT

Report 48

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

Presented by
Hon Dr Sally Talbot MLC (Chair)

November 2020

Standing Committee on Legislation

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EXECUTIVE SUMMARY

1 Medical research involving people who are not able to make reasonable judgements about whether or not they should participate in medical research (incapacitated research candidates) was previously conducted in Western Australia based on laws governing medical treatment. Although treatment and research are distinct concepts, in reality there is a broad spectrum of activities that involve both. There are no known negative consequences of medical research being conducted under medical treatment laws in Western Australia.

2 In 2018 the Department of Health sought advice from the State Solicitor's Office in relation to the legality of medical research being conducted in this way. Based on this advice the Department of Health issued guidance to health service providers in Western Australia advising them against conducting medical research on incapacitated research candidates.

3 A consequence of the Department's guidance was that the involvement of incapacitated research candidates in medical research has not occurred in Western Australia since 2018. This has negatively affected the treatment of incapacitated research candidates, especially patients with conditions such as dementia, traumatic brain injury and cardiac arrest. It has also created a barrier to developing treatments for new illnesses.

4 The Guardianship and Administration Amendment (Medical Research) Bill 2020 (Bill) and the resulting Act, the *Guardianship and Administration Amendment (Medical Research) Act 2020* (Amending Act), introduce a comprehensive framework of laws governing the involvement of incapacitated research candidates in medical research. They address the gap that was found to exist in 2018 and will enable the involvement of incapacitated research candidates in medical research to resume in Western Australia.

5 The Bill and Amending Act were passed in April 2020. Despite this, the Department of Health advised the Committee in October 2020 that nobody has actually been enrolled in medical research under the Amending Act since its introduction. This has been in part due to the time it has taken to prepare statutory forms required to undertake medical research.

6 Since the finalisation of these statutory forms on 9 October 2020 there appear to be no further legislative barriers to recommencing medical research involving incapacitated research candidates in Western Australia.

Main provisions

7 The Bill and Amending Act allow the involvement of incapacitated research candidates in medical research if consent is obtained from a research decision–maker (s 110ZR). This is consistent with the existing laws for medical treatment in Western Australia.

8 The Bill and Amending Act also permit a researcher to enrol an incapacitated research candidate in medical research in urgent circumstances where it is not practicable to obtain consent from a research decision–maker (s 110ZS). This provision is based on existing medical treatment laws however it includes additional safeguards to protect the research candidate.

Safeguards

9 The Amending Act has introduced a number of safeguards for incapacitated research candidates involved in medical research. These include:

- a lead researcher must be a medical practitioner (see paragraphs 6.5–6.25)
- medical research is to be conducted in accordance with a research candidate's advance health directive, if the candidate has one (see paragraphs 7.31–7.38)

- a research decision–maker must provide consent on behalf of an incapacitated research candidate when performing medical research in non–urgent circumstances (see paragraphs 7.6–7.13)
- a hierarchy is to be followed when appointing a research decision–maker (see paragraphs 6.27–6.32)
- a researcher must obtain a determination from an independent medical practitioner when performing urgent medical research and it is not practicable to obtain a decision from a research decision–maker (see paragraphs 7.18–7.23)
- a lead researcher is required to discontinue medical research as soon as safely practicable if a research candidate regains the ability to consent (see paragraphs 7.40–7.47)
- medical research must not involve procedures for sterilisation or electroconvulsive therapy (see paragraphs 7.48–7.54)
- applications can be made to the State Administrative Tribunal to review decisions about medical research (chapter 10)
- all medical research involving incapacitated research candidates is to be reported to the Minister for Health; and the Minister for Health is to annually report all such medical research to Parliament (chapter 11)
- the Attorney General is required to periodically review the operation of these particular medical research laws and report to Parliament (chapter 12).

Recommendations

10 The Committee is of the view that the Amending Act introduces important amendments that will protect incapacitated research candidates involved in medical research in Western Australia. The Committee has also made several recommendations to improve the current laws. These include:

- amend the definition of 'independent medical practitioner' to provide clarity that an incapacitated research candidate's treating doctor may satisfy this definition provided they are not associated with medical research being performed under Part 9E of the *Guardianship and Administration Act 1990*
- amend the definition of 'lead researcher' to allow nurses, psychiatrists, paramedics and other allied health professionals to be the lead researcher
- repeal the four–year sunset clause that will delete the provision governing the involvement of incapacitated research candidates in medical research.

Findings and recommendations

Findings and recommendations are grouped as they appear in the text at the page number indicated:

FINDING 1 Page 10

Prior to the introduction of the *Guardianship and Administration Amendment (Medical Research) Act 2020*, Western Australia did not have laws specifically dealing with the involvement of incapacitated research candidates in medical research. In the absence of specific provisions, provisions concerning substitute decision making for medical treatment were used to facilitate medical research until 2018.

FINDING 2 Page 14

The Statutory Review of the *Guardianship and Administration Act 1990* in November 2015 made 86 recommendations.

FINDING 3 Page 14

The *Guardianship and Administration Amendment (Medical Research) Act 2020* is consistent with recommendations 6.1 and 7 of the 2015 Statutory Review of the *Guardianship and Administration Act 1990*.

FINDING 4 Page 14

The *Guardianship and Administration Amendment (Medical Research) Act 2020* is contrary to recommendation 6.2 of the 2015 Statutory Review of the *Guardianship and Administration Act 1990*.

FINDING 5 Page 15

The *Guardianship and Administration Amendment (Medical Research) Act 2020* does not implement any of the remaining 84 recommendations from the 2015 Statutory Review of the *Guardianship and Administration Act 1990*. However, the government is committed to implementing the remaining supported recommendations of the 2015 Statutory Review.

FINDING 6 Page 16

The involvement of incapacitated research candidates in medical research ceased in Western Australia after the Department of Health sent guidance to health service providers advising that while a person may be authorised to make a medical treatment decision for an incapacitated patient, this did not extend to consenting to a patient's participation in medical research.

FINDING 7 Page 22

The Guardianship and Administration Amendment (Medical Research) Bill 2020 was passed as a matter of urgency between 1 and 2 April 2020 and received Royal Assent on 6 April 2020. The substantive provisions of the resulting Act, the *Guardianship and Administration Amendment (Medical Research) Act 2020*, came into operation on 7 April 2020.

FINDING 8 Page 22

Medical research under the *Guardianship and Administration Act 1990* was not undertaken between the commencement of the *Guardianship and Administration Amendment (Medical Research) Act 2020* in April 2020 and 9 October 2020, at least in part, because the necessary statutory forms were not approved until 9 October 2020.

FINDING 9 Page 38

The World Medical Association's Declaration of Helsinki states:

> 8. While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.

FINDING 10 Page 38

The World Medical Association's Declaration of Helsinki contemplates exceptions for the requirement to obtain consent in emergency situations. It states:

> 30. If no representative is available and if the research cannot be delayed, the study may proceed without informed consent provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the study has been approved by a research ethics committee. Consent to remain in the research must be obtained as soon as possible from the subject or a legally authorised representative.

FINDING 11 Page 39

Under the social model of disability, a person's will and preferences should be respected and not overruled by action thought to be in their objective best interests.

FINDING 12 Page 39

The British Medical Research Council Ethics Guide states:

> To exclude [adults who lack mental capacity to consent] from any research would be discriminatory and would diminish their ability to participate as fully as possible in society. It would also prevent researchers making progress in the understanding of many disorders that can affect the brain, and in the care and treatment of those who have such disorders. However, such research requires special safeguards to ensure that this vulnerable group are protected when they do participate in medical research.

FINDING 13 Page 43

Any medical research in Australia involving humans or requiring access to personal information requires approval from a human research ethics committee that is registered with the National Health and Medical Research Council.

FINDING 14 Page 43

When determining ethics approval for medical research, human research ethics committees must ensure compliance with the National Statement on Ethical Conduct in Human Research.

FINDING 15 Page 43

The National Statement on Ethical Conduct in Human Research does not have any legislative force but is an important guide for medical research. The National Statement includes the principle that:

> Where the researcher is also the treating health professional, it should be considered whether an independent person should make the initial approach and/or seek consent from potential participants or from others on their behalf.

FINDING 16 Page 43

The Guardianship and Administration Amendment (Medical Research) Bill 2020 and the *Guardianship and Administration Amendment (Medical Research) Act 2020* introduce appropriate safeguards to protect incapacitated research candidates in keeping with the protections proposed in the discussion paper to update the National Statement on Ethical Conduct in Human Research dated August 2020.

FINDING 17 Page 49

The definition of 'medical research' in the *Guardianship and Administration Act 1990* is effectively consistent with the definition of 'human research' in the National Statement on Ethical Conduct in Human Research.

FINDING 18 Page 51

Section 3AA(2)(l) of the *Guardianship and Administration Act 1990* is an appropriate delegation of legislative power.

FINDING 19 Page 51

A majority of the Committee, consisting of Hons Dr Sally Talbot MLC, Colin de Grussa MLC, Simon O'Brien MLC and Pierre Yang MLC finds that s 3AA(3)(b) of the *Guardianship and Administration Act 1990* is an appropriate delegation of legislative power.

FINDING 20 Page 51

A minority of the Committee, consisting of Hon Nick Goiran MLC, finds that s 3AA(3)(b) of the *Guardianship and Administration Act 1990* is not an appropriate delegation of legislative power.

FINDING 21 Page 54

An incapacitated research candidate's treating doctor may satisfy the definition of an 'independent medical practitioner' under s 110ZO of the *Guardianship and Administration Act 1990* provided they are not associated with medical research being performed under Part 9E. However, this is not clear in the *Guardianship and Administration Act 1990* and is causing confusion among stakeholders.

RECOMMENDATION 1 Page 54

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 Page 60

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.

FINDING 22 Page 67

The requirement to obtain a determination from an independent medical practitioner is an appropriate safeguard for incapacitated research candidates involved in medical research.

RECOMMENDATION 3 Page 67

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.

FINDING 23 Page 71

If the requirement to obtain a determination from an independent medical practitioner for urgent medical research is to be removed, the importance of the requirement set out in s 110ZS(3) of the *Guardianship and Administration Act 1990* is elevated.

RECOMMENDATION 4 Page 71

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 Page 74

The four–year sunset clause on s 110ZS of the *Guardianship and Administration Act 1990* be repealed.

FINDING 24 Page 77

The Department of Health has advised a central register of advance health directives is anticipated to commence in late 2021 or early 2022.

FINDING 25 Page 80

Noting the importance of the goal to obtain consent from a patient if they regain capacity, the requirement to discontinue medical research as soon as safely practicable should allow an opportunity for the researcher to discuss with the research candidate if they wish to proceed before discontinuing the research.

FINDING 26 Page 81

There is a strong body of expert opinion in favour of removing the prohibition on electroconvulsive therapy.

RECOMMENDATION 6 Page 82

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.

FINDING 27 Page 84

Section 110ZU(1)(e) of the *Guardianship and Administration Act 1990* is an appropriate delegation of legislative power.

FINDING 28 Page 88

The guidance material published by the Department of Health regarding the assessment of a research candidate regaining the ability to consent is satisfactory.

FINDING 29 Page 90

The requirement for an independent medical practitioner to provide their reasons in writing is consistent with the policy of providing appropriate safeguards for incapacitated research candidates.

FINDING 30 Page 92

The establishment of a panel of independent medical practitioners would help to facilitate the operation of the *Guardianship and Administration Act 1990*.

FINDING 31 Page 92

The requirement to obtain a determination from an independent medical practitioner when performing medical research under the *Guardianship and Administration Act 1990* is problematic for many rural and regional communities.

RECOMMENDATION 7 Page 92

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*.

CHAPTER 1
Introduction

Referral of the Bill and Amending Act

1.1 The Guardianship and Administration Amendment (Medical Research) Bill 2020 (Bill) and the resulting Act, the *Guardianship and Administration Amendment (Medical Research) Act 2020* (Amending Act), were referred to the Standing Committee on Legislation (Committee) on 2 April 2020 with a reporting date of 25 November 2020.

1.2 The referral motion as passed was:

> (1) The Guardianship and Administration Amendment (Medical Research) Bill 2020, the Bill, in the form it was agreed to by the Legislative Council and Legislative Assembly, be referred to the Legislation Committee.
>
> (2) The Committee is to inquire into the Bill and the amendments made to the *Guardianship and Administration Act 1990* by the *Guardianship and Administration Amendment (Medical Research) Act 2020*.
>
> (3) The Committee is to report by Wednesday, 25 November 2020.[1]

1.3 After being referred to the Committee the Bill was given Royal Assent on 6 April 2020.[2] The substantive provisions of the Amending Act came into operation on the following day.[3]

1.4 It is unusual for a bill and an Act to be referred together in this way. However the Legislative Council has referred a bill for post–legislative scrutiny in the past.[4]

Policy of the Bill and Amending Act

1.5 The referral motion places no limitation on the Committee's ability to inquire into the Amending Act. As such, the Committee has given consideration to the policy of the Amending Act in this inquiry.

1.6 The Department of Justice was responsible for the development of the Bill. It stated the policy of the Bill and Amending Act as follows:

> The policy behind making these amendments to the GAA [*Guardianship and Administration Act 1990*] is to provide legislative authorisation for carrying out medical research in respect of persons who do not have the capacity to consent to participation, while providing the appropriate safeguards for research candidates in allowing substitute decision–makers to provide consent.
>
> Where the situation is urgent, and it is not practicable to obtain consent within an appropriate timeframe, the policy is to allow urgent medical research to proceed, provided that appropriate safeguards are complied with.

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1 Hon Michael Mischin MLC, Western Australia, Legislative Council, *Parliamentary Debates (Hansard)*, 2 April 2020, p 2063.

2 Hon Kim Beazley, Governor of Western Australia, Message No 10, 6 April 2020.

3 This does not include the sunset clause provisions which commence on 8 April 2024. *Guardianship and Administration Amendment (Medical Research) Act 2020,* ss 2, 13, 15.

4 Western Australia, Legislative Council, Standing Committee on Reserves (Reserve 43131) Bill 2003, *Reserves (Reserve 43131) Bill 2003*, 18 November 2004, p vii.

> The Amendment Act addressed the existing lack of clarity in Western Australia as to the circumstances in which substitute decision–makers could provide consent for research candidates who lack capacity to participate in medical research.
>
> This authorisation for medical research has been enacted in the GAA. The purpose of the GAA is to provide for substitute decision–making for persons who cannot make reasonable judgements, in order to safeguard their best interests. Another principle in the Act is to impose the least restrictions possible upon the person's freedom of decision.
>
> Therefore, the policy behind the Amendment Act recognises that persons who lack capacity to consent to research were being excluded from research in which persons who could consent were able to participate. However, given their lack of capacity to consent, there must be appropriate safeguards to ensure their best interests are upheld and their freedoms and individual rights are protected.[5]

Passage of the Bill

1.7 The Bill was passed as a matter of urgency between 1 and 2 April 2020 shortly after the government of Western Australia declared a state of emergency in response to the COVID–19 pandemic.[6] The Bill was considered under temporary orders passed in the Legislative Assembly and the Legislative Council for COVID–19 related business. These temporary orders are attached as Appendix 1.

1.8 Under the temporary orders passed in the Legislative Council the maximum time limits for consideration of the Bill were modified as follows:

> second reading, 180 minutes, Committee of the Whole, 180 minutes; adoption of report, five minutes; and third reading, 45 minutes.[7]

1.9 In her second reading speech introducing the Bill in the Legislative Council, Hon Sue Ellery MLC focused on the importance of the Bill for the treatment of people who may lose the capacity to make reasonable judgements as a result of contracting COVID–19:

> The Guardianship and Administration Amendment (Medical Research) Bill 2020 provides critical legislative amendments that will enable our doctors to join the global effort to trial new and emerging treatments for COVID–19. Considerable efforts are underway worldwide to provide effective drug treatment for COVID–19. The World Health Organization is launching a multi–country clinical trial to test four drug regimens as COVID–19 therapies. A similar multi–country trial is taking place in Europe. Hundreds of other treatment trials are underway. Some COVID–19 patients are already receiving drugs that are the subject of clinical trials through compassionate–use programs.
>
> …
>
> We need treatments that will slow or kill the novel coronavirus. We need to know what treatments are most effective so that we can reduce the time patients spend

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5 Dr Adam Tomison, Director General, Department of Justice, Answer to question on notice No 6 asked at hearing held 1 October 2020, dated 14 October, p 10.

6 Hon Francis Logan MLA, Minister for Emergency Services, *Notice of Declaration of State Emergency made by Minister for Emergency Services*, 15 March 2020. See: https://www.wa.gov.au/sites/default/files/2020–08/Declaration%20of%20State%20of%20Emergency.pdf. Viewed 12 October 2020.

7 Hon Sue Ellery MLC, Western Australia, Legislative Council, *Parliamentary Debates (Hansard)*, 2 April 2020, p 2019b.

in hospital, particularly in intensive care. This knowledge can be gained only through medical research.[8]

1.10 During committee of the whole debate, Hon Sue Ellery MLC acknowledged that while the COVID–19 pandemic made the introduction of the Bill more urgent, its operation would not be limited to treating people who contract COVID–19. Rather, the Bill can apply to anyone who is not able to make reasonable judgements about their enrolment in medical research regardless of the reason for their incapacitation. This was confirmed in the following exchange:

> **Hon RICK MAZZA:** This bill was introduced into the Council as an emergency COVID–19 bill, among a suite of emergency bills. Besides COVID–19, under what other conditions is it envisaged or planned that experimental research might be carried out on patients without their consent?
>
> **Hon SUE ELLERY:** It is not possible to give the member a list. It is designed for anybody who is critically ill or injured, and that could be of any nature. I gave some examples in my second reading reply, but there is not a defined list and there could not be a defined list. It could include any condition that confronts medical practitioners when someone is in a critical condition, and that is across the broadest possible spectrum.
>
> **Hon RICK MAZZA:** Can I take it from that answer that this bill is not specifically for the COVID–19 emergency? It is, in fact, for experimental research on people without their consent for any condition?
>
> **Hon SUE ELLERY:** I think the honourable member has missed the point that I tried to make in my second reading speech and in my second reading reply. The circumstances that we face now are due to COVID–19. The member used the word "experimental", but there are medical research activities directly related to COVID–19 that could be used to save people's lives now and to save Western Australian lives and other lives in the future. The urgency is because of COVID–19, but the member was right when he made the point that the scope of the bill is not limited to COVID–19. What makes it urgent is that we are confronting COVID–19 right now.[9]

Main provisions of the Amending Act

1.11 The Amending Act introduces 'Part 9E—Medical research' to the *Guardianship and Administration Act 1990*, together with other consequential amendments. Part 9E is divided as follows:

- Division 1—Preliminary
- Division 2—Decisions about medical research
- Division 3—Provisions about research decisions and urgent medical research decisions
- Division 4—Effect of research decisions and urgent medical research decisions
- Division 5—Jurisdiction of the State Administrative Tribunal
- Division 6—Reporting

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8 Hon Sue Ellery MLC, Western Australia, Legislative Council, *Parliamentary Debates (Hansard)*, 1 April 2020, p 1955b.

9 Hon Sue Ellery MLC, Western Australia, Legislative Council, *Parliamentary Debates (Hansard)*, 2 April 2020, p 2040.

- Division 7—Reviews.

1.12 The main operational provisions of Part 9E are contained in Division 2. They are:

- section 110ZR—Medical research with consent of research decision–maker
- section 110ZS—Urgent medical research without consent.

1.13 Section 110ZR is based on the existing provisions governing medical treatment in Parts 9C and D of the *Guardianship and Administration Act 1990*. It extends this legislative framework by allowing a research decision–maker to make decisions on behalf of an incapacitated research candidate in relation to medical research. The hierarchy of people who can be a research decision–maker is helpfully set out in Figure 1 in paragraph 6.28 of this report.

1.14 Section 110ZS allows a researcher to involve incapacitated research candidates in urgent medical research where it is not practicable to obtain a decision from a research decision–maker. Section 110ZS reflects the existing provisions for urgent medical treatment without consent. However, it introduces a more comprehensive legislative framework.

1.15 Sections 110ZR and ZS include additional safeguards that are not contained in the existing provisions governing medical treatment. This is necessary in recognition of the fact that while treatment and research are frequently not distinct concepts and include a broad spectrum of activities that include both, there is a need to consider safeguards for incapacitated research candidates. This includes the requirement for an independent medical practitioner to make an assessment of an incapacitated research candidate's best interests, the likelihood they will regain the ability to consent and the risks involved in the research.[10]

Sunset clause

1.16 The Bill was amended in the Legislative Council to include a clause that deletes the provision for urgent medical research (s 110ZS) four years after Royal Assent.[11] Clauses that delete provisions in this way are known as sunset clauses. The sunset clause in the Bill and Amending Act is considered in paragraphs 7.25–7.30.

Procedure

1.17 The Committee called for submissions from the stakeholders listed in Appendix 2 and advertised the inquiry on Facebook and in *The West Australian* newspaper. The Committee received 28 submissions, all of which were made public.

1.18 Public hearings were held over two days on 30 September and 1 October 2020 and broadcast live on the internet.[12] The witnesses who appeared at these hearings are listed in Appendix 2.

1.19 The Committee extends its appreciation to those who contributed to the inquiry.

Fundamental legislative principles

1.20 As with previous inquiries, the Committee's method of scrutiny included an assessment of whether the Bill and Amending Act are consistent with fundamental legislative principles (FLPs).[13]

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10 *Guardianship and Administration Act 1990,* ss 110ZU, ZV, ZW.

11 *Guardianship and Administration Amendment (Medical Research) Act 2020*, ss 2, 13, 15.

12 Videos of each broadcast are available on the Committee's webpage: www.parliament.wa.gov.au/leg.

13 The fundamental legislative principles are set out in Appendix 3.

1.21 FLPs are principles relating to legislation that underlie a parliamentary democracy based on the rule of law.[14] They fall under two broad headings:

- Does the Bill have sufficient regard for the rights and liberties of individuals? (FLP 1–11)
- Does the Bill have sufficient regard to the institution of Parliament? (FLP 12–16).

1.22 The Committee has routinely used FLPs as a convenient and informal framework for scrutinising proposed legislation since 2004. They are not enshrined in Western Australian law, and for some bills, many FLPs do not apply. The question the Committee asks is not whether there is strict compliance with FLPs but whether a bill has sufficient regard to them.

1.23 The Committee has specifically considered issues relating to FLP 1 and 12 in this report.

Structure of this report

1.24 Chapter 2 begins with a brief explanation of medical research involving people who are unable to make reasonable judgements about their involvement in medical research (incapacitated research candidates) in Western Australia prior to 2018. It then summarises the events that led to the discontinuance of this practice and those leading to the introduction of the Bill and Amending Act.

1.25 Chapter 3 begins with a short history of guardianship laws before considering the laws governing the involvement of incapacitated research candidates in medical research in Australia today.

1.26 Chapter 4 considers the ethical framework for the involvement of incapacitated research candidates in medical research in Australia.

1.27 Chapter 5 considers the differences between medical treatment and medical research. The Committee's scrutiny of the Bill and Amending Act begins in chapter 5 with consideration of the definition of 'medical research' introduced into the *Guardianship and Administration Act 1990*.

1.28 The Bill and Amending Act introduce 'Part 9E—Medical Research' into the *Guardianship and Administration Act 1990*. Chapter 6 considers the provisions in 'Part 9E, Division 1—Preliminary'. Division 1 includes s 110ZO which defines a number of terms used in Part 9E. It also contains ss 110ZP and ZQ which determine the appointment of a research decision–maker.

1.29 Chapter 7 considers the provisions in 'Part 9E, Division 3—Provisions about research decisions and urgent medical research decisions' of the *Guardianship and Administration Act 1990*. This includes the two main provisions introduced by the Amending Act, ss 110ZR and ZS. These provisions allow medical research to be performed on incapacitated research candidates in urgent and non–urgent circumstances.

1.30 Chapter 8 considers the provisions in 'Part 9E, Division 3—Provisions about research decisions and urgent medical research decisions' of the *Guardianship and Administration Act 1990*. This includes ss 110ZU, ZV, ZW which require an independent medical practitioner to make an assessment of the research candidate's best interests, the likelihood they will regain the ability to consent and the risks involved.

1.31 Chapter 9 considers the provisions in 'Part 9E, Division 4—Effect of research decisions and urgent medical research decisions' of the *Guardianship and Administration Act 1990*. These

[14] The fundamental legislative principles are based on principles set out in the *Legislative Standards Act 1992* (Qld), though other Parliaments often rely on similar principles.

provisions protect researchers from civil and criminal liability as long as they comply with the provisions of the *Guardianship and Administration Act 1990*.

1.32 Chapter 10 considers the provisions in 'Part 9E, Division 5—Jurisdiction of the State Administrative Tribunal' of the *Guardianship and Administration Act 1990*. These provisions govern applications made to the State Administrative Tribunal to review medical research decisions.

1.33 Chapter 11 considers the provisions in 'Part 9E, Division 6—Reporting' of the *Guardianship and Administration Act 1990*. These provisions require all medical research conducted under Part 9E to be reported to the Minister for Health; and for the Minister for Health to annually report all such medical research to Parliament.

1.34 Chapter 12 considers 'Part 9E, Division 7—Reviews' of the *Guardianship and Administration Act 1990*. Division 7 contains one provision which requires the Attorney General to periodically review the operation and effectiveness of Part 9E and prepare a report based on that review.

1.35 Chapter 13 summarises the Committee's findings on whether the Amending Act achieves the policy objectives of legislating to allow the involvement of incapacitated research candidates in medical research while providing appropriate safeguards.

CHAPTER 2
Medical research in Western Australia

Introduction

2.1 Prior to 2018, medical research involving incapacitated research candidates was conducted in Western Australia under laws governing medical treatment. This chapter begins with a brief explanation of this practice. It then summarises the events that led to its discontinuance in 2018 and the subsequent introduction of the Bill and Amending Act.

2.2 The involvement of incapacitated research candidates in medical research was discontinued in 2018 when the Department of Health advised health service providers in Western Australia against performing medical research under laws governing medical treatment. This guidance was based on legal advice from the State Solicitor's Office. A copy of the guidance from the Department of Health is attached as Appendix 4.

2.3 The discontinuance of medical research in 2018 resulted in a series of submissions to the Attorney General of Western Australia about the unsatisfactory consequences of this outcome. A draft bill addressing these consequences was subsequently prepared in January 2020 and was distributed to a limited number of stakeholders for consideration. This led to further submissions and finally resulted in the introduction of the Bill and Amending Act.

Medical research in Western Australia prior to 2018

2.4 Prior to the introduction of the Amending Act, Western Australia did not have laws specifically dealing with the involvement of incapacitated research candidates in medical research. In the absence of specific provisions, provisions concerning substitute decision–making for medical treatment were used to facilitate medical research until 2018.

2.5 The laws governing medical treatment allow a substitute decision–maker to make a decision about medical treatment on behalf of a patient who lacks the capacity to do so themselves.

2.6 When the *Guardianship and Administration Act 1990* was introduced in the Legislative Assembly, the Minister for Health at the time, Hon Keith Wilson MLA made the following comments in relation to medical treatment:

> An important aspect of any form of guardianship is the consent for medical procedures. The *Guardianship and Administration Act* will allow an appointed guardian to consent to the medical or dental treatment of the represented person. However, it will not be necessary to appoint a guardian merely to consent to medical or dental treatment for a person who is not otherwise in need of a guardian. Where there is no guardian appointed, a doctor or dentist may provide the appropriate health care or treatment to a person who, in the opinion of the doctor or dentist, is incapable of consenting to the care or treatment and is a person for whom a guardian could not be appointed under the Act. Before treatment can commence the consent of the person in apparent charge of the person to whom the care or treatment is to be given, must be obtained.[15]

[15] Hon Keith Wilson MLA, Minister for Health, Western Australia, Legislative Assembly, *Parliamentary Debates (Hansard)*, 7 September 1989, pp 2035–6.

2.7 In 2008 the *Guardianship and Administration Act 1990* was amended to include more comprehensive laws governing medical treatment.[16] This was achieved by inserting the following parts in the *Guardianship and Administration Act 1990*:

- Part 9C—Persons responsible for patients
- Part 9D—Treatment decisions in relation to patients under legal incapacity.

2.8 A number of stakeholders gave evidence about the practice of involving incapacitated research candidates in medical research under medical treatment laws, including those noted below:

- Hon Eric Heenan QC:

> For many years before the HDWA [Department of Health Western Australia] directives of 2018 medical researchers, institutes, hospitals and other doctors had worked on the assumption that patients who were temporarily or permanently incapacitated from giving personal informed consent to participation in a clinical trial or other medical research could be enrolled in such a trial or research if a close relative, spouse, guardian or trusted friend responsible for the patient's care was prepared to make an informed decision to consent on the patient's behalf to participate in the trial or research. This was done much in the same way as doctors and hospitals accepted the consent of such a person on a patient's behalf to undergo surgery or other forms of treatment, especially urgent treatment, when the patient was unconscious or unable to consent himself or herself. There are obvious comparisons here with the well accepted practice of parental consent on behalf of children too young to consent to participate in surgical, medical or dental treatment.[17]

The Committee asked Mr Heenan to expand on this submission at the hearing on 30 September 2020 and explain the legal basis for conducting medical research prior to the introduction of the Amending Act. He gave the following answer:

> This is a difficult matter. The question assumes that this practice was not legal until the introduction of the amendment, and that is something which I think is probably controversial. There was certainly the opinion from the State Solicitor's Office to the Health Department, which I have never seen and as far as I am aware has not been published, which advanced the opinion that research of this kind was not permitted, but I know there are shades of opinion about whether that is entirely correct. My own view is that in certain kinds of research, it probably is correct, but there are other kinds of research—what doctors call the comparative analysis between existing orthodox treatments—and I would not have expected that to be in contravention. I think the situation really is that up until 2018, the medical profession and the universities genuinely believed that it was permissible to have research for people who could not consent, so long as consent was forthcoming from some responsible adult carer or guardian or parent, in the same way that treatment could be given.
>
> But, as I have said in the paper, in 2008, the *Guardianship and Administration Act* was amended to identify people who could consent to ordinary treatment—not research; ordinary treatment—for disabled persons or persons who were unable to consent, and there is a hierarchy of people that we all know about. My own view is that by defining those people who could consent for this form of treatment, there was an unintentional implication that they could not consent to anything else. If you couple that with the idea that research is distinctly different from treatment,

[16] *Acts Amendment (Consent to Medical Treatment) Act 2008.*

[17] Submission 13 from Hon Eric Heenan QC, 5 June 2020, p 5.

you see that the consent powers are confined to treatment, and not this different activity of research. Although I have not seen the opinion, I have heard others express that view, and it seems to me to be quite a logical inference to draw. I think it is a flawed inference. I think certain types of research could not be classified as treatment, but other forms of research certainly could, and for those that could be classified as treatment, I do not see that there was any departure from the existing law or proper practice in the procedures that had been followed.[18]

- Dr James Williamson, Assistant Director General, Clinical Excellence Division, Department of Health:

  The original Act, I think, allowed for consent not just for treatment, but for 'other health care'.[19] I think there was an assumption on the part of clinicians that that 'other health care' might have included research. I think there was ambiguity which existed for a number of years. It was perhaps brought to the fore in the statutory review in 2015. Then specifically in 2017, judgement was given in respect of the EXACT study, which looked at two different concentrations of oxygen being administered to patients with cardiac arrest, which identified that the existing interpretation of the Act was not consistent with the meaning of the Act. In 2016, the *Health Services Act* established health service providers as independent entities, if you like, each governed by a board and each able to seek its own counsel. From the time that they began to do that in respect of research decisions, it was clear that there was continuing confusion. Those were the circumstances under which further discussions were entered into with the research community to establish what the current understanding of the Act should be. I understand there might have been some communication through the HSPs [health service providers] and their research governance officers to the research community … Suffice to say that from about June 2018, with the assistance of the DOH [Department of Health] and SSO [State Solicitor's Office], we prepared some advice to HSPs as to how the Act should be interpreted which was communicated to them in December 2018.[20]

- Dr Stephen Macdonald, Staff Specialist in Emergency Medicine, Royal Perth Hospital appearing for Australasian College for Emergency Medicine:

  our understanding is that up until that point, research had happened involving patients who lacked capacity under an interpretation of the treatment provisions that were within the existing *Guardianship and Administration Act 1990*. We also understand that there was a diversity of legal opinion within the various research governance bodies in the health service and our understanding was that an opinion was sought from the State Solicitor. That advice, obviously, has not been made public and we are not familiar with the details of that, but the consequence of that advice was that the Health Department instructed that all research involving patients who lacked capacity to provide consent in Western Australia had to cease and that, since then, no new research involving patients in this category has been approved.[21]

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18 Hon Eric Heenan QC, transcript of evidence, 30 September 2020, pp 5–6.

19 *Guardianship and Administration Act 1990,* s 3 (see definition of 'treatment').

20 Dr James Williamson, Assistant Director General, Clinical Excellence Division, Department of Health, transcript of evidence, 1 October 2020, p 3.

21 Dr Stephen Macdonald, Staff Specialist in Emergency Medicine, Royal Perth Hospital, Australasian College for Emergency Medicine, transcript of evidence, 30 September 2020, p 9.

- Western Australian Health Translation Network and Health Consumer's Council:

  Prior to the 2020 Bill, the *Guardianship and Administration Act 1990* was silent on research. Legal opinion allowed trials with no known negative consequences, but with obvious benefits for West Australians, to proceed. For instance, WA was a leader in the conduct of clinical trials in cardiac arrest.[22]

FINDING 1

Prior to the introduction of the *Guardianship and Administration Amendment (Medical Research) Act 2020*, Western Australia did not have laws specifically dealing with the involvement of incapacitated research candidates in medical research. In the absence of specific provisions, provisions concerning substitute decision making for medical treatment were used to facilitate medical research until 2018.

Experience of stakeholders prior to 2018

2.9 The Committee asked stakeholders whether they were aware of any negative consequences that arose from conducting medical research on incapacitated people prior to 2018. None of those asked were able to provide examples of negative consequences resulting from this practice:

- Clinical Associate Professor David Mountain, Australian Medical Association (WA):

  No. That was one of the strangest things about it. There are lots and lots of trials and lots and lots of human beings, so there are errors and audits that would have said, "You can do this better", but, no, we had no serious adverse outcomes or no trials that had been stopped with major harms to patients because of a poor trial process. In fact, we follow very similar practices to the rest of Australia, it is just that our legislation happened to be silent. The interpretation was about whether silence meant that it was precluded or silence meant that you could follow what was the best practice at the time. Certainly, we had no evidence that there was any significant, serious malpractice going on within Western Australia. In fact, we would probably be seen as one of the legislatures with very good levels of practice, particularly in critical care, because we had a high number of international–level researchers in these areas.[23]

- Dr Stephen Macdonald, Staff Specialist in Emergency Medicine, Royal Perth Hospital appearing for Australasian College for Emergency Medicine:

  I am not aware [of any adverse consequences]. I am happy to be put right on that. My understanding was that the provisions within the guardianship act were interpreted, obviously, for proxy decision–making by a substitute decision–maker for treatment, and that the approval by ethics committees was based upon the principles set out in the National Statement. In other words, for that to apply, all the criteria that are set out in the National Statement were used in the ethics decision–making process, and that from a research–governance point of view, the research could happen, particularly involving emergency care in scenarios such as I have explained where there might be observational research where there is low–risk negligible research, as defined by the NHMRC [National Health and Medical Research Council] statement, was permissible. Obviously, I am not privy to legal opinion. I am not a legal expert. I understand that all legislation is subject to

[22] Submission 17 from Western Australian Health Translation Network and Health Consumer's Council (WA), 8 June 2020, p 4.

[23] Clinical Associate Professor David Mountain, Emergency Medicine Representative, Australian Medical Association (WA), transcript of evidence, 1 October 2020, p 4.

interpretation and that there are differing views, which is essentially what the situation was where there was a diversity of opinion, and that is why formal advice was sought.[24]

- Professor Adrian Regli, Intensive Care Specialist, St John of God Hospital:

  We all commonly treat patients who lack capacity, and we discussed treatments with the relatives, and we talk about different treatments and ask, "What do you think?" We always probably consider it as a research treatment, so therefore it is a type of treatment. Nobody, we felt, was unhappy—like patients or relatives—with that. Nobody came up with, "How can you? This is not in keeping." It was more like the lawyers, I think, coming and saying, "Because it's not mentioned, is it actually lawful?[25]

- Professor Gary Geelhoed, Executive Director, Western Australian Health Translation Network:

  Not that I am aware of, and that was as a researcher for all those years and I was assistant director general, Chief Medical Officer, for five or six years—no. To make a point, too, there was a revision. In 2015, people were asked to look at the guardianship act and give feedback on that. When this all arose since 2018 when that index case was blocked, it never came across my desk. I was responsible for research in the Health Department. The research development unit was mine, and yet I was never asked to comment on that back in 2015 because obviously my view would have been very different and strong. Something came back from the Health Department but it did not come from me as someone who was assistant director general for clinical services and research.[26]

Statutory Review in 2015

2.10 In November 2015, the Department of the Attorney General (now known as the Department of Justice) published a review of the *Guardianship Administration Act 1990* (Statutory Review).[27]

2.11 During initial consultations for the Statutory Review, the Public Advocate and the Department of Health advised that consent to medical research was a major issue in relation to the treatment of people with decision making disabilities. As a result, this issue was specifically included in the Statutory Review's terms of reference.[28]

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24 Dr Stephen Macdonald, Staff Specialist in Emergency Medicine, Royal Perth Hospital, Australasian College for Emergency Medicine, transcript of evidence, 30 September 2020, p 9.

25 Professor Adrian Regli, Intensive Care Specialist, Sir Charles Gairdner Hospital, transcript of evidence, 30 September 2020, pp 9–10.

26 Professor Gary Geelhoed, Executive Director, Western Australian Health Translation Network, transcript of evidence, 1 October 2020, p 6.

27 This review was done in accordance with the *Acts Amendment (Consent to Medical Treatment) Act 2008*, s 14.

28 Department of the Attorney General, *Statutory Review of the Guardianship and Administration Act 1990,* November 2015, p 5.

2.12 The Statutory Review ultimately made 86 recommendations. The Amending Act has implemented Recommendation 6.1 and 7. Recommendation 6.1, 6.2 and 7 are set out below:

> **Recommendation 6:** That the *Guardianship and Administration Act 1990* is amended to include:
>
> 6.1 That in addition to treatment decisions, a decision may be made on behalf of a person, including a represented person, for that person to participate in medical research, including treatment that is part of research when:
>
> - it is deemed to be in the person's best interests
> - the research will not involve any known substantial risks to the participants or if there are existing treatments for the condition concerned, will not involve material risks greater than the risks associated with those treatments
> - the research has been approved by a human research ethics committee
>
> and consideration is given to
>
> - the wishes of the person, so far as they can be ascertained
> - the nature and degree of any benefits, discomforts and risks for the person in having or not having the procedure
> - any other consequences to the person if the procedure is or is not carried out
> - any other prescribed matters.
>
> 6.2 Health professionals acting under the urgent provisions in sections 110ZI and 110Z1A will not be permitted to make a decision on behalf of a represented person for that person to participate in medical research, including treatment that is part of research.
>
> **Recommendation 7:** That the definition of 'research' is to be the same as the definition in the National Statement on Ethical Conduct in Human Research prepared by the National Health and Medical Research Council, the Australian Research Council and the Australian Vice–Chancellor's Committee. [29]

2.13 The Amending Act differs from recommendation 6.2 in that it permits medical research on an incapacitated research candidate in urgent circumstances. This was confirmed by Hon Sue Ellery MLC during the second reading debate of the Bill as follows:

> Proposed section 110ZR, which is not the one we are looking at now, gives effect to recommendation 6.1. Proposed section 110ZS is contrary to recommendation 6.2.[30]

2.14 The Committee asked the Department of Justice to explain the basis for recommendation 6.2:

> **Ms DELLAR:** As you would have seen in the review, that report does not actually state what the basis of recommendation 6.2 is. It does not explain why that recommendation was made, so it is not obvious, on first read, why that was made. I could only guess that it is to do with the consent issues in terms of an emergency

[29] ibid., recommendation 6–7.

[30] Hon Sue Ellery MLC, Western Australia, Legislative Council, *Parliamentary Debates (Hansard)*, 2 April 2020, p 2044.

situation—that it did not allow the consent of the person. That is just a guess of mine. I do not know the basis of that recommendation.

The CHAIR: Is proposed section 110ZS of the Amendment Act inconsistent with recommendation 6.2?

Ms DELLAR: Yes, it is recognised that is inconsistent with recommendation 6.2. However, following the review, as some of the Department of Health people here today have just said, prominent research bodies demonstrated after that time that there was a need to be able to conduct research upon incapacitated people in urgent situations.[31]

2.15 The Department of Health provided the following explanation as to why recommendation 6.2 was not being implemented by the Amending Act:

> The adoption of this recommendation would prevent research in emergency situations where participation in research is time–critical and a research decision–maker is not available to make a decision on behalf of the person. There is a significant niche of research that focuses on the discovery and application of time–critical diagnostics, decision–making and treatment that saves lives, prevents or reduces disability and restores health. This research is essential to generate evidence to support a new treatment or demonstrate which treatment has the best health outcomes.
>
> Following feedback provided by research stakeholders, the Attorney General and Minister for Health requested the Department [of Health] to provide recommendations with regard to research in emergency situations so this could be considered in the Act amendments. In light of this, the Amending Act amended the Act to include s 110ZS which allows for a person needing urgent treatment to be included in medical research approved by a HREC [human research ethics committee] without a research decision–maker.[32]

Implementing the recommendations of the Statutory Review

2.16 Except for recommendations 6.1 and 7, none of the recommendations of the Statutory Review have been implemented by legislation. In their written submission, the Law Society of Western Australia requested urgent consideration be given to progressing the other recommendations of the Statutory Review.[33]

2.17 In a letter to the Select Committee into Elder Abuse in 2018, the Attorney General, Hon John Quigley MLA said that the government supports 77 of the 86 recommendations with nine recommendations not supported.[34] The Attorney General also advised that a bill to amend the *Guardianship and Administration Act 1990* had been approved by Cabinet in December 2017 and 'will be introduced in the Spring session [of Parliament in 2018]'.[35]

2.18 The Select Committee into Elder Abuse recommended the government introduce a bill to implement the recommendations of the Statutory Review as a matter of urgency.[36] This

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31 Subhan Dellar, Acting Principal Policy Officer, Department of Justice, transcript of evidence, 1 October 2020, p 7.

32 Submission 25 from Department of Health, 9 June 2020, pp 5–6.

33 Submission 28 from Law Society of Western Australia, 17 June 2020, p 3.

34 These were recommendations 10, 17, 32, 33, 34, 35, 37, 39 and 67. Western Australia, Legislative Council, Select Committee into Elder Abuse, '*I Never Thought It Would Happen to Me: When Trust is Broken*', 13 September 2018, p 87. Hon John Quigley MLA, Attorney General, letter, 26 April 2018.

35 Western Australia, Legislative Council, Select Committee into Elder Abuse, '*I Never Thought It Would Happen to Me: When Trust is Broken*', 13 September 2018, p 87.

36 ibid., recommendation 24.

Committee notes that a bill to implement the remaining supported recommendations has not been introduced at the time of writing this report in November 2020.[37]

2.19 The government's commitment to implementing the supported recommendations was noted by Hon Sue Ellery MLC during the second reading debate of the Bill:

> The government is committed to implementing all the supported recommendations from that statutory review. However, in the current environment, the recommendations that address the issue of consent to medical research are crucial. The amendments in the Guardianship and Administration Amendment (Medical Research) Bill 2020 will ensure that Western Australians have the opportunity to participate in world–leading medical research specifically targeted at combating COVID–19. The drafting of a broader amendment bill will progress as soon as the legislative priorities occur.[38]

2.20 A similar response was given by the Department of Justice when asked to explain what steps have been taken to implement the remaining recommendations:

> **The CHAIR**: The Amendment Act seeks to make recommendations 6.1 and 7 of the statutory review. What steps have been taken to implement the remaining 84 recommendations?
>
> **Ms DELLAR**: The government is committed to implementing all the supported recommendations. However, the amendments in respect of the consent to medical research became prioritised in 2018 due to the lack of ability to carry out research. In February this year, it then became critical and we received instruction to urgently progress those particular recommendations—those amendments. The broader amendment bill will continue to be drafted when the priorities allow for it.[39]

FINDING 2

The Statutory Review of the *Guardianship and Administration Act 1990* in November 2015 made 86 recommendations.

FINDING 3

The *Guardianship and Administration Amendment (Medical Research) Act 2020* is consistent with recommendations 6.1 and 7 of the 2015 Statutory Review of the *Guardianship and Administration Act 1990*.

FINDING 4

The *Guardianship and Administration Amendment (Medical Research) Act 2020* is contrary to recommendation 6.2 of the 2015 Statutory Review of the *Guardianship and Administration Act 1990*.

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37 That is, a bill to implement the 77 supported recommendations other than 6.1 and 7 as implemented by the Guardianship and Administration Amendment (Medical Research) Bill 2020 and *Guardianship and Administration Amendment (Medical Research) Act 2020*.

38 Hon Sue Ellery MLC, Western Australia, Legislative Council, *Parliamentary Debates (Hansard)*, 2 April 2020, p 2036.

39 Subhan Dellar, Acting Principal Policy Officer, Department of Justice, transcript of evidence, 1 October 2020, p 7.

FINDING 5

The *Guardianship and Administration Amendment (Medical Research) Act 2020* does not implement any of the remaining 84 recommendations from the 2015 Statutory Review of the *Guardianship and Administration Act 1990*. However, the government is committed to implementing the remaining supported recommendations of the 2015 Statutory Review.

Discontinuance of the involvement of incapacitated research candidates in medical research in 2018

2.21 The involvement of incapacitated research candidates in medical research came to an end in 2018. This was confirmed by submissions received from the following stakeholders who gave evidence that the practice was discontinued after the Department of Health provided guidance to all health service providers in Western Australia:

- Hon Eric Heenan QC:

  > In or about the first half of 2018 the Health Department of Western Australia (HDWA) issued directions that no clinical trials or medical research could be conducted or continued involving patients who, either temporarily or permanently, were unable to provide personal informed consent to participation in that study. This prohibition extended to patients who were sentient at the commencement of the trial or study but who had become, either progressively or suddenly, incapacitated during the course of the continuing study.[40]

- Western Australian Health Translation Network and Health Consumer's Council:

  > An alternative legal opinion in 2018 shutdown all such research in WA, resulting in Western Australians being denied access to clinical trials comparing existing therapies and of new therapies becoming available in other Australian states and territories. Local researchers were forced to return grant funding to the NHMRC [National Health and Medical Research Council], research infrastructure and trained staff were lost and WA's reputation for research was adversely affected. Most importantly it precluded incapacitated WA patients from the benefits of being involved in vital research.[41]

Guidance from the Department of Health

2.22 The Committee wrote to the Minister for Health, Hon Roger Cook MLA, requesting a copy of the guidance issued by the Department of Health in 2018 that led to the discontinuance of medical research involving research candidates. The Minister responded as follows:

> The DOH is unaware of a formal directive of the nature referred to in your letter.
>
> Notwithstanding this, the following information may be relevant:
>
> - From June 2018, with assistance from the DOH [Department of Health] and the State Solicitor's Office (SSO), WA Health Services Providers (HSPs) were requested to review research projects that potentially did not comply with the Act at that time, and if required to suspend projects or amend the research protocols to ensure compliance with the Act.

[40] Submission 13 from Hon Eric Heenan QC, 5 June 2020, p 2.

[41] Submission 17 from Western Australian Health Translation Network and Health Consumer's Council (WA), 8 June 2020, p 4.

- In December 2018, responding to requests for clarification regarding the WA legislative environment for the involvement of incapacitated adults in research, the DOH provided a statement to WA HSP Chief Executives to provide guidance pending amendment of the Act.[42]

2.23 The Committee asked the Department of Health to explain the reason for the request in June 2018 for health service providers to review their research projects for compliance with the *Guardianship and Administration Act 1990*. The Committee received the following response:

> It is understood that Health Service Providers (HSPs) sought legal advice with respect to particular research projects involving incapacitated patients. This highlighted confusion around the distinction between treatment and research (due to the interpretation of "other health care") and also the application of an ethical waiver of consent. HSPs reviewed projects to determine if there were any that had enrolled incapacitated adults in a manner inconsistent with the interpretation of the legislation at that time.
>
> In December 2018, the DoH provided a Statement to HSP Chief Executives to clarify the legislative environment. This Statement was endorsed by the State Solicitor's Office.[43]

2.24 A copy of the guidance provided by the Department of Health in December 2018 is set out in Appendix 4. This guidance appears to recommend health service providers discontinue the involvement of incapacitated research candidates in medical research. Relevantly it states:

> The *Guardianship and Administration Act 1990* (the Act) enables a substitute decision–maker to be appointed to make decisions in the best interests of an adult with a decision–making disability.
>
> It has been recognised that the Act supports consent (or refusal of consent) by substitute decision–makers with regards to the provisions of treatment but not for participation in research projects. (Emphasis in original)
>
> …
>
> There appears to be some misconception that a person who is authorised by the Act to make a "treatment decision" that they consider to be in the best interests of the incapacitated patient may also consent to the patient's participation in any research that includes an element of "treatment".[44]

FINDING 6

The involvement of incapacitated research candidates in medical research ceased in Western Australia after the Department of Health sent guidance to health service providers advising that while a person may be authorised to make a medical treatment decision for an incapacitated patient, this did not extend to consenting to a patient's participation in medical research.

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42 Hon Roger Cook MLA, Minister for Health, letter, dated, 7 July 2020.

43 Dr James Williamson, Assistant Director General, Clinical Excellence Division, Department of Health, Answer to question on notice No 2 asked at hearing held 1 October 2020, dated 9 October 2020, p 3.

44 Attached as Appendix 4. Hon Roger Cook MLA, Minister for Health, letter, dated, 7 July 2020, pp 2–5.

Response to discontinuance of the involvement of incapacitated research candidates in medical research in 2018

2.25 The discontinuance in 2018 of the involvement of incapacitated research candidates in medical research was seen by many as an unsatisfactory outcome. The following stakeholders gave their views on the effect of the discontinuance:

- Hon Eric Heenan QC:

  > the directives from the HDWA [Health Department of Western Australia] in early 2018 were seen by many doctors, hospitals and research institutions as very surprising, unheralded and disturbing. Many important trials then running were disrupted or had to be halted because they involved, to a greater or lesser extent, participation by patients unable, or who had become unable, to give personal informed consent.[45]

- Australian Medical Association (WA):

  > As a result of legislative interpretation applied in WA from 2018 onwards, patients highly dependent on medical care who were unable to give consent to research participation were unable to benefit from medical research, despite the fact that their involvement in such research would have met NHMRC's [National Health and Medical Research Council] standards and would have been permitted in other states and territories. This has damaged the research capabilities of WA's critical care clinicians, resulted in loss of investment of research grant funding in WA and detracted from the goal of developing WA's medical research capabilities.[46]

- Australasian College for Emergency Medicine:

  > In 2018, a new legal interpretation of the Act determined that clinical research was not permitted under the provisions for substitute decision making. All ongoing research involving incapacitated patients in WA ceased, and no new research studies involving incapacitated patients have been approved. As a consequence, many critically ill and injured patients in WA have been denied access to HREC [human research ethics committee] approved clinical research into better treatments which are available to their counterparts in all other states and territories.[47]

- Sir Charles Gairdner Osborne Park Health Care Group:

  > Prior to the Amendment WA was very limited in the research that could be conducted in Emergency Medicine, Intensive Care and prehospital care, due to many of their patients being incapacitated whilst on ventilators, critically ill or having impaired capacity i.e. dementia. As a result West Australians did not have the opportunity to access potentially life–saving research which was available in other Australian jurisdictions.[48]

Preparation of the Bill and Amending Act

2.26 The discontinuance of medical research in 2018 caused a number of stakeholders to contact the Attorney General to express their dissatisfaction. Hon Eric Heenan QC gave the following account of the events that followed:

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45 Submission 13 from Hon Eric Heenan QC, 5 June 2020, p 5.

46 Submission 19 from Australian Medical Association (WA), 8 June 2020, pp 3–4.

47 Submission 21 from Australasian College for Emergency Medicine, 8 June 2020, p 2.

48 Submission 26 from Sir Charles Gairdner Osborne Park Health Care Group, 12 June 2020, p 1.

> As a result, a series of submissions was made to the Attorney General about the unsatisfactory consequences of this new approach and the great need for a solution to be found, preferably by amending legislation or by any other acceptable means. As a consequence, the Hon J Quigley LLB JP MLA, Attorney General, and the Hon Roger Cook MLA, Minister for Health, received a deputation from several interested parties and advisors in April 2019. Present at that meeting were the Ministers, the State Solicitor, the State Chief Medical Officer, representatives of the Australian Medical Association (WA Branch) (AMA), the Harry Perkins Research Institute, and of St John of God Health Care Inc. Both Ministers recognised the need for reform and attention turned to the best and most efficient way of achieving this. Assurances were given that amending legislation would be introduced as soon as practicable to permit, under suitable protective rules, medical research involving participation by patients temporarily or permanently unable to give personal informed consent. This was the genesis of this current G&AMRA [*Guardianship and Administration Amendment (Medical Research) Act* 2020] which followed an extensive period of consultation between the interested parties, HDWA [Health Department of Western Australia], SSO [State Solicitor's Office] and the Ministers.
>
> Extensive consideration of solutions adopted in other States and Territories was undertaken and in January 2020 a preliminary discussion draft of a Bill was distributed in confidence to the interested parties for consideration and comment. This led to renewed rounds of submissions in the first quarter of this year. It is a reflection of the considerable attention given by the government to the submissions of the interested parties that many of those further submissions were also accepted before the Bill was introduced to the Parliament. This is only to emphasise that long and careful consideration was given to the drafting of the legislation.[49]

2.27 Ms Jodie Hegarty, Manager, Research Development Unit, Department of Health provided evidence about further consultation that was undertaken:

> In October 2018, we provided recommendations because the Bill was being expedited but then there were concerns that statutory review recommendation 6.2, which did not allow for research in urgency treatment situations, was not going to be included. These were being put on hold and we were asked to do a consultation with stakeholders and provide some recommendations. At that time, we consulted with the human research ethics committee chairs and researchers, including those that would be involved in emergency medicine research. There was the Chief Psychiatrist proxy, research directors and consumer representation, so it was a targeted consultation, but it was allied health representatives and nursing representatives. There was an aim to cover a scope there.[50]

Recommencing medical research under the Amending Act

2.28 The Bill was passed as a matter of urgency between 1 and 2 April 2020 and received Royal Assent on 6 April 2020. The substantive provisions of the Amending Act came into operation on the following day.[51]

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49 Submission 13 from Hon Eric Heenan QC, 5 June 2020, pp 7–8. Also see, Dr James Williamson, Assistant Director General, Clinical Excellence Division, Department of Health, transcript of evidence, 1 October 2020, p 4.

50 Jodie Hegarty, Manager, Research Development Unit, Department of Health, transcript of evidence, 1 October 2020, p 5.

51 This does not include the sunset clause provisions which commence on 8 April 2024. *Guardianship and Administration Amendment (Medical Research) Act 2020,* ss 2, 13, 15.

2.29 As of 9 October 2020, nobody was enrolled in medical research pursuant to the amendments introduced by the Amending Act.[52]

2.30 The Department of Health gave the following explanation for the delay in medical research being recommenced under the Amending Act:

> Our understanding is that there have not yet been enrolment using this legislation, however there are projects which are close to being approved and in a position to recruit candidates.
>
> The following points are provided to explain the delay between the passing of the Act amendments and candidate enrolment.
>
> Supporting Framework
>
> - The Act Amendment was expedited through Parliament.
> - Time was required following this to understand the Act Amendment legislation (DoH [Department of Health], HSPs [health service providers], HREC [human research ethics committee] Chairs, Research Governance Officers, researchers).
> - DoH has undertaken the following work to develop supporting documents (Guidance Document, Research Decision Forms, Research Decision Report) which will assist with implementation of the legislation and ensure compliance:
>   - involved a consultation process with public health system Research Directors and HREC Chairs
>   - public and private stakeholders were advised that this work was in progress and asked to contact DoH if they needed to proceed before the supporting documents were made public (so that we could ensure this did not delay the commencement of research activity using this legislation)
>   - the DoH has been contacted by HRECs, ethics officers, governance officers and researchers from public hospitals, private hospitals and universities for clarifications on the legislation and updates on the supporting documents
>   - Communication has also occurred with the Public Advocate and the Mental Health Commission
>   - MfH [Minister for Health] approval for report template received 29/09/2020 (as per legislative requirement); work then progressed to make the supporting documents publicly available and communicate this.
>
> Research Activity
>
> - To use the new legislation researchers are either making amendments to existing research projects (national or local) or developing new projects.
> - In some cases, ethics approval may already be in place (i.e. if national project) and only research governance approval is required; and in other

[52] Dr James Williamson, Assistant Director General, Clinical Excellence Division, Department of Health, Answer to question on notice No 42 asked at hearing held 1 October 2020, dated 9 October 2020, p 12.

cases, where there is a new or amended research protocol, both ethics approval and research governance approval are required.

- Time is required to develop appropriate research protocols and ensure that research is ethically and scientifically sound, and that the site governance requirements are met.
- The ethics and governance approval processes are more complex due to the fact that this is new legislation which affects vulnerable people and caution is being taken to ensure it is being applied correctly.
- The DoH is aware that HSPs are working closely with researchers to assist them to develop projects and ensure their compliance.
- Due to the fact that the Act Amendments were less than 6 months ago these activities are still in progress.
- While the DoH is not aware of any enrolments that have yet occurred, it is expected that enrolment of participants in these projects will commence in the near future as a number of projects have indicated that they will require the Research Decision Report in the coming weeks.
- Some examples of potential research activity includes, research into COVID–19 ventilated or critically ill patients, brain injury/disease, aged care.[53]

Statutory forms

2.31 In his written submission to the Committee in June 2020, Hon Eric Heenan QC noted statutory forms required by s 110ZZC of the *Guardianship and Administration Act 1990* would need to be approved by the Minister for Health in order for medical research to be performed under the Act:

> The reporting obligations under section 110ZZC, while specific, are not as yet fully known. This is because the researcher must give the Minister for Health a written notice in a form to be approved stating the particulars required by that section. At the time of writing this submission the details of the form for the written notice approved by the Health Minister are not known so this needs to be clarified with some urgency.[54]

2.32 At the hearing with Mr Heenan on 30 September 2020, the Committee heard that these forms had not been finalised and were delaying the recommencement of medical research:

> **Hon NICK GOIRAN**: I am just interested to get a further understanding as to a remark that was made earlier about what I paraphrase as the lack of use of these new provisions. I think these provisions were passed by Parliament in April.
>
> **Mr HEENAN**: April—yes.
>
> **Hon NICK GOIRAN**: And it sounds like they have not been used.
>
> **Mr HEENAN**: The answer to that is the necessary forms required by the legislation to be submitted to the minister have not yet been approved.

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53 Dr James Williamson, Assistant Director General, Clinical Excellence Division, Department of Health, Answer to question on notice No 37 asked at hearing held 1 October 2020, dated 13 October 2020, pp 10–11.

54 Submission 13 from Hon Eric Heenan QC, 5 June 2020, p 20.

Hon NICK GOIRAN: So the situation in Western Australia remains as it was pre the passage of this bill, at the current time?

Mr HEENAN: I am afraid it does. I met with one of my colleagues only on Monday of last week to discuss this situation, because the St John of God Health Care HREC [human research ethics committee] has deferred or modified applications for new trials which did involve disabled persons. There was one multicentre trial which had originated from Victoria—Ballarat and Bendigo—and they wanted to do it in Perth in relation to COVID studies, but it was going to involve some people who could not consent. Our conclusion was that until these forms had been approved, it could not be operated in Western Australia, so while it could go ahead under Victorian law, it could not in WA. I have been informed by a representative of Royal Perth Hospital that the HREC there has approved some studies involving incapacitated people, but they have not been commenced yet because of the lack of forms. I am under the impression that approval is imminent.[55]

2.33 The Committee received a draft copy of the statutory forms on 30 September 2020.[56] They were made publicly available on 9 October 2020 following approval from the Minister for Health.[57] The statutory forms are attached as Appendix 5.

Human research ethics committee approval

2.34 A number of witnesses gave evidence that the process of obtaining human research ethics committee approval had delayed the recommencement of medical research. This was due to the difficulties in understanding the new legislative framework introduced by the Amending Act:

- Professor Jim Codde, Director, Institute for Health Research, University of Notre Dame:

  It has taken us over three months to navigate through questions and queries by the Notre Dame HREC [human research ethics committee] group to understand the role ostensibly of the independent medical prescriber or practitioner, and some other nuances where they wanted some legal input and all the rest of it. We are the first cab off the rank, if you like, and there is a lot of learning to go and a lot of interpretation and a lot of uncertainty and wanting to do it correctly, and I admire them for that, but it has meant that at this point we finally—only two days ago—got HREC approval to progress our study.[58]

- Professor Adrian Regli, Intensive Care Specialist, St John of God:

  We are preparing one of the trials and still going through understanding this law and what it means and then trying to see what HREC [human research ethics committee] advises and what the legal advisers and all the governance officers advise. We are trying to explain that to who we have now identified who could potentially be an independent medical practitioner, and we have to get them up to speed and see if they are happy to take part, and to operationalise this. We are still in that process. But we will have eventually, hopefully, a study that will enable patients with COVID to be enrolled and have the benefit of being enrolled.[59]

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55 Hon Eric Heenan QC, transcript of evidence, 30 September 2020, pp 9–10.

56 Dr James Williamson, Assistant Director General, Clinical Excellence Division, Department of Health, Answer to question on notice No 36 asked at hearing held 1 October 2020, dated 9 October 2020, p 10.

57 ibid.

58 Professor Jim Codde, Director, Institute for Health Research, University of Notre Dame, transcript of evidence, 30 September 2020, p 2.

59 Professor Adrian Regli, Intensive Care Specialist, St John of God, transcript of evidence, 30 September 2020, p 11.

2.35 The Committee notes that the Department of Health published a guidance document on 9 October 2020 to assist researchers and health service providers understand the new medical research laws.[60]

COVID–19 in Western Australia

2.36 The Committee heard evidence from the following witnesses that medical research for COVID–19 has not occurred in Western Australia due to a lack of patients in this state:

- Professor Anthony Celenza, Australasian College for Emergency Medicine:

> As I have mentioned, there are no enrolees for any research, whether it is COVID or not. The other problem is that there are no COVID patients really, and no COVID patients that lack capacity that would be enrolled. But the potential is there for that to happen—hopefully not.[61]

- Professor Gary Geelhoed, Executive Director, Western Australian Health Translation Network:

> COVID–19 is obviously a fantastic problem to have as a researcher—we do not have any patients! There were two studies that were already in place, theoretically, for when we got the next pandemic, and that was the ASCOT trial, which was to treat patients already in hospital and try to keep them out of the intensive care unit by trying different modes of treatment, and then there was the REMAP–CAP trial, which was actually for people in the intensive care unit to try the different treatments, but I believe that the ethics around that, even though it is theoretical at the moment, have stalled … but the last time I heard, the ethics committees and governance around the hospital are still very confused and with the conditions they are putting on all these trials, they are just not being passed. In theory and in practice they just would not work.[62]

FINDING 7

The Guardianship and Administration Amendment (Medical Research) Bill 2020 was passed as a matter of urgency between 1 and 2 April 2020 and received Royal Assent on 6 April 2020. The substantive provisions of the resulting Act, the *Guardianship and Administration Amendment (Medical Research) Act 2020*, came into operation on 7 April 2020.

FINDING 8

Medical research under the *Guardianship and Administration Act 1990* was not undertaken between the commencement of the *Guardianship and Administration Amendment (Medical Research) Act 2020* in April 2020 and 9 October 2020, at least in part, because the necessary statutory forms were not approved until 9 October 2020.

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60 Department of Health, *Guidance Document: Involving Incapacitated Adults in Health and Medical Research,* 6 October 2020, p 5. See: https://rgs.health.wa.gov.au/Documents/GAA%20Medical%20Research%20Guidance%20Document.pdf. Viewed 12 October 2020.

61 Professor Antonio Celenza, Professor of Emergency Medicine, St John of God, Australasian College for Emergency Medicine, transcript of evidence, 30 September 2020, p 11.

62 Professor Gary Geelhoed, Executive Director, Western Australian Health Translation Network, transcript of evidence, 1 October 2020, pp 7–8.

CHAPTER 3
Laws governing medical research in Australia

Introduction

3.1 This chapter considers the legal requirements for medical research in Australia. It begins with a short history of guardianship laws before considering the laws governing the involvement of incapacitated research candidates in medical research in Australia today.

3.2 The legislative framework of medical research laws in Australia is largely comprised of state and territory guardianship laws. They fall into two broad categories: jurisdictions that have laws specifically governing medical research and those that conduct medical research pursuant to non–specific laws governing medical treatment.

3.3 The Amending Act provides a specific legislative framework to provide clearer guidelines for medical research where research candidates in Western Australia lack the capacity to make decisions for themselves. This will move Western Australia to the category of jurisdictions that have laws specifically governing the involvement of incapacitated research candidates in medical research.

Origin of guardianship laws

3.4 Guardianship laws have a long history that can be traced back to the first written laws in ancient Rome, the Twelve Tables.[63] According to the Twelve Tables, a family member or paternal relative is responsible for protecting a person and their goods if they are unable to take care of themselves.[64]

3.5 There is also evidence of guardianship laws dating back to medieval England.[65]

3.6 During the 13th century, the introduction of the statute *De Praereogativa Regis* in the United Kingdom made the Crown responsible for the property and personal interests of people with an intellectual disability or who suffered from a mental illness.[66] This jurisdiction, known as *parens patriae*, arises from the direct responsibility of the Crown to take care of those who cannot look after themselves.[67]

3.7 The Crown later delegated the *parens patriae* power to the Lord Chancellor.[68] The Lord Chancellor (or a Master of the Chancery Court) could conduct an inquiry into whether or not a person was able to make reasonable judgements. If not, a family member would usually be appointed to manage the person's estate and person.

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63 Antonio Buti, *The Early History of the Law of Guardianship of Children: From Rome to the Tenures Abolition Act 1660,* (2003) 7(1) University of Western Sydney Law Review 92.

64 Frank Johns and Vicki Joiner Bowers, *Guardianship Folly: The Misgovernment of Parens Patriae and the Forecast of its Crumbling Linkage to Unprotected Older Americans in the Twenty–First Century—A March of Folly? Or Just a Mask of Virtual Reality?*, (1997) 27 Stetson Law Review 1, 10.

65 Antonio Buti, *The Early History of the Law of Guardianship of Children: From Rome to the Tenures Abolition Act 1660,* (2003) 7(1) University of Western Sydney Law Review 92.

66 Nick O'Neill and Carmelle Pesiah, *Capacity and the Law*, [2011] Sydney University Press Law Books 1, 5.2.1.

67 *Secretary, Department of Health & Community Services v B* (1992) 175 CLR 218 (commonly known as Marion's Case).

68 Henry Montagu Randall Pope, *A Treatise on the Law and Practice of Lunacy*, Sweet and Maxwell, London, 1890, p 25.

3.8 When the colony of New South Wales was established, the Governor was at first responsible for people who could not exercise reasonable judgement.[69] This power was later transferred to the Supreme Court through Letters Patent by the *New South Wales Act 1923* (UK).[70] The Supreme Court of Western Australia was later given this same power pursuant to the *Supreme Court Act 1935*.[71]

3.9 Although the Supreme Court's inherent power continues to apply where there are gaps in the legislation, matters of guardianship in Western Australia today are largely determined by the *Guardianship and Administration Act 1990*.[72]

Modern guardianship laws in Australia

3.10 Between 1986 and 2000 all states and territories in Australia underwent legal reform that introduced the modern guardianship laws that exist today. This reform was motivated by a move to deinstitutionalise people with intellectual disabilities and to assist them to live in the community.[73] The current *Guardianship and Administration Act 1990* is an example of legislation passed at this time.

3.11 All jurisdictions in Australia have guardianship laws that provide for a substitute decision–maker to authorise medical treatment on behalf of a person who is unable to make reasonable decisions about their own medical treatment. However not all jurisdictions have laws providing for a substitute decision–maker to provide consent to medical research for a person in this position.

Western Australia

3.12 In Western Australia, the provisions that govern the process of conducting medical research on incapacitated research candidates are contained in Part 9E of the *Guardianship and Administration Act 1990*. These provisions prescribe requirements about who can make a substitute decision for a person who is unable to make reasonable judgements in respect of their involvement in medical research.

3.13 The *Guardianship and Administration Act 1990* provides a hierarchy of people who can make a research decision in relation to a research candidate.[74]

3.14 'Medical research' is defined in the *Guardianship and Administration Act 1990* as:

- research conducted with or about individuals, or their data or tissue, in the field of medicine or health
- an activity that is undertaken for the purposes of that research.[75]

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69 J McClemens and J Bennett, *Historical Notes on the Law of New South Wales*, (1962–1964) 4 Sydney Law Review, 49, 58–60.

70 *New South Wales Act 1923* (UK), 4 George IV Ch 96.

71 *Supreme Court Act 1935,* s 16(1)(d)(ii).

72 *Guardianship and Administration Act 1990,* s 3A.

73 Lawrence Laikind, *The Application of Article 12 of the Convention on the Rights of Persons with Disabilities (CRPD) to Decisions of Australian Tribunals and Court Administering Guardianship Legislation,* Queensland University of Technology, 2016, p 12.

74 *Guardianship and Administration Act 1990,* ss 110ZP and ZQ.

75 ibid., s 3AA.

State Administrative Tribunal

3.15 The State Administrative Tribunal of Western Australia has jurisdiction to make guardianship and administration orders.[76]

3.16 The Bill and Amending Act have introduced provisions for reviewing medical research decisions made under Part 9E of the *Guardianship and Administration Act 1990*. Among other things, these provisions set out the procedure to be followed for an application to review a medical research decision. They are discussed further in chapter 10.

3.17 Unlike some other jurisdictions, the State Administrative Tribunal is not required to approve medical research. The main hurdle in obtaining approval for a medical research project in Western Australia is obtaining ethics approval from a human research ethics committee. This is discussed further in chapter 4.

Urgent research and treatment

3.18 Section 110ZS of the *Guardianship and Administration Act 1990* as introduced by the Bill and Amending Act allows the involvement of incapacitated research candidates in urgent medical research without obtaining consent from a research decision–maker where it is not practicable to do so.

3.19 Section 110ZI of the *Guardianship and Administration Act 1990* allows urgent medical treatment to be provided without obtaining consent from a person responsible for the patient where it is not practicable to do so.

Australian Capital Territory

3.20 In the Australian Capital Territory (ACT), three categories of substitute decision–makers may provide consent for a person who is unable to make reasonable judgements to participate in medical research:

- a medical research attorney appointed under the *Powers of Attorney Act 2006* (ACT)
- a guardian appointed under the *Guardianship and Management of Property Act 1991* (ACT)
- a health care attorney appointed under the *Guardianship and Management of Property Act 1991* (ACT) (low–risk research only).

Medical research attorney

3.21 A person who has been appointed under a medical research power of attorney can make decisions about medical research or low–risk research. A medical research attorney is an enduring attorney who has been authorised to make decisions about medical research on behalf of a person who lacks that capacity themselves. They may also have authority to make decisions about medical research if they have been authorised to make decisions about health care matters and their appointment was made prior to the commencement of the *Powers of Attorney Act 2006* (ACT).

3.22 A medical research attorney can authorise low–risk medical research on a person who is not able to make reasonable judgements if the research has been approved by an ethics committee.[77] Research may be considered low–risk if it poses no additional risk of harm than is associated with the person's condition.

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76 ibid., s 13.

77 *Powers of Attorney Act 2006* (ACT), s 41C.

3.23 In order for the medical research attorney to authorise medical research that is not low–risk, all of the following must be satisfied:

- the research has been approved by an ethics committee
- an independent medical practitioner has assessed that the research candidate is unlikely to regain capacity before the latest time that they may meaningfully participate in the research
- the research relates to the research candidate's condition
- the benefit of the research to the research candidate or others with the same condition outweighs potential risks to the research candidate
- participating in the research will not interfere with the research candidate's privacy.[78]

3.24 A medical research attorney must comply with the following principles:

- the research candidate's wishes must be given effect without significantly adversely affecting their interests
- the research candidate's life must be interfered with to the least possible extent
- the research candidate must be encouraged to look after themselves in the community.[79]

Guardian

3.25 Under the *Guardianship and Management of Property Act 1991* (ACT), a person may be appointed as a guardian by the ACT Administrative Tribunal to give consent for medical research.[80]

3.26 A guardian can make a decision to enrol a research candidate in low–risk medical research if it has been approved by an ethics committee and doing so is consistent with any health directive made by the research candidate.

3.27 The requirements for enrolment in medical research that is not low–risk are the same as those for medical research attorneys (see paragraph 3.23).

3.28 The guardian must exercise their decision to enrol a research candidate in medical research:

- consistently with any existing health directive
- having regard to the decision–making principles set out in s 4(2) of the *Guardianship and Management of Property Act 1991* (ACT).

Health care attorney

3.29 Under the *Guardianship and Management of Property Act 1991* (ACT), a health care attorney can make a decision on behalf of a research candidate who is unable to make reasonable judgements about their enrolment in low–risk medical research. The health care attorney for a research candidate is the first person in the following hierarchy:

- domestic partner
- carer
- close relative or close friend.[81]

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78 ibid., s 41D.

79 ibid., s 41B.

80 *Guardianship and Management of Property Act 1991* (ACT), s 7.

81 ibid., s 32B.

3.30 The requirements for a health care attorney to make a decision about low–risk medical research are:

- the research has been approved by an ethics committee
- a health professional determines that the research candidate is likely to benefit from participating in the low–risk research
- a health professional provides the health care attorney information about the following:
  - the condition of the research candidate that is relevant to the research
  - the low–risk research
  - any options for alternative low–risk research
  - the nature and degree of risks involved
  - the likely effect of not participating in the low–risk research
  - the decision–making principles set out in s 4(2) of the *Guardianship and Management of Property Act 1991* (ACT)
  - any other matter the health professional considers relevant.[82]

Role of ACT Administrative Tribunal

3.31 The ACT Administrative Tribunal has the power to:

- give an opinion to assist the substitute decision–maker, if requested[83]
- review a substitute decision–maker's decision about medical research.[84]

Urgent research

3.32 There are no specific provisions in the ACT permitting the involvement of incapacitated research candidates in urgent medical research without obtaining consent from a substitute decision–maker.

New South Wales

3.33 In New South Wales, the involvement of incapacitated research candidates in medical research is governed by the *Guardianship Act 1987* (NSW).

Clinical trials

3.34 Clinical trials conducted in New South Wales involving research candidates who lack the capacity to make reasonable judgements require approval from the New South Wales Civil and Administrative Tribunal.[85]

3.35 A clinical trial is defined by s 33 of the *Guardianship Act 1987* (NSW) as:

> a trial of drugs or techniques that involves carrying out medical or dental treatment on the participants in the trial.

3.36 This is a broad definition. The definition of clinical trial was considered in the following two cases:

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82 ibid., s 32G.

83 *Powers of Attorney Act 2006* (ACT), s 18.

84 *Guardianship and Management of Property Act 1991* (ACT), s 32JB.

85 *Guardianship Act 1987* (NSW), s 45AA.

- In 2015, the New South Wales Civil and Administrative Tribunal ruled that a research project that proposed using technologies including Nintendo Wii, Xbox Kinect and Fitbit to determine physical activity levels in people with mobility limitations was a clinical trial. It held the definition of clinical trial is 'unambiguously wide'.[86]
- In 2016, the New South Wales Civil and Administrative Tribunal Appeals Panel ruled that medical research involving the administration of an approved drug listed on the Therapeutic Goods Administration's Register of Therapeutic Goods was not a clinical trial despite it being administered for a longer period than it had approval for. The Appeals Panel held the definition of clinical trial is 'limited to trials of drugs or techniques that necessarily involve new medical (or dental) treatment that has not yet gained the support of a substantial number of medical practitioners (or dentists) specialising in the area of practice'.[87]

3.37 The New South Wales Civil and Administrative Tribunal may approve a clinical trial if it is satisfied that:

- it has been approved by an ethics committee
- the trial is intended to cure or alleviate a condition which the research candidate suffers from
- the trial will not involve any known substantial risk to the research candidate greater than the risks associated with existing treatments
- the trial has reached a stage at which safety and ethical considerations make it appropriate that it be available to research candidates who are not able to consent
- it is in the best interests of research candidates who suffer from that condition that they take part in the trial.[88]

3.38 If the New South Wales Civil and Administrative Tribunal approves an application for a clinical trial it can determine whether consent for an incapacitated research candidate can be given by the Tribunal itself, or a person responsible for the research candidate.[89] In most cases the Tribunal will delegate this decision to a person responsible for the research candidate.[90]

3.39 A person responsible for the research candidate is the first person in the following hierarchy:

- guardian
- spouse
- carer
- close friend or relative.[91]

3.40 A request to enrol a research candidate in a clinical trial must include the following information:

- the grounds on which the research candidate can be enrolled

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86 *Application for approval for adults unable to consent to their own treatment to participate in a clinical trial (AMOUNT Rehabilitation Trial)* [2015] NSWCATGD 1, [34].

87 *Shehabi v Attorney General (NSW)* [2016] NSWCATAP 137, [84].

88 *Guardianship Act 1987* (NSW), s 45AA(2).

89 ibid., s 45AB.

90 Rallis Legal, *Laws relating to the giving of consent for persons with impaired capacity to provide informed consent to participate in research in each Australian State and Territory,* Victoria, April 2016, p 22.

91 *Guardianship Act 1987* (NSW), s 33A.

- the condition of the research candidate that is relevant to the trial
- the effect and risks of any alternative treatments.[92]

3.41 In considering a request to make a decision about a research candidate's enrolment in medical research, the New South Wales Civil and Administrative Tribunal or a person responsible for the research candidate must consider the views of the research candidate.[93]

Non–clinical trials

3.42 Medical research that is not a clinical trial and does not involve medical or dental treatment can be approved by a person who is responsible for the research candidate. Examples of this may include observational studies and patient interviews.

Urgent research and treatment

3.43 New South Wales does not have specific provisions allowing for medical research to be conducted on incapacitated research candidates without substitute consent being provided from the New South Wales Civil and Administrative Tribunal or a responsible person.

3.44 However, it does contemplate urgent medical treatment being performed on an incapacitated research candidate without substitute consent.[94] The treatment must be necessary as a matter of urgency to:

- save the patient's life
- prevent serious damage to the patient's health
- prevent the patient from suffering or continuing to suffer significant pain.

Queensland

3.45 In Queensland, medical research involving research candidates is governed by the *Guardianship and Administration Act 2000* (Qld).

3.46 The legislative approach in Queensland is similar to that in New South Wales.

3.47 All medical research in Queensland requires approval from the Queensland Civil and Administrative Tribunal. Applications are distinguished based on whether it involves:

- special medical research or experimental health care
- clinical research.

Special medical research or experimental health care

3.48 Special medical research or experimental health care is defined by the *Guardianship and Administration Act 2000* (Qld) as:

> (a) medical research or experimental health care relating to a condition the adult has or to which the adult has a significant risk of being exposed; or
>
> (b) medical research or experimental health care intended to gain knowledge that can be used in the diagnosis, maintenance or treatment of a condition the adult has or had.[95]

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92 ibid., s 40(2).

93 ibid., s 40(3).

94 ibid., s 37.

95 *Guardianship and Administration Act 2000* (Qld), schedule 2, s 13(2)(a).

Psychological research is excluded.[96]

3.49 In 2006 the Queensland Guardianship and Administration Tribunal (which previously had jurisdiction for guardianship matters) held that treatment for a particular genetic condition did not satisfy the definition of medical research or experimental health care because it was an accepted form of treatment by specialists in the field.[97]

3.50 The Queensland Civil and Administrative Tribunal may approve special medical research or experimental health care if it:

- has been approved by an ethics committee
- the risk and inconvenience to the research candidate is small
- it may result in significant benefit to the research candidate
- the potential benefit cannot be achieved in another way.[98]

3.51 In the case of special medical research or experimental healthcare, the Queensland Civil and Administrative Tribunal may approve medical research that falls into this category and give the required consent for a research candidate to participate in that research.[99]

Clinical research

3.52 Clinical research is defined in the *Guardianship and Administration Act 2000* (Qld) as:

> (a) medical research intended to diagnose, maintain or treat a condition affecting the participants in the research; or
>
> (b) a trial of drugs or techniques involving the carrying out of health care that may include the giving of placebos to some of the participants in the trial.[100]

3.53 The *Guardianship and Administration Act 2000* (Qld) contains the following as examples that are excluded from the definition of clinical research:

- a comparative assessment of administering a proven drug in different ways
- a comparative assessment of the angle at which to set a bed to assist a research candidate's breathing.[101]

3.54 The definition of clinical research was considered by the Queensland Civil and Administrative Tribunal in the following two cases:

- In *Re application by Dr Matthew Hope* [2012] QCAT 191 it was held that a purely observational study satisfied the definition of clinical research because it involved a procedure intended to diagnose a condition affecting the participants.
- In *Avent* [2011] QCAT 598 it was held that a comparative study of antibiotics did not satisfy the definition of clinical research because it was merely comparing known beneficial treatments.

3.55 The Queensland Civil and Administrative Tribunal may approve clinical research on a research candidate if:

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96 ibid., schedule 2, s 13(1).

97 *Re MP* [2007] QGAAT 86.

98 *Guardianship and Administration Act 2000* (Qld), s 72.

99 ibid., s 72.

100 ibid., schedule 2, s 13(1).

101 ibid., schedule 2, s 13(1A).

- it has been approved by an ethics committee
- the clinical research is intended to diagnose, maintain or treat a condition affecting the research candidates
- it will not involve known material risk to the research candidates greater than the risk associated with existing health care
- it has reached a stage at which safety and ethical considerations make it appropriate for the research candidates despite their inability to consent
- it is not adverse to the interests of the research candidates to participate.[102]

3.56 If a clinical trial is approved by the Queensland Civil and Administrative Tribunal, a substitute decision–maker can make a decision regarding an incapacitated research candidate's enrolment in medical research. The process of substitute decision–making is similar to that used in Western Australia. It is determined according to the following hierarchy:

- the terms of an advance health directive
- a guardian
- an attorney appointed by an enduring document
- a spouse
- a carer
- a close friend or relation
- the public guardian.[103]

Urgent research and treatment

3.57 There are no specific provisions in Queensland that allow urgent medical research without the requirement to obtain consent from a substitute decision–maker.

3.58 However, the *Guardianship and Administration Act 2000* (Qld) does permit urgent medical treatment without consent from a substitute decision–maker if it is required to:

- meet imminent risk to the patient's life or health
- prevent significant pain or distress.[104]

Northern Territory

3.59 In the Northern Territory, the involvement of incapacitated research candidates in medical research is governed by the *Advance Personal Planning Act 2013* (NT) and the *Guardianship of Adults Act 2016* (NT).

3.60 In the Northern Territory, an incapacitated research candidate may be involved in medical research through:

- an advance personal plan
- a guardian
- consent provided by the Northern Territory Civil and Administrative Tribunal.

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102 ibid., schedule 2, s 13(3).

103 ibid., s 66.

104 ibid., s 63.

Advance personal plan

3.61 Under the *Advance Personal Planning Act 2013* (NT), a person can make an advance personal plan about their future treatment. This may set out their views, wishes and beliefs in relation to medical research or include the appointment of one or more people to make decisions on their behalf.

3.62 The Northern Territory Civil and Administrative Tribunal may order that an advance personal plan be disregarded if:

- there is no reasonable possibility that the person would have intended it to apply in the circumstances
- it would cause the person unacceptable pain and suffering or would otherwise be wholly unreasonable.[105]

3.63 A person who is appointed in an advance personal plan cannot make decisions about:

- sterilisation
- termination of a pregnancy
- removal of non–regenerative tissue
- special medical research or experimental health care
- health care that is not accepted as best practice.[106]

Guardian

3.64 The *Guardianship of Adults Act 2016* (NT) allows the Northern Territory Civil and Administrative Tribunal to appoint a guardian to make decisions on behalf of a person who is unable to make reasonable judgements. Although a guardian can make decisions regarding health care they are prohibited from making decisions about 'restricted health care'.[107] 'Restricted health care' is defined in the *Guardianship of Adults Act 2016* (NT) as:

> new health care of a kind that is not yet accepted as evidence–based, best practice health care by a substantial number of health care providers specialising in the relevant area of health care.[108]

3.65 Guardians are also prohibited from making decisions about 'health care provided for medical research purposes'.[109] The following activities are excluded from the definition of 'health care for medical research purposes':

- non–intrusive examination
- observation
- collecting information
- health care prescribed by regulations.[110]

3.66 In this way, while a guardian cannot enrol a research candidate in most medical research that involves the provision of medical treatment, they may have authority in some cases to

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105 *Advance Personal Planning Act 2013* (NT), s 41(3).

106 ibid., s 25; *Advance Personal Planning Regulations 2014* (NT), r 4.

107 *Guardianship of Adults Act 2016* (NT), s 23(2).

108 *Guardianship of Adults Regulations 2016* (NT), r 3.

109 *Guardianship of Adults Act 2016* (NT), s 8(1)(d).

110 ibid., s 8(4).

provide substitute consent for non–intrusive activities, including observation or collecting information.

Northern Territory Civil and Administrative Tribunal

3.67 The Northern Territory Civil and Administrative Tribunal has jurisdiction to make a substitute decision on behalf of an incapacitated research candidate if:

- the research candidate has not made a valid advance consent decision about the relevant decision
- the research candidate does not have a guardian who is willing and able to make the relevant decision.[111]

Urgent research

3.68 There are no laws in the Northern Territory that allow urgent medical research on a person who is unable to make reasonable judgements.

3.69 The following comments by the Northern Territory Department of Health were noted in a report prepared for the National Health Medical Research Council in relation to laws governing medical research:

> After reviewing this document, a Northern Territory Department of Health representative informed NHMRC [National Health Medical Research Council] that for certain research studies—for example, an ambulance–administered trial for head injuries—consent is not ordinarily sought from NTCAT [Northern Territory Civil and Administrative Tribunal] for an adult who meets the relevant study's enrolment criteria, unless that person is already subject to a guardianship order.[112]

Victoria

3.70 On 1 March 2020, the *Guardianship and Administration Act 2019* (Vic) came into operation. This Act includes decision–making principles that guardians must consider when making decisions for a represented person.

3.71 Medical research in Victoria is largely governed by the provisions of the *Medical Treatment Planning and Decisions Act 2016* (Vic). It defines 'medical research procedure' as:

> (a) a procedure carried out for the purposes of medical research, including, as part of a clinical trial—
>
> (i) the administration of pharmaceuticals; or
>
> (ii) the use of equipment or a device; or
>
> (b) a prescribed medical research procedure—[113]

3.72 The definition of medical research procedure excludes the following:

- a visual examination of the mouth, throat, nasal cavity, eyes or ears
- measuring a research candidate's height, weight or vision
- observing a research candidate's activities

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111 *Advance Personal Planning Act 2013* (NT), s 44.

112 Rallis Legal, *Laws relating to the giving of consent for persons with impaired capacity to provide informed consent to participate in research in each Australian State and Territory,* Victoria, April 2016, p 30.

113 *Medical Treatment Planning and Decisions Act 2016* (Vic), s 3 (see definition of 'medical research procedure').

- undertaking a survey
- collecting personal or health information
- any procedure prescribed not to be a medical research procedure.[114]

3.73 A medical practitioner may conduct medical research on a research candidate if:

- the research has been approved by an ethics committee

  and

- the research candidate has consented to the procedure under an instructional directive

  or

- the research candidate's medical treatment decision–maker has consented to the research.[115]

3.74 The involvement of incapacitated research candidates in medical research is allowed in circumstances where a medical practitioner has been unable to locate a research candidate's instructional directive or contact their medical treatment decision–maker if the medical practitioner believes on reasonable grounds:

- that inclusion of the research candidate would not be contrary to their values
- one of the purposes of the research is to assess the effectiveness of the procedure being researched
- the research poses no more of a risk to the research candidate than the risk that is inherent in their condition and alternative medical treatment
- the research is based on valid scientific hypotheses that support a reasonable possibility of benefit for the research candidate compared to standard treatment.[116]

Urgent research and treatment

3.75 A health practitioner can administer medical treatment or medical research to an incapacitated person without obtaining consent if they believe on reasonable grounds that it is necessary as a matter of urgency to:

- save the research candidate's life
- prevent serious damage to the research candidate's health
- prevent the research candidate from suffering or experiencing pain or distress.[117]

South Australia and Tasmania

3.76 South Australia and Tasmania do not have legislation that specifically deals with the involvement of incapacitated research candidates in medical research.

3.77 In South Australia medical research can be performed under laws governing medical treatment. This is set out in a policy directive published by SA Health as follows:

> Where an individual lacks the capacity to consent, a person exercising lawful authority for the individual can decide whether the individual will participate in the proposed research.

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114 ibid.

115 ibid., s 75.

116 ibid., s 80.

117 ibid., s 53.

> For clarification, consent provided by a patient or legally authorised person for personal information to be disclosed and used for medical treatment and care is separate to the use of that information for medical and social research purposes.[118]

Urgent research and treatment

3.78 There are no laws in South Australia or Tasmania that authorise the involvement of incapacitated research candidates in urgent medical research.

3.79 In South Australia, a medical practitioner may lawfully administer urgent medical treatment to a patient who is unable to make reasonable judgments if the following apply:

- the medical practitioner and an independent medical practitioner have made an assessment that the treatment is necessary to meet an imminent risk to life or health
- the patient has not refused consent to the treatment
- the medical practitioner has made reasonable inquiries to ascertain if the patient has made an advance health directive.[119]

3.80 In Tasmania, a medical practitioner may lawfully administer urgent medical treatment to a patient who is unable to make reasonable judgments if it is required to:

- save the patient's life
- prevent serious damage to their health
- prevent suffering, pain or distress.[120]

Commonwealth

3.81 There are no Commonwealth laws that specifically deal with the giving of consent for an adult who lacks legal capacity to participate in medical research.

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118 Government of South Australia, SA Health, *Research Governance Policy Directive*, South Australia, 30 July 2020, p 12.

119 *Consent to Medical Treatment and Palliative Care Act 1995* (SA), s 13.

120 *Guardianship and Administration Act 1995* (Tas), s 40.

CHAPTER 4
Ethics of medical research

Introduction

4.1 In addition to the legal framework that has been introduced by the Amending Act, there are also ethical principles that guide the governance and conduct of medical research. This chapter considers the ethical framework for the involvement of incapacitated research candidates in medical research in Australia.

4.2 The National Statement on Ethical Conduct in Human Research (National Statement) contains the guiding principles and standards for medical research in all Australian states and territories.[121] It has a chapter which specifically addresses the involvement of people in medical research who are unable to give consent. The National Statement is based on international standards that have derived from the Nuremburg Code and has evolved and been influenced by the following watershed developments:

- Nuremburg Code
- Helsinki Declaration
- United Nations Convention on the Rights of Persons with Disabilities (UNCRPD)
- British Medical Research Council Ethics Guide.

4.3 Every research institution in Australia has its own Human Research Ethics Committee (HREC). Each of these HREC's is registered with the National Health and Medical Research Council (NHMRC). The NHMRC is a statutory authority and the primary agency of the Australian Government responsible for medical and public health research. Researchers must obtain approval from an HREC before commencing medical research that involves incapacitated research candidates. Each HREC complies with the National Statement.

4.4 The requirement to obtain HREC approval protects the rights of participants by ensuring compliance with ethical codes of practice in medical research.

Ethics—international standards

4.5 For many years attempts have been made to establish fundamental principles of ethical conduct in medical research. In his submission, Hon Eric Heenan QC noted the importance of these ethical standards in the following way:

> There is widespread consensus about the ethical principles governing medical research at the highest level of the medical profession and among Australian national authorities. These principles are of great importance because, in practical terms, they are often very powerful influencing factors for those conducting research and as prominent in their minds as proscriptive legislative rules.[122]

Nuremburg Code

4.6 The Nuremberg Code was formulated in 1947 by American judges sitting in judgement of Nazi doctors accused of conducting medical experiments during World War II. This

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121 National Health and Medical Research Council, Australian Research Council, *National Statement on Ethical Conduct in Human Research* 2007, Canberra. See: https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018. Viewed 12 October 2020.

122 Submission 13 from Hon Eric Heenan QC, 5 June 2020, p 8.

document is commonly recognised as the first list of principles set out to govern modern research ethics.

4.7 The Nuremburg Code contains 10 principles that guide decisions about when medical research is permissible. These are:

1. Voluntary consent is essential
2. The results of any experiment must be for the greater good of society
3. Human experiments should be based on previous animal experimentation
4. Experiments should be conducted by avoiding physical/mental suffering and injury
5. No experiments should be conducted if it is believed likely to cause death/disability
6. The risks should never exceed the benefits
7. Adequate facilities should be used to protect subjects
8. Experiments should be conducted only by qualified scientists
9. Subjects should be able to end their participation at any time
10. The scientist in charge must be prepared to terminate the experiment when injury, disability, or death is likely to occur.[123]

Declaration of Helsinki

4.8 The next major attempt to codify medical research ethics was the development of the Declaration of Helsinki by the World Medical Association in 1964. The Declaration of Helsinki introduced the idea that medical research should require prior approval.

4.9 The 1975 revision of the Declaration of Helsinki specifically required the assessment of research by an independent ethics committee.[124] HREC approval is an important requirement of medical research in Australia today.

4.10 Although the Declaration of Helsinki emphasised the ethical standards that should govern medical research it contemplated exceptions to complying with consent procedures in certain circumstances such as in emergency situations:

> If no [legally authorised representative] is available and if the research cannot be delayed, the study may proceed without informed consent provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the study has been approved by a research ethics committee. Consent to remain in the research must be obtained as soon as possible from the subject or a legally authorised representative.[125]

4.11 The following are key principles of the Declaration of Helsinki in relation to the involvement of incapacitated research candidates in medical research:

5. Medical progress is based on research that ultimately must include studies involving human subjects.

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123 The Nuremburg Code (1947).

124 World Medical Association, *Declaration of Helsinki*, October 1975, principle 2.

125 World Medical Association, *Declaration of Helsinki*, October 2013, principle 30.

6. The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best proven interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.

7. Medical research is subject to ethical standards that promote and ensure respect for all human subjects and protect their health and rights.

8. While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.

16. In medical practice and in medical research, most interventions involve risks and burdens. Medical research involving human subjects may only be conducted if the importance of the objective outweighs the risks and burdens to the research subjects.[126]

FINDING 9

The World Medical Association's Declaration of Helsinki states:

9. While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.

FINDING 10

The World Medical Association's Declaration of Helsinki contemplates exceptions for the requirement to obtain consent in emergency situations. It states:

31. If no representative is available and if the research cannot be delayed, the study may proceed without informed consent provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the study has been approved by a research ethics committee. Consent to remain in the research must be obtained as soon as possible from the subject or a legally authorised representative.

United Nations Convention on the Rights of Persons with Disability

4.12 In 2008, Australia ratified the UNCRPD. The UNCRPD requires people with a disability to have access to the same standard of healthcare as other people. It requires signatories to prevent 'discriminatory denial of health care or health services … on the basis of disability'.[127]

4.13 The UNCRPD adopts the 'social model' of disability, which is now widely considered the leading model. Some important principles of the social model of disability include:

- Supported decision–making (which emphasises that a person with impaired decision–making ability can make decisions for themselves provided they have the necessary support) should be preferred over substitute decision–making.

[126] World Medical Association, *Declaration of Helsinki*, October 2013, principle 5–8, 16.

[127] United Nations General Assembly, *Convention on the Rights of Persons with Disabilities,* 24 January 2007, article 25(f).

- A person's will and preferences should be respected and not overruled by action thought to be in their objective best interests.[128]

FINDING 11

Under the social model of disability, a person's will and preferences should be respected and not overruled by action thought to be in their objective best interests.

British Medical Research Council Ethics Guide

4.14 Another helpful expression of the ethical principles for medical research in Australia is the British Medical Research Council Ethics Guide. In the United Kingdom, the Medical Research Council published guidelines for the involvement of incapacitated people in medical research in 1991. The latest revision of this guide was published in 2007.

4.15 The introduction to the British Medical Research Council Ethics Guide contains the following passage:

> Medical research involving adults who lack mental capacity to consent can lead to innovations in health care that can substantially improve their health and quality of life and that of others with similar conditions. It is therefore important that these adults are given the opportunity to participate in such research. To exclude them from any research would be discriminatory and would diminish their ability to participate as fully as possible in society. It would also prevent researchers making progress in the understanding of many disorders that can affect the brain, and in the care and treatment of those who have such disorders. However, such research requires special safeguards to ensure that this vulnerable group are protected when they do participate in medical research.[129]

FINDING 12

The British Medical Research Council Ethics Guide states:

> To exclude [adults who lack mental capacity to consent] from any research would be discriminatory and would diminish their ability to participate as fully as possible in society. It would also prevent researchers making progress in the understanding of many disorders that can affect the brain, and in the care and treatment of those who have such disorders. However, such research requires special safeguards to ensure that this vulnerable group are protected when they do participate in medical research.

Human research ethics committee approval

4.16 Any research in Australia involving humans, or requiring access to personal information, requires approval from an HREC that is registered with the NHMRC.

4.17 When determining ethics approval for medical research in Australia, HRECs must ensure compliance with the National Statement.

National Statement on Ethical Conduct in Human Research

4.18 The National Statement sets out the requirements for the composition of an HREC and the relevant ethical principles and values by which research should be designed and conducted

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128 New South Wales Law Reform Commission, *Review of the Guardianship Act 1987,* Report 145, May 2019, p xxi.

129 Medical Research Council, *MRC Ethics Guide: medical Research involving adults who cannot consent*, 2007, p 4.

and to which HRECs should refer when reviewing research proposals.[130] The National Statement is jointly developed by the NHMRC, the Australian Research Council and Universities Australia.

4.19 The National Statement does not have any legislative force but witnesses referred to it as an important guide for the design and conduct of medical research. It emphasises the entitlement of people who are unable to make reasonable decisions to participate in research. Due to the person's vulnerability, the risks to and burdens imposed on them by the research must be justified by the potential benefits of the research. Guidelines of the National Statement regarding incapacitated research candidates include:

- consent should be sought from the research candidate themselves or from a person authorised to consent on their behalf[131]
- where the researcher is also the treating health professional, it should be considered whether an independent person should make the initial approach and/or seek consent from potential participants or from others on their behalf[132]
- people with a cognitive impairment, an intellectual disability, or a mental illness are entitled to participate in research, and to do so for altruistic reasons[133]
- where the research candidate's incapacity is episodic, an attempt should be made to obtain consent when their condition does not interfere with their capacity[134]
- the process of seeking consent should include discussion of any possibility of the person losing their capacity to consent and the person's wishes in that circumstance followed unless doing so would not be in their best interests[135]
- consent should be witnessed by a person who has capacity to understand the merits, risks and procedures of the research and is familiar with the research candidate's condition[136]
- where consent is obtained from a substitute decision–maker, the researcher should still explain to the research candidate as far as possible what the research is about[137]
- researchers should inform HRECs how they propose to determine capacity (including how the decision will be made and by whom, criteria used and the process for reviewing capacity during research)[138]
- refusal or reluctance to participate in research should be respected.[139]

4.20 The importance of HREC approval and compliance with the National Statement was noted by a number of stakeholders:

- Clinical Associate Professor David Mountain, Australian Medical Association (WA):

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130 National Health and Medical Research Council, Australian Research Council, *National Statement on Ethical Conduct in Human Research* 2007, Canberra, 5.1.29–33, section 1.

131 ibid., 4.4.9, 4.5.3.

132 ibid., 4.4.12.

133 ibid., 4.5.3.

134 ibid., 4.5.6.

135 ibid., 4.5.7.

136 ibid., 4.5.8.

137 ibid., 4.5.9.

138 ibid., 4.5.10.

139 ibid., 4.5.11.

> The NHMRC National Statement is an extremely robust document and is seen as world's best practice. Every research project or trial that comes through Western Australia has to follow those guidelines and has to get through an ethics committee and a scientific review committee to be able to be started, so we already follow some of the strictest guidelines in the world.
>
> …
>
> I sit on an ethics committee and they go through a very exhaustive process—that, and the scientific committees that I am also on. I have already been through the paper in a fairly exhaustive way; some of these papers are 1 000 pages long, with the protocols that come in, so it is a very exhaustive process in the first place.[140]

- Professor Daniel Fatovich, Director of Research, Royal Perth Hospital appearing for Department of Health:

> Researchers are very much guided by the NHMRC National Statement on the Ethical Conduct of Research. If you look at the section on people who are highly dependent on medical care, it does make the point about the importance of, as much as is reasonably practicable, getting somebody else to provide the consent. It goes through all the stages but then there is a final comment, which says that in reality there are exceptions to this and there are some circumstances where it is simply not possible. That needs to be taken into account by the ethics committee as to whether or not, for that particular study, they will approve it or otherwise.[141]

Discussion paper to update National Statement

4.21 The NHMRC is proposing to revise and update the National Statement in relation to human research. The discussion paper on which the update will be based includes revised sections that provide advice for researchers and HRECs when addressing ethical considerations related to potentially vulnerable participants.[142]

4.22 The Committee asked the Australian Medical Association (WA) to identify any protections that have been listed in the discussion paper that they consider worthy of legislating in Western Australia. They identified the following:

- Obtaining valid consent from the research participant is the standard for all research, including emergency care research, intensive care research and research involving terminally ill participants, unless otherwise justified.
- The National Statement requires researchers and reviewers to consider potential sources of vulnerability arising from the characteristics and circumstances of individual participants, when viewed in the context of a specific research project.
- Characteristics of participants that may give rise to vulnerability include those related to the individual's particular life stages, physical and cognitive states, or other circumstances.
- In order to provide equitable opportunities for inclusion in research, a risk assessment may be useful. This approach can help to identify potential

[140] Clinical Associate Professor David Mountain, Emergency Medicine Representative, Australian Medical Association (WA), transcript of evidence, 1 October 2020, p 2, 4.

[141] Professor Daniel Fatovich, Director of Research, Royal Perth Hospital, Department of Health, transcript of evidence, 1 October 2020, p 20.

[142] National Health and Medical Research Council. *An invitation to make a submission*, August 2020. See: https://online.nhmrc.gov.au/sites/default/files/ethics/explanatory_material_national_statement_sections_4_5_public_consultation.pdf. Viewed 12 October 2020.

sources of vulnerability and hence the multi–dimensional nature of risk, which reflects a nexus of the individual participant, their community, the research context and the research processes.

- In the context of emergency care, where it is not possible to obtain consent, approval for research to proceed without consent can be granted by an HREC provided that it is satisfied that the conditions outlined in draft Section 4.3, point 19 have been met as expressly stated, provided the draft is approved.[143]

4.23 Draft section 4.3, point 19 of the revised National Statement is set out below:

> 19. Approval for research to proceed without consent can be granted by an HREC provided that it is satisfied that the following conditions have been met:
>
> (a) obtaining consent from the participant, the participant's guardian or an authorised representative is not possible, including when recruitment into the research project has to be achieved very rapidly in an emergency care setting
>
> (b) the research carries a risk that is proportionate to the natural history of the participant's underlying condition(s)
>
> (c) the potential future benefits from the research justify any risk of harm associated with not seeking consent
>
> (d) there is no known or likely reason for thinking that participants would have withheld their consent if they had been asked to provide it, including the absence of any known advance directive that precludes participation in the research
>
> (e) there is sufficient protection of participants' privacy
>
> (f) there is an adequate plan to protect the confidentiality of any data or information collected
>
> (g) the possibility of commercial exploitation of derivatives of any data or tissue collected will not deprive the participants of any financial benefits to which they would be entitled
>
> (h) in making the request for approval, researchers have provided adequate justification for
>
> i. not seeking participant consent or consent from a participant's guardian, or authorised representative, and
>
> ii. not requesting a waiver of the requirement for consent, as provided in 2.3.9–2.3.10, and
>
> (i) in making the request for approval, researchers are aware of and complying with any limitations imposed by state, federal or international law.[144]

4.24 The Committee notes that the Bill and Amending Act introduce appropriate safeguards to protect incapacitated research candidates in keeping with the protections identified by the Australian Medical Association (WA) in paragraphs 4.22–4.23.

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[143] David Copeland, Policy and Research Lead (Industrial/Political/Legal), Australian Medical Association (WA), Answer to question on notice No 1 asked at hearing held 1 October 2020, dated 16 October 2020, p 1.

[144] National Health and Medical Research Council, *Draft Section 4 of the National Statement*, 4 June 2020. See: https://online.nhmrc.gov.au/sites/default/files/ethics/draft_section_4_Jun2020.pdf. Viewed 12 October 2020.

FINDING 13

Any medical research in Australia involving humans or requiring access to personal information requires approval from a human research ethics committee that is registered with the National Health and Medical Research Council.

FINDING 14

When determining ethics approval for medical research, human research ethics committees must ensure compliance with the National Statement on Ethical Conduct in Human Research.

FINDING 15

The National Statement on Ethical Conduct in Human Research does not have any legislative force but is an important guide for medical research. The National Statement includes the principle that:

> Where the researcher is also the treating health professional, it should be considered whether an independent person should make the initial approach and/or seek consent from potential participants or from others on their behalf.

FINDING 16

The Guardianship and Administration Amendment (Medical Research) Bill 2020 and the *Guardianship and Administration Amendment (Medical Research) Act 2020* introduce appropriate safeguards to protect incapacitated research candidates in keeping with the protections proposed in the discussion paper to update the National Statement on Ethical Conduct in Human Research dated August 2020.

CHAPTER 5
Definition of medical research

Introduction

5.1 This chapter begins with an explanation of the similarities between medical research and medical treatment. A number of witnesses and submitters raised this in order to emphasise that while the idea of medical research may be alarming for some people, the term embraces a range of conduct from intrusive procedures to low–risk conduct such as comparing accepted medical treatments.

5.2 This chapter then considers the definition of medical research introduced by the Amending Act in s 3AA of the *Guardianship and Administration Act 1990*. In particular, it considers the following aspects of this definition:

- consistency with the definition used in the National Statement
- modelling of the definition on the equivalent Victorian provision
- inclusion of placebos in the definition of medical research
- allowance for the government to prescribe activities which can be included, or excluded, from the definition of medical research.

Medical research and medical treatment

5.3 A number of stakeholders who contributed to the inquiry emphasised that medical research and medical treatment often go hand–in–hand. This was articulated in the submission from Hon Eric Heenan QC who provided examples to illustrate that medical research and medical treatment co–exist on a wide spectrum:

> **Treatment v Research – A false dichotomy – The wide range of clinical trials and research projects**
>
> While there are many forms of treatment not involving research and much research not involving treatment, those are at the opposite ends of a spectrum with much treatment involving research lying between them. It is very common, when approaching this subject to focus on the stereotypical medical trial involving the use of a novel procedure or drug on a patient directly under the care of a researcher who is present or proximate to the test. However, that is a narrow focus and tends to obscure the great range of research projects of broader scope. This perhaps can best be illustrated by examples of various forms of medical research in the wide spectrum. These examples are not comprehensive but merely illustrative:
>
> (i) Typical clinical trials involving the use of a drug or procedure on a series of patients, that is, involving actual intervention by the researcher.
>
> (ii) Multi–centre studies (other versions of the above) with the principal researcher located at one participating site but not at the various other participating sites.
>
> (iii) Retrospective studies of patients' records to compare their diagnosis, disease, treatment methods and results, especially any complications. Here the researcher has no contact with patients. No treatment of any kind is involved. The researcher may be located at one participating site or may be elsewhere

conducting a multi–centre study. This often requires (subject to exceptions) approved waiver of consent by HRECs in advance for this use of records.

(iv) As in (iii) above, involving studies of tissues, bio–specimens and other samples taken from patients during normal care and then stored for possible future investigation. The researcher may be on site or elsewhere if a multi–centre study.

(v) Studies including a survey, questionnaire or sometimes interview with patients about their—

- past treatment
- present condition
- reaction to certain procedures, etc

but not involving any intrusive intervention. These may also involve multi–centre studies with no direct contact between researchers and patients.

(vi) Observational research, for example, on patients with Alzheimer's Disease to test their levels of depression and dementia by observing their responses to computer based programmes requiring responses – eg, pressing a button or ticking one of several items, in comparison to a random controlled group not given the computer based choice. Again, no physical intrusion, or treatment, but simply observation of responses to innocuous stimuli.

(vii) Another example is an observational study of dementia patients or of those cognitively impaired to assess their self–feeding capacity (these patients are at risk of malnutrition when living alone at home through self neglect) by checking their reactions to use finger food (no preparations needed) and to measure their consumption. No treatment or intrusion involved.

(viii) Multi–centre prospective audit study to compare daily clinical data and after care of 10,000 patients over 10 years undergoing laparotomies in Australia with a view to identifying the best performing methods of treatment among many current modalities of care. This collected (de–identified/coded) data can also be used for future individual sub–studies to improve patient outcomes. No direct treatment or care of patients is involved, but this type of survey may lead to improved national guidelines being developed for emergency laparotomies.

(ix) Studies involving the comparative results of different forms of standard care in surgical or medical treatment where these are accepted options of choice for any such situation and where the study seeks to identify whether any of the accepted options or combinations of them is preferable. It involves active treatment, often intrusive, but this is not novel, controversial or non–standard.[145]

5.4 The Committee heard from a number of medical professionals who criticised the ban on involving incapacitated research candidates in medical research which existed between 2018 and October 2020. They gave real world examples of medical research involving comparative studies of accepted medical treatments to illustrate the importance of allowing medical research to resume under the *Guardianship and Administration Act 1990*. These included the following:

[145] Submission 13 from Hon Eric Heenan QC, 5 Jun 2020, p 12.

- Professor Gary Geelhoed, Western Australian Health Translation Network:

  > Many studies over the years that have been done in this space have dramatically improved the outcomes for patients and even practical ones like giving fluids. Years ago, I remember there was a big controversy about whether you give patients albumin, which is like body fluids, to resuscitate them or you just give them normal saline because, theoretically, the body fluids would perhaps be better, even though they are much more expensive. They did a trial and, again, that decision had to be made immediately. These people, in extremis, came in where they got one fluid or the other. What that showed was normal saline was just as good, about 100th of the cost and freely available everywhere.[146]

- Dr Stephen Macdonald, Staff Specialist in Emergency Medicine, Royal Perth Hospital appearing for Australasian College for Emergency Medicine:

  > I will give another example: there is a clinical trial called the EXACT clinical trial, which committee members may be familiar with, which was looking at patients with out–of–hospital cardiac arrest—a group of patients who have a very high mortality. The current accepted treatment is to deliver those patients oxygen at a high concentration. There is increasing evidence from other settings that giving high concentrations of oxygen may actually be harmful and the EXACT trial was approved for enrolment under, obviously, patients in cardiac arrest being enrolled at the roadside by paramedics, who need to institute and randomise the patient to one or two of the treatment arms, which were both within the accepted treatment paradigm—there is a diversity of opinion. That trial was approved by ethics in Western Australia, Victoria and South Australia. It commenced recruitment in South Australia and in Victoria but was not granted regulatory approval, so never commenced here. As a result, that trial has had to cease. We still do not know what the best way to treat patients with cardiac arrest is. Tomorrow when we see someone in the emergency department I do not know whether to give them 100 per cent oxygen, 50 per cent oxygen or 30 per cent oxygen is the right thing to do. What I do know is that half the patients who are being treated across the spectrum of care are probably receiving sub–optimal care. I just do not know which ones because I am not in a position to evaluate that. So I think this actually has real world, real life implications for patients.[147]

Definition of medical research (s 3AA)

5.5 The Amending Act introduced a definition of 'medical research' under s 3AA of the *Guardianship and Administration Act 1990*.[148] According to the explanatory memorandum for the Bill, this definition was modelled on the equivalent provision in Victoria.[149] The Amending Act also seeks to implement recommendation 7 of the Statutory Review by defining medical research in the same way as the National Statement.[150]

5.6 The definition of medical research introduced in the *Guardianship and Administration Act 1990* is set out below:

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146 Professor Gary Geelhoed, Executive Director, Western Australian Health Translation Network, transcript of evidence, 1 October 2020, pp 10–11.

147 Dr Stephen Macdonald, Staff Specialist in Emergency Medicine, Royal Perth Hospital, Australasian College for Emergency Medicine, transcript of evidence, 30 September 2020, p 18.

148 *Guardianship and Administration Amendment (Medical Research) Act 2020,* s 5.

149 Explanatory Memorandum, Legislative Council, Guardianship and Administration Amendment (Medical Research) Bill 2020, p 2. See, *Medical Treatment Planning and Decisions Act 2016* (Vic), s 3(1).

150 Department of the Attorney General, *Statutory Review of the Guardianship and Administration Act 1990,* November 2015, recommendation 7.

s 3AA. Term used: medical research

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

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

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

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

(a) the administration of pharmaceuticals or placebos;

(b) the use of equipment or a device;

(c) providing health care that has not yet gained the support of a substantial number of practitioners in that field of health care;

(d) providing health care to which paragraph (c) does not apply to carry out a comparative assessment referred to in paragraph (e);

(e) carrying out a comparative assessment of the health care provided under paragraphs (c) and (d);

(f) taking samples from an individual, including—

(i) a blood sample; or

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

(g) any non–intrusive examination, including—

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

(ii) the measuring of an individual's height, weight or vision;

(h) observing an individual;

(i) undertaking a survey, interview or focus group;

(j) collecting, using or disclosing information, including personal information;

(k) considering or evaluating samples or information taken under an activity listed in this subsection;

(l) any other activity prescribed by the regulations to be medical research.

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

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

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

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

and

(b) any other activity prescribed by the regulations not to be medical research.[151]

[151] *Guardianship and Administration Act 1990*, s 3AA.

Consistency with National Statement

5.7 The Statutory Review undertaken in 2015 recommended including a definition of medical research in the same terms as those used in the National Statement.[152]

5.8 Section 3AA is largely consistent with the definition used in the National Statement with some omissions. These omissions are underlined below:

> Human research is conducted with or about people, or their data or tissue. Human participation in research is therefore to be understood broadly, to include the involvement of human beings through:
>
> - taking part in surveys, interviews or focus groups;
> - undergoing psychological, physiological or medical testing or treatment;
> - being observed by researchers;
> - researchers having access to their personal documents or other materials;
> - the collection and use of their body organs, tissues or fluids (eg skin, blood, urine, saliva, hair, bones, tumour and other biopsy specimens) or their exhaled breath;
> - access to their information (in individually identifiable, re–identifiable or non–identifiable form) as part of an existing published or unpublished source or database.[153]
>
> (Emphasis added)

5.9 The Committee asked why these parts of the definition were omitted at its hearing with the Department of Justice and the Department of Health on 1 October 2020. The following exchange took place:

> **Hon NICK GOIRAN**: I understand that section 3AA adopts the definition used in the National Statement, but there were some omissions made. I note that three omissions appear to have been made. One is about undergoing psychological, physiological or medical testing or treatment, another one deals with body organs and the third one was exhaled breath. Is anyone in a position to advise us as to the basis upon which it was determined that we should exclude those provisions from the National Statement?
>
> **Ms DELLAR**: The first point is that the definition in the National Statement, those listed activities under that definition do not form part of the definition; they are examples of types of medical research activities, whereas the actual definition of "human research" is contained above that. There is not necessarily a need to exactly model it on the list that is provided as examples.
>
> **Hon NICK GOIRAN**: So we basically decided not to include examples in our approach?
>
> **Ms DELLAR**: There are examples in our approach, yes.
>
> **Hon NICK GOIRAN**: But they do not include those particular elements?

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152 Department of the Attorney General, *Statutory Review of the Guardianship and Administration Act 1990,* November 2015, recommendation 7.

153 National Health and Medical Research Council, Australian Research Council and Universities Australia, *National Statement on Ethical Conduct in Human Research*, 2007, p 7.

> **Ms DELLAR**: They include most of those elements, I believe, that are in the National Statement.
>
> **Dr WILLIAMSON**: I could not see a reason, for instance, to exclude "exhaled breath" from any list. I am not in a position to say why some were left in and some were not.
>
> **Hon NICK GOIRAN**: "Body organs" I can certainly understand, but "exhaled breath"?
>
> **Ms HEGARTY**: I cannot explain why some are in and some are not, but I guess from our perspective, without [the examples in subsection (2)] limiting subsection (1) of the definition, we did not look to ensure that everything was in there.[154]

5.10 Although the definition of medical research in the *Guardianship and Administration Act 1990* does not contain all of the examples in the National Statement, the broad scope of the definition in s 3AA(1), which is not limited by the examples in s 3AA(2), is likely to capture the examples that have been omitted.

FINDING 17

The definition of 'medical research' in the *Guardianship and Administration Act 1990* is effectively consistent with the definition of 'human research' in the National Statement on Ethical Conduct in Human Research.

Modelled on Victorian legislation

5.11 The explanatory memorandum for the Bill states that the definition of medical research in s 3AA has been modelled on the Victorian legislation.[155] The Committee asked the Department of Justice to explain why the Victorian legislation was chosen as the preferred model. Ms Subhan Dellar, Acting Principal Policy Officer from the Department of Justice responded as follows:

> The definition is actually modelled on the National Statement definition of "human research". The approach in providing examples of the types of medical research is something that was modelled on the Victorian approach, compared with other jurisdictions that do not define medical research by listing activities; they define it by using just a definition of what research is. It was not exactly modelled on the Victorian definition; it was just the approach taken by listing activities.[156]

5.12 The definition in s 3AA includes a number of activities that have been specifically excluded in the Victorian legislation. These activities include:

- any non–intrusive examination, including:
  - a visual examination of the mouth, throat, nasal cavity, eyes or ears
  - the measuring of an individual's height, weight or vision
- observing an individual
- undertaking a survey, interview or focus group

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154 Subhan Dellar, Acting Principal Policy Officer, Department of Justice; Dr James Williamson, Assistant Director General, Clinical Excellence Division, Jodie Hegarty, Manager, Research Development Unit, Department of Health, transcript of evidence, 1 October 2020, pp 9–10.

155 Explanatory Memorandum, Legislative Council, Guardianship and Administration Amendment (Medical Research) Bill 2020, p 2.

156 Subhan Dellar, Acting Principal Policy Officer, Department of Justice, transcript of evidence, 1 October 2020, p 9.

- collecting, using or disclosing information, including personal information.

5.13 The inclusion of these activities in s 3AA is consistent with the definition in the National Statement.

Administration of placebos

5.14 The use of placebos is included in the definition of 'medical research'.[157] The Amending Act has also introduced the following definition of 'placebo':

> ***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;[158]

5.15 For an extended discussion of placebos see paragraphs 8.8–8.12.

Prescribed activities

5.16 Sections 3AA(2)(l) and (3)(b) allow regulations to prescribe which activities are to be included, or excluded, from the definition of medical research. This approach is also taken in the Victorian legislation.[159]

5.17 The provisions described above allow the government to extend the definition of medical research and declare certain activities not to be medical research, respectively. The ability to exclude prescribed activities from the definition of medical research is significant because it will result in those activities not being subject to the safeguards required by Part 9E of the *Guardianship and Administration Act 1990*.

5.18 Mr Joshua Thomson SC, Solicitor General of Western Australia made the following points on the retention of these provisions:

- The purpose of the ability to prescribe activates by regulation which may or may not be included in the definition of medical research is to obtain flexibility to accommodate unforeseen circumstances.
- The ability to prescribe matters is a matter of convenience, and should not affect the width of the operation of the Act in any substantial sense, due to implied limits upon the ability to prescribe matters. These allow prescription of matters which complement but which do not supplement the Act.
- The definition of "medical research" has been broadly drafted, but has excluded anonymised data analysis, as this should not require consent of a candidate in any event, as there is no prospect of the candidate being affected by this form of research.
- It may be that removal of the ability to prescribe matters within or outside the concept of "medical research" will not have any great affect upon the operation of the Act. However, the ability to prescribe matters is effectively to ensure the effective operation of the Act as intended, not to allow its operation to be extended into new areas or contracted from existing areas.[160]

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157 *Guardianship and Administration Act 1990,* s 3AA(2)(g).

158 ibid., s 3.

159 *Medical Treatment Planning and Decisions Act 2016* (Vic), s 3(1) (see definition of 'medical research procedure').

160 Joshua Thomson SC, Solicitor General of Western Australia, Answer to question on notice No 10 asked at hearing held 1 October 2020, dated 1 October 2020, p 3.

5.19 The Department of Health did not have a strong view about retaining these provisions but noted the importance of allowing flexibility to respond to future developments in medical research:

> I am not sure that the Department of Health has a strong view on this, but it was to allow some flexibility in the interpretation of what constituted medical research. It is sometimes difficult to know what might be coming over the horizon, so to speak, which is not necessarily covered in what is prescribed in the Act. I might talk about some of the advances in machine learning and artificial intelligence, for instance, which is guiding decision–making and which is not necessarily covered in this at the moment. It might be an area on which a decision has to be made in the future. It might be desirable to have the opportunity to include that or related areas in definitions of "medical research" without having to go back to legislation. I think that was the thinking behind it.[161]

5.20 In the Committee's view, the ability to prescribe activities as medical research under s 3AA(2)(l) is appropriate.

FINDING 18

Section 3AA(2)(l) of the *Guardianship and Administration Act 1990* is an appropriate delegation of legislative power.

5.21 Section 3AA(3)(b) allows activities prescribed by the regulations not to be medical research.

5.22 A majority of the Committee, consisting of Hons Dr Sally Talbot MLC, Colin de Grussa MLC, Simon O'Brien MLC and Pierre Yang MLC are of the view that the ability to exclude prescribe activities from the definition of medical research under 3AA(3)(b) is appropriate.

FINDING 19

A majority of the Committee, consisting of Hons Dr Sally Talbot MLC, Colin de Grussa MLC, Simon O'Brien MLC and Pierre Yang MLC finds that s 3AA(3)(b) of the *Guardianship and Administration Act 1990* is an appropriate delegation of legislative power.

5.23 A minority of the Committee, consisting of Hon Nick Goiran MLC, is of the view that allowing prescribed activities to be excluded from the definition of medical research under s 3AA(3)(b) will result in safeguards not applying to research candidates for those kinds of research. This is not consistent with the policy objective of requiring medical research to be conducted pursuant to appropriate safeguards.

FINDING 20

A minority of the Committee, consisting of Hon Nick Goiran MLC, finds that s 3AA(3)(b) of the *Guardianship and Administration Act 1990* is not an appropriate delegation of legislative power.

[161] Dr James Williamson, Assistant Director General, Clinical Excellence Division, Department of Health, transcript of evidence, 1 October 2020, pp 7–8.

CHAPTER 6
Part 9E Division 1—Preliminary

Introduction

6.1 The Amending Act introduced Part 9E into the *Guardianship and Administration Act 1990*.[162] This chapter considers 'Part 9E Division 1—Preliminary'. Division 1 contains the following three provisions:

- s 110ZO—Terms used
- s 110ZP—Term used: research decision–maker
- s 110ZQ—Substitute decision–maker for a research candidate.

6.2 Section 110ZO defines a number of terms used in Part 9E. Sections 110ZP and ZQ contain provisions regarding the appointment of a research decision–maker.

6.3 In relation to s 110ZO, a number of stakeholders recommended the following amendments:

- The definition of 'independent medical practitioner' should allow a patient's treating doctor to make the relevant assessments required under ss 110ZU, ZV, ZW.
- The definition of 'lead researcher' should not be limited to medical professionals and should be expanded to allow other professionals such as nurses, psychiatrists, paramedics and allied health professionals to perform medical research.

6.4 Sections 110ZP and ZQ are largely consistent with the existing provisions in relation to medical treatment and stakeholders did not comment on these provisions.

Definition of independent medical practitioner (s 110ZO)

6.5 In order to access medical research under Part 9E of the *Guardianship and Administration Act 1990* an independent medical practitioner is required to make an assessment of the:

- research candidate's best interests[163]
- likelihood they will regain the ability to consent[164]
- risks involved.[165]

6.6 The requirement to obtain an assessment from an independent medical practitioner reflects the cautious approach to enabling incapacitated people being enrolled in medical research. There is no such requirement in respect of medical treatment under Parts 9C and D.

6.7 The term 'independent medical practitioner' is defined in the *Guardianship and Administration Act 1990* as follows:

> ***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

[162] *Guardianship and Administration Amendment (Medical Research) Act 2020,* s 12.

[163] *Guardianship and Administration Act 1990,* s 110ZU.

[164] ibid., s 110ZV.

[165] ibid., s 110ZW.

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, defacto 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.[166]

6.8 A number of stakeholders made submissions to the Committee arguing that the treating doctor, not an independent medical practitioner, would be better placed to assess the research candidate's wishes, disease and timeframe of incapacity.[167]

6.9 In the Committee's view, these stakeholders need not be concerned. The definition only excludes practitioners who are involved in providing treatment as part of medical research performed under Part 9E. In other words, it prohibits the research candidate's treating doctor from making these determinations when the treating doctor is providing treatment that is part of the research.[168]

6.10 In their written submission, the Department of Health confirmed that a person's treating doctor may act as the independent medical practitioner as follows:

> The treatment referred to in s 110ZO(a) is confined to treatment provided under Part 9E, it does not capture other general treatment provided to a person. Accordingly, a person's GP [general practitioner] may act as the independent medical practitioner for the purposes of Part 9E provided that the GP is not involved in providing the treatment that forms part of the medical research and does not fall within any of the exceptions. This is considered desirable as the person's GP may be well placed to determine whether inclusion in research is in the person's best interests.[169]

6.11 This interpretation was shared by the Department of Justice:

> The independent medical practitioner, who carries out assessments of the candidate's best interests, whether the candidate will regain the capacity to consent within the timeframe required by the research, and of risks involved in the research, must be a medical practitioner who is not providing treatment under Part 9E (that is, treatment associated with the medical research).
>
> Therefore, provided that a candidate's treating doctor is not in any way associated with the medical research, the candidate's usual treating doctor can provide an assessment of these criteria.[170]

6.12 The Department of Health has included the following note in a guidance document to assist researchers and health service providers understand when a treating doctor can act as the independent medical practitioner:

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166 *Guardianship and Administration Act 1990,* s 110ZO.

167 Submission 14 from South Metropolitan Health Service, 3 June 2020, pp 3–4; Submission 21 from Australasian College for Emergency Medicine, 8 June 2020, pp 4–5; Submission 22 from St John of God Murdoch – ICU Research Group, 8 June 2020, pp 1–2.

168 Unless they fail to satisfy the requirements in s 110ZO(b)–(d).

169 Submission 25 from the Department of Health, 9 June 2020, p 7.

170 Dr Adam Tomison, Director General, Department of Justice, Answer to question on notice No 20 asked at hearing held 1 October 2020, dated 14 October 2020, p 4.

> 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.[171]

6.13 The publication of this guidance document is an important step in clarifying the operation of this provision for researchers and health service providers in Western Australia.

FINDING 21

An incapacitated research candidate's treating doctor may satisfy the definition of an 'independent medical practitioner' under s 110ZO of the *Guardianship and Administration Act 1990* provided they are not associated with medical research being performed under Part 9E. However, this is not clear in the *Guardianship and Administration Act 1990* and is causing confusion among stakeholders.

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.

Definition of lead researcher (s 110ZO)

6.14 The Amending Act has introduced the following definition of lead researcher in the *Guardianship and Administration Act 1990*:

> ***lead researcher***, in relation to medical research, means a medical practitioner who has sole or joint overall responsibility for conducting the research;[172]

6.15 Mr Joshua Thomson SC, Solicitor General of Western Australia gave evidence that the intention of this definition is to require the lead researcher to be a medical practitioner:

> I can speak to the way in which the legislation is in fact worded and it is correct that it was the intention of the legislation as it is drafted that there must be a medical practitioner as the lead researcher … The research itself can be carried out by any researcher and does not have to be carried out by the lead researcher, but no medical research can be carried out upon an incapacitated person unless the research is under the general responsibility of a medical practitioner.[173]
>
> (Emphasis added)

6.16 A lead researcher has three statutory obligations under the *Guardianship and Administration Act 1990*. These were explained by the Solicitor General as follows:

> There are only a small number of specific obligations that relate to a lead researcher, and perhaps it is worth mentioning those. Sections 110ZR(7) and 110ZS(5) impose an obligation upon a lead researcher to discontinue research safely if a research candidate regains the ability to make reasonable judgements in respect of medical research. Those are two specific sections about what a lead researcher has to do. Section 110ZS(3) provides in relation to research that has not received consent from a research decision–maker that a lead researcher must take,

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171 Department of Health, *Guidance Document: Involving Incapacitated Adults in Health and Medical Research*, 6 October 2020, p 5. See: https://rgs.health.wa.gov.au/Documents/GAA%20Medical%20Research%20Guidance%20Document.pdf. Viewed 12 October 2020.

172 *Guardianship and Administration Act 1990*, s 110ZO.

173 Joshua Thomson SC, Solicitor General of Western Australia, transcript of evidence, 1 October 2020, pp 11–12.

and continue to take, reasonable steps to obtain a research decision under section 110ZR in relation to a research candidate from the research decision–maker for the candidate.[174]

Expanding the definition of lead researcher

6.17 The Committee received a number of written submissions from stakeholders who expressed concern that the definition of lead researcher excludes non–medical practitioners.[175] They argued that this could:

- prevent access to medical research being undertaken by non–medical practitioners such as nurses, psychiatrists, paramedics and allied health professionals
- result in medical practitioners being nominally appointed as lead researcher for the sake of compliance with the *Guardianship and Administration Act 1990*.

6.18 After considering these submissions in favour of expanding the definition of lead researcher, the Committee asked witnesses who attended hearings if they supported this proposal. All witnesses were supportive, noting that medical research is often undertaken by non–medical practitioners such as nurses and allied health professionals:

- Dr James Williamson, Assistant Director General, Department of Health:

> Yes, this is one of the things that the Department of Health would be keen to have reconsidered. At the moment it is necessary to be a medical practitioner to be a principal investigator or lead researcher. There is a lot of research that is conducted in nursing and allied health, for instance, where there is no need, because of the type of research that is being conducted, for a medical practitioner to be part of the research team. The requirement therefore that one be appointed solely to satisfy legislation means that researchers within those professions are perhaps denied the opportunity to be seen to be leading research. It also potentially causes difficulties when it comes to the authoring of research, because the contribution of that medical practitioner might be really insignificant to the design and conduct of the trial.
>
> We would suggest that somebody with the appropriate qualifications be the lead researcher, whether that be an allied health professional or a nurse or potentially another member of the health workforce.[176]

- Clinical Associate Professor David Mountain, Australian Medical Association (WA):

> Yes, there is lots of research going on that has no medical practitioners involved. "Medical practitioner" is obviously the old term for a doctor, but, yes, we have lots of nurse–led, physio–led and all sorts of other practitioners who lead research, or, in fact, when there are no doctors involved at all in the research. There is plenty of nurse–led research out there now and where no doctors are involved, so, yes, we

174 ibid.,

175 Submission 9 from Institute for Health Research, University of Notre Dame, 25 May 2020, pp 2–3; Submission 14 from South Metropolitan Health Service, 3 June 2020, pp 4–5; Submission 15 from Western Australian Country Health Service Human Research Ethics Committee and Sir Charles Gairdner Hospital and Osborne Park Group Human Research Ethics Committee, 8 June 2020, p 5; Submission 21 from Australasian College for Emergency Medicine, 8 June 2020, p 4; Submission 25 from Department of Health, 9 June 2020, pp 9–10 and 11; and Submission 26 from Sir Charles Gairdner Osborne Park Health Care Group, 12 June 2020, p 4.

176 Dr James Williamson, Assistant Director General, Clinical Excellence Division, Department of Health, transcript of evidence, 1 October 2020, p 11.

would certainly accept that it should be anybody who is one of the registered medical professions who can lead the research.[177]

- Professor Gary Geelhoed, Executive Director, Western Australian Health Translation Network:

  you have very highly qualified people now doing a lot of very good research, so that includes a lot of allied health people, physiotherapists, paramedics, nurses and obviously nurse practitioners. They are doing that research already, so it just makes sense to broaden that definition. Again, I would make the point that an ethics committee would be setting up what was appropriate such as looking at that person's qualifications and what their record was and so on, to make sure that it was completely appropriate. More and more research is being done in other areas, specifically nursing and allied health, where doctors are not involved in all—that is speaking much more broadly.[178]

- Ms Pip Brennan, Executive Director, Health Consumers' Council:

  from a consumer perspective it is obviously really important for the consumer to have access to research done by a range of different clinicians. What a nurse does is different from what a doctor does and what an allied health professional does is also different. All of those create more opportunities for wellness for consumers. As Gary said, things have very much moved on. Health professionals need to be considered lead researchers.[179]

- Professor Jim Codde, Director, Institute for Health Research, University of Notre Dame:

  [Expanding the definition of lead researcher] gets my vote! … I will be quite honest with you: many of the grant applications that come from some of the doctors I have worked with, both senior and junior, are absolutely scientifically rubbish. To assume because you have got a medical degree that somehow you are an expert in research and biostatistics and a whole range of other factors is wrong … … There are many other people, and in the field of dementia, not all of them will be dealing with patients who are unable to give their own consent, but there are many researchers involved in medical research who are science trained.[180]

- Ms Pauline Bagdonavicius, Public Advocate:

  I was recently approached about whether or not I could consent to a research proposal where a represented person was being considered for some research where the lead researcher was a doctor of clinical psychology. I guess, for me, that really brought it home to me that I think it is too narrow to talk about it in terms of a lead researcher always having to be a medical practitioner. There are certainly certain types of research for which you would want a medical practitioner leading, particularly very medical in their focus, but there is a range of medical research that is captured, such as the one for which I was approached, where it is appropriate for that research to be undertaken by another professional group. So, based on that experience, taking into account the views that have been expressed,

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177 Clinical Associate Professor David Mountain, Emergency Medicine Representative, Australian Medical Association (WA), transcript of evidence, 1 October 2020, p 11.

178 Professor Gary Geelhoed, Executive Director, Western Australian Health Translation Network, transcript of evidence, 1 October 2020, p 12.

179 Pip Brennan, Executive Director, Health Consumers' Council (WA) Inc., transcript of evidence, 1 October 2020, p 12.

180 Professor Jim Codde, Director, Institute for Health Research, University of Notre Dame, transcript of evidence, 30 September 2020, p 11.

as I say, from various submissions, I would support the committee giving further consideration to that requirement.[181]

- Professor Antonio Celenza, Australasian College for Emergency Medicine:

  The CHAIR: The submission from the College notes the definition of "lead researcher" should include all health professionals, not just medical practitioners. Would you like to talk to us for a bit about what types of health professionals you think should be included?

  Prof. CELENZA: Yes. I have done research with paramedics. One of the studies which was recently published was done by a nurse. We have had occupational therapists do research, so it does not need to be a medical practitioner. In fact, some of the best researchers I know are not doctors; they are nurses or paramedics or scientists. However, in this particular context where we are talking about patients without capacity, we are looking more at the pointy end, the critical end, of research, so that would be predominantly medical practitioners, nurses and paramedics that would be involved. All those professions are regulated by AHPRA [Australian Health Practitioner Regulation Agency], so they have their own professional standards and sanctions. I think that having a lead researcher as just a medical practitioner is not really what is happening in research today.[182]

6.19 South Metropolitan Health Service recommended the definition of lead researcher be expanded by replacing it with the following definition of 'health professional' in the *Civil Liability Act 2002*.[183]

> ***health professional*** means—
>
> (a) a person registered under the Health Practitioner Regulation National Law (Western Australia) in any of the following health professions—
>
> (i) Aboriginal and Torres Strait Islander health practice;
>
> (ii) Chinese medicine;
>
> (iii) chiropractic;
>
> (iv) dental;
>
> (v) medical;
>
> (vi) medical radiation practice;
>
> (vii) midwifery;
>
> (viia) nursing;
>
> (viii) occupational therapy;
>
> (ix) optometry;
>
> (x) osteopathy;
>
> (xa) paramedicine;

[181] Pauline Bagdonavicius, Public Advocate, Office of the Public Advocate Western Australia, transcript of evidence, 30 September 2020, p 7.

[182] Professor Antonio Celenza, Professor of Emergency Medicine, St John of God, Australasian College for Emergency Medicine, transcript of evidence, 30 September 2020, p 16.

[183] Submission 14 from South Metropolitan Health Service, 3 June 2020, p 5.

(xi) pharmacy;

(xii) physiotherapy;

(xiii) podiatry;

(xiv) psychology; or

(b) any other person who practises a discipline or profession in the health area that involves the application of a body of learning.[184]

6.20 This definition is also used in Part 9D of the *Guardianship and Administration Act 1990* to define who can conduct medical treatment involving people who are unable to make reasonable judgements about their own treatment.

Safeguard of lead researcher being a medical practitioner

6.21 The Solicitor General gave evidence that the definition of lead researcher does not actually prevent medical research being undertaken by non–medical professionals. However, he noted that it does require a medical practitioner to be responsible for the research as a safeguard to protect incapacitated research candidates:

> The research itself can be carried out by any researcher and does not have to be carried out by the lead researcher, but no medical research can be carried out upon an incapacitated person unless the research is under the general responsibility of a medical practitioner.
>
> …
>
> Obviously, a medical practitioner in charge will have certain professional obligations that are supervised and subject to ethics themselves. There is a level of protection provided by the lead researcher having those particular obligations about discontinuance imposed upon them in the application of it to a particular person. You are quite correct: that is an additional level of safeguard. Whether it is an appropriate one is a matter of policy.[185]

6.22 Hon Nick Goiran MLC asked representatives from the Department of Health whether this safeguard is appropriate in relation to the obligation of a lead researcher to discontinue medical research when a research candidate regains capacity. They gave evidence that it may be appropriate to involve a medical practitioner in certain cases however it is not a significant safeguard for incapacitated research candidates in relation to discontinuing research:

> **Hon NICK GOIRAN**: If the Committee were to recommend something along those lines—the expansion of the definition—would it have a consequential impact on the other part of the Act? The Solicitor–General has kindly taken us to the provision which indicates that the lead researcher "must ensure that the research is discontinued as soon as is safely practicable". That is where the patient—the research candidate—has regained capacity and is in a position to make decisions themselves. That type of task, that duty that we are imposing on the lead researcher to discontinue the research "as soon as is safely practicable", is that something that could only be done by a medical practitioner, or not necessarily?
>
> **Dr WILLIAMSON**: I do not think so. I might pass to Daniel [Fatovich] in a minute, but an example might be mobilisation of patients after a period of ventilation in ICU [intensive care unit], for instance, which is a subset of research which might be

184 *Civil Liability Act 2002*, s 5PA.

185 Joshua Thomson SC, Solicitor General of Western Australia, transcript of evidence, 1 October 2020, p 12.

> conducted under the principal investigator, who is a physiotherapist; but it would be done as part of a team, which undoubtedly would include medical practitioners. I think the risks of discontinuing mobilisation would be the sort of decisions that a physiotherapist in an ICU would be making all the time. They would be making calls on that sort of thing.
>
> **Ms HEGARTY**: I am just thinking as well that this scenario of having to discontinue someone in research could happen when someone has given consent. Someone may give consent to being in research and then decide that they no longer wish to be involved in that research. That is a scenario that can exist in scenarios with consent. At the moment, those research projects would be led by medical, allied health and nursing.
>
> **Prof. FATOVICH**: I agree with everything said. If you had "the lead researcher or their delegate", that would add flexibility. But, as Jodie [Hegarty] said, research is a team of people so that people with the right skills to deal with the issue at that time would be able to do it. Whether that is a doctor or not may or may not be contextually appropriate.
>
> **Ms HEGARTY**: I have one more point. I have actually been approached by some people who have said that, "Is that really what it is saying, that it has to be a medical practitioner?" because they have scenarios where it would not normally be a medical practitioner that would be the lead, and that if they wish to proceed with their projects, that they would need to find a medical practitioner to be the lead, who may not be the most appropriate person.[186]

6.23 While these witnesses did not acknowledge requiring a lead researcher to be a medical practitioner was an important safeguard in relation to discontinuing research, they did contemplate involving a medical practitioner as a member of the wider research team for certain research. One example given by Professor Daniel Fatovich from the Department of Health was medical research that is relevant to clinical care:

> Research these days is conducted by teams. The lead researcher, the number one researcher, may not be a medical practitioner, but if the research is relevant to clinical care, which obviously it would be, there will be a medical practitioner to be invited as a part of the team for that site.[187]

6.24 This evidence suggests that involving a medical practitioner may protect incapacitated research candidates in certain cases however this protection is not dependent on the lead researcher being a medical practitioner.

6.25 Acknowledging that medical research may be undertaken by a team of researchers, the Solicitor General noted the following points to consider should the definition of lead researcher be expanded:

> Can I make three drafting points? The first is that there must be certainty of the obligation to discontinue the research, so that the difficulty becomes imposing it upon a corporate team as opposed to a particular person in the team. If there is to be any recommendation about changing it, then it would be my suggestion that

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[186] Dr James Williamson, Assistant Director General, Clinical Excellence Division, Jodie Hegarty, Manager, Research Development Unit, Professor Daniel Fatovich, Director of Research, Royal Perth Hospital, Department of Health, transcript of evidence, 1 October 2015, pp 13–14.

[187] Professor Daniel Fatovich, Director of Research, Royal Perth Hospital, Department of Health, transcript of evidence, 1 October 2015, p 13.

there needs to be some certainty of definition about who is the subject of the obligation.

The second point is that the definition at the moment is confined to medical practitioners. If you are going to enlarge that definition, do you enlarge it to any allied health professional and how do you define that person, because there is quite a range of people that may well be within the concept of an allied health professional at a general level, so you need to find some other way of defining that person.

The third drafting point is: this is the only thing that applies in the implementation of the obligation at the point of discontinuance of the research as opposed to the point of it commencing. We are speaking here not of research generally, and it is quite common, in my understanding, for there to be lead researchers in medical research who are not necessarily medical practitioners, but we are talking here about a subset of research, which is research related only to incapacitated persons. At a policy level, the question is: is there a need for an obligation about discontinuance of research in relation to this particular subset of people who are the subject of the research? That is only incapacitated persons because there is no problem about medical research generally being led by somebody who is not a medical practitioner. No doubt, human research ethics committees will have appropriate oversight to make sure that there is a team with the proper skills, but here we are talking about the particular subset of incapacity.[188]

6.26 The Committee acknowledges that the intention of the definition of lead researcher in s 110ZO of the *Guardianship and Administration Act 1990* is to introduce safeguards for incapacitated research candidates in some cases. However, this safeguard could equally be achieved by requiring a medical practitioner to be a member of the broader research team. Should consideration be given to amending the definition of lead researcher, such amendments should acknowledge medical research is often conducted in teams while ensuring certainty about who is ultimately responsible for the discontinuance of medical research.

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.

Appointing a research decision–maker (s 110ZP, ZQ)

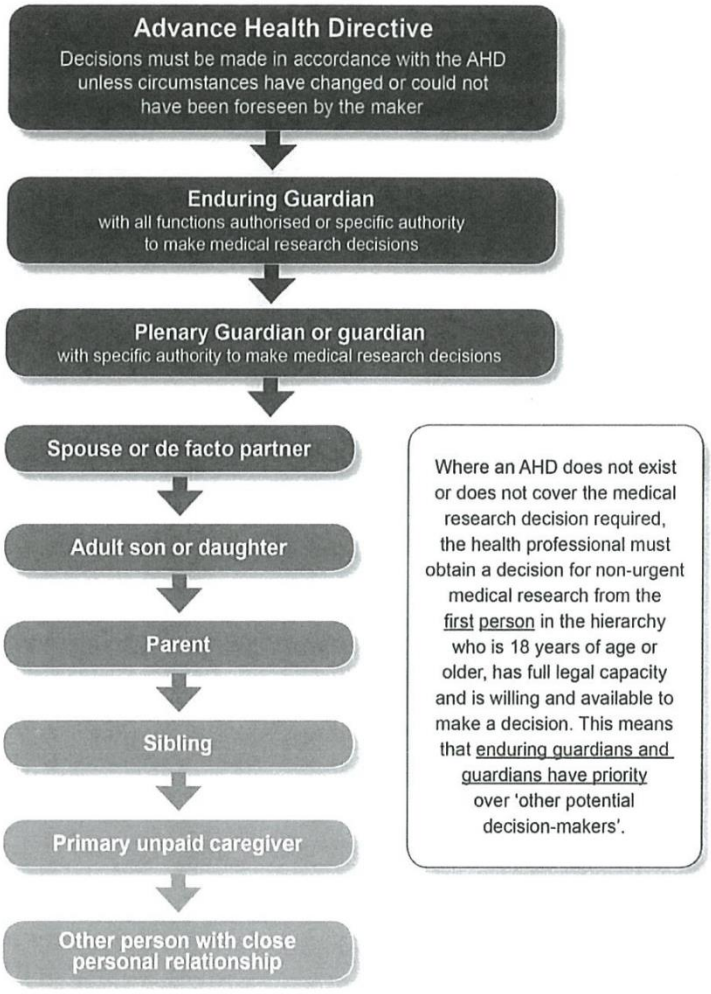
6.27 Section 110ZP and ZQ of the *Guardianship and Administration Act 1990* set out a hierarchy to be followed when determining who may decide whether an incapacitated research candidate will participate in medical research under the *Guardianship and Administration Act 1990*. This person is known as the 'research decision–maker'.

6.28 The process has been adopted from the existing process in relation to medical treatment.[189] The process is shown in Figure 1.

[188] Joshua Thomson SC, Solicitor General of Western Australia, transcript of evidence, 1 October 2020, pp 14–15.

[189] *Guardianship and Administration Act 1990*, ss 110ZD, ZJ.

Figure 1. *Hierarchy to be followed when appointing a research decision–maker*



***Explanatory notes:**

A health professional must consult the order above (spouse/de facto partner, adult child, parent, sibling) in seeking a research decision

De facto partner: "It does not matter whether (a) the persons are different sexes or the same sex; or (b) either of the persons is legally married to someone else or in another de facto relationship." *The Acts Amendment (Lesbian and Gay Law Reform) Act 2002*.

A researcher does not have to seek a research decision from the eldest person within any category as there is no distinction in relation to age, therefore all adult children of a person have equal priority.

A person is to be regarded as maintaining a 'close personal relationship' with the person needing the research decision if the relationship is maintained through frequent personal contact and a personal interest in the welfare of the person.

[Source: Submission 16, Office of the Public Advocate, p 10.]

6.29 Hon Aaron Stonehouse MLC expressed doubt that 'a person with a close personal relationship' (the last category shown above) should be able to make such a decision:

> The last category—any person who has reached 18 years of age and maintains a close personal relationship with the patient—gives me the most concern. My reading of that is that it implies that a friend or close acquaintance could make decisions for an unconscious patient and opt them into medical research and experimental treatment. That decision may be made in the best interests of the patient but we are really starting to stretch the definition of "guardian" and "next of kin". I have some very close friends but I might be a little concerned about a third party determining which of those close friends was best placed to make a

decision about what experimental treatment I may or may not have conducted upon me.[190]

6.30 Other jurisdictions that allow medical research decisions to be made by a person who has a close personal relationship with an incapacitated research candidate include:

- Australian Capital Territory (see paragraph 3.29)
- New South Wales (see paragraph 3.39)
- Queensland (see paragraph 3.56).

6.31 Victoria has legislated a similar hierarchy as that introduced in Western Australia however it does not contemplate a person with a close personal relationship making medical research decisions.[191]

6.32 The Committee did not receive evidence from stakeholders expressing concern about the hierarchy introduced by ss 110ZP and ZQ of the *Guardianship and Administration Act 1990*.

[190] Hon Aaron Stonehouse MLC, Western Australia, Legislative Council, *Parliamentary Debates (Hansard)*, 2 April 2020, p 2020.

[191] *Medical Treatment Planning and Decisions Act 2016* (Vic), s 55.

CHAPTER 7
Part 9E Division 2—Decisions about medical research

Introduction

7.1 This chapter considers 'Part 9E Division 2—Decisions about medical research' of the *Guardianship and Administration Act 1990*.[192] Division 2 contains the following three provisions:

- s 110ZR—Medical research with consent of research decision–maker
- s 110ZS—Medical research without consent of research decision–maker
- s 110ZT—Particular medical research not permitted.

7.2 Section 110ZR permits the involvement of incapacitated research candidates in medical research by allowing a research decision–maker to make a decision on the candidate's behalf. This chapter briefly explains the legislative requirements of s 110ZR. It also considers the benefits of requiring an independent medical practitioner to make an assessment of the research candidate's best interests, the likelihood they will regain the ability to consent and the risks involved.

7.3 Section 110ZS allows a researcher to conduct medical research on an incapacitated research candidate in urgent circumstances where it is not practicable to obtain a decision from a research decision–maker. This chapter briefly explains the legislative requirements of s 110ZS. It also considers whether the four–year sunset clause on this provision should be removed and the practicality of the requirement for an independent medical practitioner to make an assessment in urgent circumstances.

7.4 Sections 110ZR and ZS both require:

- decisions about medical research to be made in accordance with a research candidate's advance health directive if they have made one
- medical research to be discontinued as soon as practicable after a research candidate regains the ability to consent.

This chapter considers the practicality of these requirements.

7.5 Section 110ZT prohibits the use of electroconvulsive therapy and sterilisation procedures for the purpose of medical research.

Medical research with consent of research decision–maker (s 110ZR)

7.6 Under s 110ZR of the *Guardianship and Administration Act 1990*, a research decision–maker can provide consent to medical research on behalf of an incapacitated research candidate.[193] According to the Department of Health, it is expected that the majority of patient enrolments will occur under this provision.[194]

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192 Part 9E was introduced by the *Guardianship and Administration Amendment (Medical Research) Act 2020,* s 12.

193 The research decision–maker is determined according to *Guardianship and Administration Act 1990*, ss 110ZP, ZQ.

194 Department of Health, *Guidance Document: Involving Incapacitated Adults in Health and Medical Research,* 6 October 2020, p 8. See: https://rgs.health.wa.gov.au/Documents/GAA%20Medical%20Research%20Guidance%20Document.pdf. Viewed 12 October 2020.

7.7 Section 110ZR reflects the existing provisions for determining who can make a treatment decision in respect of an incapacitated person under Parts 9C and D of the *Guardianship and Administration Act 1990*.

Legislative requirements of s 110ZR

7.8 Under s 110ZR a research decision–maker may make a decision to consent, or refuse consent, to an incapacitated research candidate's participation in medical research if:

- it has been approved by an HREC[195]
- the research candidate is unable to make reasonable judgements about their participation in the research[196]
- it is not inconsistent with any advance health directive[197]
- an independent medical practitioner has made an assessment about:
    - the research candidate regaining the ability to consent within the timeframe approved by the HREC[198]
    - whether the research candidate's participation will be in their best interests or not adverse to their interests[199]
    - the risks involved in the research candidate's involvement in the medical research compared to existing treatment.[200]
- having regard to the independent medical practitioner's assessment the research decision–maker determines that the research candidate's participation is in their best interests, or not adverse to their interests[201]
- having regard to the independent medical practitioner's assessment the research decision–maker determines that the research candidate's participation will:
    - only involve observation of the research candidate or another non–invasive examination/treatment/procedure[202]
    - not involve any known substantial risk[203]
    - not involve any known substantial risks greater than risks associated with existing treatments[204]
    - not involve substantial risks greater than non–participation.[205]

195 *Guardianship and Administration Act 1990*, s 110ZR(1)(a).

196 ibid., s 110ZR(1)(b).

197 ibid., s 110ZR(4).

198 ibid., s 110ZR(1)(c).

199 ibid., s 110ZR(3)(a).

200 ibid., s 110ZR(3)(b).

201 ibid., s 110ZR(2)(b).

202 ibid., s 110ZR(2)(c)(i).

203 ibid., s 110ZR(2)(c)(ii).

204 ibid., s 110ZR(2)(c)(iii).

205 ibid., s 110ZR(2)(c)(iv).

Independent medical practitioner

7.9 A number of stakeholders expressed concern that the requirement to obtain a determination from an independent medical practitioner will delay access to medical research.[206] This included the Department of Health who made a submission that consideration should be given to removing this requirement for low–risk research:

> the DoH supports consideration being given to an independent medical practitioner determination not being required in the case of medical research where the level of risk is assessed by a HREC to be at an acceptable level.
>
> Further, as expressed in the DoH written submission to the Inquiry, the DoH's view is that "… consideration should be given to the need for an independent medical practitioner to make a determination with regards to best interests and risk when there is a research decision–maker available who is willing to make a decision as their decision will be based on the provision of information as per the process applicable to a person making their own decision." This would apply to 'non–urgent' research.[207]

7.10 The Australasian College for Emergency Medicine made a submission that the requirement to obtain a determination from an independent medical practitioner might be too burdensome. They suggested this requirement should be made optional for non–urgent research:

> When it comes to 110ZR, the concern is that introducing this independent medical practitioner could, potentially, if they are, for example, not available or the process is too burdensome, that is actually going to pose a barrier to enrolling eligible people into research which might be of benefit for them and into which, indeed, their research decision–maker might be willing to consent. One practical solution might be to say, where 110ZR is concerned, that access to a second opinion is something that should be made available, but there are a lot of circumstances where we will have clinical decisions with families all the time, and I do not necessarily routinely seek a second opinion from somebody, particularly somebody who, as defined here, is separate from the clinical process. That could, from some point of view, be seen as breaching the trust of that therapeutic alliance that you are building with the family member and through them the participant.[208]

7.11 In the Committee's view, these concerns arise at least partly from a lack of clarity in the *Guardianship and Administration Act 1990* already noted in this report in paragraphs 6.5–6.13. Nevertheless, the Committee considers it is worth noting these concerns in full.

7.12 The Institute of Health Research at the University of Notre Dame and the Western Australian Health Translation Network argued that non–urgent studies would be better managed through the HREC approval process rather than involving an independent medical practitioner:

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206 Submission 9 from Institute for Health Research, University of Notre Dame, 25 May 2020, pp 2–3; Submission 14 from South Metropolitan Health Service, 3 June 2020, p 3; Submission 17 from Western Australian Health Translation Network, 8 June 2020, pp 1, 10 and 11; Submission 19 from Australian Medical Association (WA), 8 June 2020, p 4; Submission 21 from Australasian College for Emergency Medicine, 8 June 2020, pp 4, 7 and 9; Submission 25 from Department of Health, 9 June 2020, pp 8 and 11; and Submission 26 from Sir Charles Gairdner Osborne Park Health Care Group, 12 June 2020, pp 3 and 4–5.

207 Dr James Williamson, Assistant Director General, Clinical Excellence Division, Department of Health, Answer to question on notice No 19 asked at hearing held 1 October 2020, dated 9 October 2020, p 4.

208 Dr Stephen Macdonald, Staff Specialist in Emergency Medicine, Royal Perth Hospital, Australasian College for Emergency Medicine, transcript of evidence, 30 September 2020, pp 13–14.

- Institute of Health Research, University of Notre Dame:

> For studies covered by Section 110ZR, the candidate (or now, the research decision maker) is always provided with a HREC approved Participant Information Sheet (PIS). The PIS describes in layman's language all aspects of the study including is objectives, eligibility requirements, data collection and storage, information sharing, methods of withdrawing from the study and potential risks. Involving an independent medical practitioner in studies like that described above adds additional cost and unnecessary burden on the medical workforce that is currently better managed through the existing HREC review process.[209]

Professor Jim Codde, Director, Institute of Health Research, University of Notre Dame expanded on this submission at the hearing on 30 September 2020 by explaining some of the practical difficulties of obtaining a determination from an independent medical practitioner:

> The challenge for us is finding an independent medical practitioner who has experience in aged care and in dealing with patients with dementia, but also, in our case, in the use of medical cannabis. Medical cannabis has been legal in Canada, for example, for a number of years, but less than 10 per cent of the general practitioner population actually seem to be able to engage in the use of it. There is not enough evidence out there where they feel that they can prescribe it in a medical situation. In Australia, we are not even at that point. We have found a person who is not part of our research team who meets those criteria but actually resides in another state; it has been that hard to find one.[210]

- Professor Gary Geelhoed, Executive Director, Western Australian Health Translation Network:

> My point was not why it was necessary to remove the IMP [independent medical practitioner] from non–critical research but why was it necessary in the first place if an independent Ethics committee sanctioned the research and an appropriate person/relative/guardian had agreed. It just seems a completely unnecessary step and one that in practice would virtually never change the decision made and offers no added protection to the subject.[211]

7.13 Ms Judy Allen, Chair of the Western Australian Country Health Service Human Research Ethics Committee and Dr Felicity Flack, Chair of the Sir Charles Gairdner Hospital and Osborne Park Group Human Research Ethics Committee were largely supportive of requiring an independent medical practitioner to provide determinations for non–urgent medical research because many of the determinations require medical expertise.[212] However, they also observed that an independent medical practitioner may not be in the best position to know the wishes of the research candidate.[213]

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209 Submission 9 from Institute for Health Research, University of Notre Dame, 25 May 2020, p 2.

210 Professor Jim Codde, Director, Institute of Health Research, University of Notre Dame, transcript of evidence, 30 September 2020, p 3.

211 Professor Gary Geelhoed, Executive Director, Western Australian Health Translation Network, Answer to question on notice No 2 asked at hearing held 1 October 2020, dated 16 October 2020, p 1.

212 Submission 15 from Western Australian Country Health Service Human Research Ethics Committee and Sir Charles Gairdner Hospital and Osborne Park Group Human Research Ethics Committee, 8 June 2020, p 4.

213 Which is something that must be taken into account as the paramount consideration of what is in the research candidate's best interests under s 110ZU(1)(a) of the *Guardianship and Administration Act 1990*.

7.14 The Committee notes that it is the research decision–maker, not the independent medical practitioner, who must ultimately decide what is in an incapacitated research candidate's best interests. This may go some way to addressing this concern.[214]

7.15 The Committee asked the Department of Justice to respond to the submissions that the requirement to obtain a determination from an independent medical practitioner can create additional costs and unnecessary burdens for non–urgent and low–risk medical research. The Department of Justice argued that it was important to retain it as a safeguard for incapacitated research candidates:

> The requirement for an independent medical practitioner's assessment of whether research would be in the best interests of the candidate, and of whether there would be any known substantial risks to the candidate, even in a non–urgent research situation, is an important safeguard that has been included to ensure the best interests and wellbeing of each individual person who is proposed to be a possible research candidate by researchers. It is important that there is an independent assessment of whether the proposed research will be in the best interests of the individual research candidate. To remove the independent medical practitioner's assessment may represent a departure from the best interests standards contained in the GAA [*Guardianship and Administration Act 1990*].[215]

7.16 The Department of Justice also made the following points in favour of retaining the requirement to obtain a determination from an independent medical practitioner:

- it would allow the research decision–maker (i.e. a spouse or other family member) to make a decision by reference to an independent assessment
- it would ensure individual assessment of the research candidate's best interests in addition to the more generalised HREC approval process
- it is likely that for many cases the independent medical practitioner will be the treating doctor and the additional costs may not be as dramatic as suggested by some stakeholders.[216]

7.17 In the Committee's view, the requirement to obtain a determination from an independent medical practitioner, who may be the treating doctor, for non–urgent medical research is consistent with the policy of providing appropriate safeguards for incapacitated research candidates. However, the Attorney General should consider the appropriateness of this requirement in the statutory review of Part 9E required by s 110ZZE(1)(a) after there has been an opportunity to review the operation of this requirement.

FINDING 22

The requirement to obtain a determination from an independent medical practitioner is an appropriate safeguard for incapacitated research candidates involved in medical research.

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.

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214 *Guardianship and Administration Act 1990*, s 110ZR(2)(b).

215 Dr Adam Tomison, Director General, Department of Justice, Answer to question on notice No 19, asked at hearing held 1 October 2020, dated 14 October 2020, p 3.

216 ibid., pp 3–4.

Urgent medical research without consent of research decision–maker (s 110ZS)

7.18 Under s 110ZS a researcher may involve an incapacitated research candidate in urgent medical research without obtaining consent from a research decision–maker if it is not practicable to do so.[217] While a researcher can use this provision as an interim measure, the lead researcher must continue to take reasonable steps to obtain consent from a research decision–maker.[218]

Legislative requirements of s 110ZS

7.19 Under s 110ZS, a researcher may conduct urgent medical research involving an incapacitated research candidate without obtaining consent from a research decision–maker if:

- the research has been approved by an HREC[219]
- the research candidate requires urgent treatment to:
  - save their life
  - prevent serious damage to their health
  - prevent suffering, pain or distress[220]
- the research candidate is unable to make reasonable judgements about their participation in the research[221]
- a decision to consent, or refuse consent, to the medical research has not already been made[222]
- it is not practicable to obtain a decision from a research decision–maker[223]
- it is unlikely to be practicable to obtain a decision from a research decision–maker within the timeframe for the research approved by the HREC[224]
- the researcher receives a determination from an independent medical practitioner that:
  - the research candidate is unlikely to regain the ability to consent within the timeframe approved by an HREC[225]
  - the research candidate's participation will be in their best interests or not adverse to their interests[226]
- an independent medical practitioner determines that the medical research will:
  - only involve observation of the research candidate or another non–invasive examination/treatment/procedure[227]

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217 The research decision–maker is determined according to *Guardianship and Administration Act 1990*, ss 110ZP, ZQ.

218 ibid., s 110ZS(3).

219 ibid., s 110ZS(1)(a).

220 ibid., ss 110ZH, ZS(1)(b).

221 ibid., s 110ZS(1)(c).

222 ibid., s 110ZS(1)(d).

223 ibid., s 110ZS(1)(e).

224 ibid., s 110ZS(1)(f).

225 ibid., s 110ZS(1)(g).

226 ibid., s 110ZS(1)(h).

227 ibid., s 110ZS(1)(i)(i).

- not involve any known substantial risk[228]
- not involve any known substantial risks greater than risks associated with existing treatments[229]
- not involve substantial risks greater than non–participation[230]

- the research is not inconsistent with any advance health directive.[231]

Independent medical practitioner

7.20 The Committee heard mixed views about the requirement to obtain a determination from an independent medical practitioner for urgent medical research. Some stakeholders considered it to be an appropriate safeguard, while others argued it could delay access to medical research and potentially be harmful to patient care.

7.21 Hon Eric Heenan QC noted there have been no opportunities for this requirement to be tested in practice. While he considered it to reflect a cautious approach he argued it would be appropriate for the Attorney General to consider this when Part 9E of the *Guardianship and Administration Act 1990* comes up for statutory review:

> In relation to the particular matters that we are concerned with in this legislation, I think on reflection that there is probably scope for some moderation of the role of the independent medical practitioner who is brought in as a check on all forms of research, particularly in the emergency situation. I have been informed by doctors and physicians whose views I respect that they are apprehensive about the existing regime being unduly time–consuming and bureaucratic, but I think that some of those anticipations are premature because the matter has not been tested in practice. As far as I am aware, there have been no occasions when this legislation has yet been put into operation in those fields.
>
> …
>
> I think this is a cautious approach. I do not think it is essential to have an independent medical practitioner in every situation. For example, in the critical care and emergency situations that we have just been speaking about, there is going to be a lot of problems with time and resources. I think that the need for an IMP [independent medical practitioner] and the role of the IMP in those situations could well deserve review. But, as yet, none of this has been trialled and we do not know how it is working. I would have thought that the time to address these questions is when the act comes up for review.[232]

7.22 Stakeholders who were in favour of retaining the requirement to obtain a determination from an independent medical practitioner for urgent medical research included the following:

- Professor Jim Codde, Director, Institute for Health Research, University of Notre Dame:

  > **The CHAIR**: what I am hearing you say suggests to me that you would not agree that in urgent cases the need for that determination could delay access to medical treatment.

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228 ibid., *1990*, s 110ZS(1)(i)(ii).

229 ibid., s 110ZS(1)(i)(iii).

230 ibid., s 110ZS(1)(i)(iv).

231 ibid., s 110ZS(2).

232 Hon Eric Heenan QC, transcript of evidence, 30 September 2020, pp 2–3, 9.

> **Prof. CODDE**: In a tertiary setting, no, I do not think so. I think it is an important step and I said that before. I think it does provide the intent of ensuring that patients who do not have dementia, who may recover their cognitive capacity but need an immediate decision made not for treatment but for participation in a research program which may have better outcomes—I think it is a worthwhile step. I support it.[233]

- Ms Pauline Bagdonavicius, Public Advocate:

  > I think the legislation provides a lot of safeguards for us, and that is where I take comfort from the role of the independent medical practitioner in particular having to look at all of that information and provide written advice to a research decision–maker, regardless of whether it is someone like myself in a statutory position or a family member as a substitute decision–maker. I think that is a critical element of the process in giving us some reassurances around the fact that it will be in a person's best interests or not adverse to their interests.
  >
  > …
  >
  > If we look at both the role of the independent medical research practitioner, as well as all the other elements that have to be complied with, I think we have a lot of safeguards that we have not had before but, at the same time, a lot of much better information for everyone to consider and be aware of as they are making a research decision on behalf of somebody.[234]

- Dr Stephen Macdonald, Staff Specialist in Emergency Medicine, Royal Perth Hospital appearing for Australasian College for Emergency Medicine:

  > In terms of 110ZS, I think absolutely that where a research decision is being made in the absence of a substitute decision–maker, having the safeguard of a second opinion, if you like, is a reasonable one, provided that that is framed in a way that actually achieves that objective…[235]

7.23 Stakeholders who were against the requirement to obtain a determination from an independent medical practitioner for urgent medical research are set out below.

- The Australian Medical Association (WA):

  > This group of patients rely on decisions being made in minutes, not hours or days. It is often actually hard to find people who are available, where they are going to pick up the phone or are willing to take on what is a fairly onerous task, and may be busy with their own jobs and their own patients at the same time. There is no credible evidence that they add any benefits to patient rights or outcomes. In fact, it probably delays or stops patients getting access to care and research that would actually, in the long–term, benefit certainly the population's outcomes but quite possibly the patient's outcome as well.[236]

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233 Professor Jim Codde, Director, Institute for Health Research, University of Notre Dame, transcript of evidence, 30 September 2020, p 6.

234 Pauline Bagdonavicius, Public Advocate, Office of the Public Advocate Western Australia, transcript of evidence, 30 September 2020, pp 3–4.

235 Dr Stephen Macdonald, Staff Specialist in Emergency Medicine, Royal Perth Hospital, Australasian College for Emergency Medicine, transcript of evidence, 30 September 2020, p 13.

236 Clinical Associate Professor David Mountain, Emergency Medicine Representative, Australian Medical Association (WA), transcript of evidence, 1 October 2020, pp 2–3.

- South Metropolitan Health Service:

  > Whilst the IMP [independent medical practitioner] is entirely appropriate for research involving experimental therapy as a safeguard, the IMP is not appropriate and indeed may be harmful to a patient's interest in other scenarios, most notably research where two interventions are being compared, both of which are deemed usual care alternatives.
  >
  > ...
  >
  > Involvement of an IMP in urgent comparative effectiveness studies under s 110ZS will cause delays in the administration of an otherwise standard treatment when this delay would not otherwise have occurred. There is high quality evidence that mandating delays for these sorts of research studies worsens patient outcomes.[237]

- Professor Gary Geelhoed, Executive Director of the Western Australian Health Translation Network:

  > The idea then that you call an independent medical practitioner—now, if they take their responsibilities seriously, clearly that means it is going to be delayed a quarter of an hour, half an hour, an hour, trying to come to grips with the particular trial, although they may be briefed on those if it is in the hospital. But on the particular patient's circumstances, if they are taking that seriously, it is just impractical. They cannot give an informed decision in a timely fashion. The practical reality as it stands is that no research in this area will go ahead in Western Australia—it is just not practical.[238]

7.24 In the Committee's view, the requirement to obtain a determination from an independent medical practitioner may make it impossible for some patients to be enrolled in some medical research and cause delays in other circumstances. However, since there have been no opportunities for this safeguard to be tested in practice, it should be reviewed by the Attorney General in the statutory review of Part 9E required by s 110ZZE(1)(a).

FINDING 23

If the requirement to obtain a determination from an independent medical practitioner for urgent medical research is to be removed, the importance of the requirement set out in s 110ZS(3) of the *Guardianship and Administration Act 1990* is elevated.

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.

237 Submission 14 from South Metropolitan Health Service, 3 June 2020, p 3.

238 Professor Gary Geelhoed, Executive Director, Western Australian Health Translation Network, transcript of evidence, 1 October 2020, p 5.

Sunset clause

7.25 The laws providing for urgent medical research without consent of a research decision–maker (s 110ZS) will be deleted after four years unless renewed by an Act of Parliament.[239] A provision that repeals laws in this way is commonly referred to as a sunset clause.

7.26 The sunset clause provisions which activate the lapsing of s 110ZS and introduces transitional provisions (Sunset Clause) are contained in the Amending Act. They are:

- section 13 of the Amending Act which deletes 'Section 110ZS—Urgent medical research without consent'
- section 15 of the Amending Act which inserts 'Schedule 5, Division 3—Transitional provision regarding the effect of repealed s 110ZS on continuing urgent medical research'
- section 2 of the Amending Act which delays the commencement of ss 13 and 15 until four years after Royal Assent, 8 April 2024.

Impact on ability to obtain funding

7.27 The Committee received one submission in support of the Sunset Clause from the Mental Health Commission:

> This 'sunset clause' is a safeguard against the misuse of section 110ZS, by limiting its life and repealing it after four years. The MHC welcomes this repeal limit on section 110ZS.[240]

7.28 The remaining evidence received by the Committee argued the Sunset Clause should be removed. Submissions from the Department of Health and Sir Charles Gairdner Osborne Park Health Care Group recommended the removal of the Sunset Clause on the basis that it might impact the ability to obtain funding for medical research projects with an expected timeline greater than four years.[241]

7.29 The Committee asked a number of witnesses for their views on removing the Sunset Clause at its hearings. Every witness who gave evidence at hearings was in favour of removing the Sunset Clause:

- Hon Eric Heenan QC:

> I think it should be removed. I think it is a possible impediment to the commencement of long–scale or long–duration studies. I watched the debates in the Parliament about this, and the impression I got was that this was a price that had to be paid to overcome concerns that the enrolment of patients without consent in emergency situations may be a step too far. But I think on mature consideration, you will be persuaded, or I hope you will be persuaded, that it is an acceptable arrangement, and that being the case, there should be no need for a sunset clause.[242]

- Dr Stephen Macdonald, Staff Specialist in Emergency Medicine, Royal Perth Hospital appearing for Australasian College for Emergency Medicine:

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239 *Guardianship and Administration Amendment (Medical Research) Act 1990,* ss 2, 13.

240 Submission 12 from Mental Health Commission, 3 June 2020, p 1.

241 Submission 25 from Department of Health, 9 June 2020, p 6–7, 11; Submission 26 from Sir Charles Gairdner Osborne Park Health Care Group, 12 June 2020, p 6.

242 Hon Eric Heenan QC, transcript of evidence, 30 September 2020, pp 7–8.

We do have concerns in terms of the sunset clause that the life of many clinical research projects is in the order of three to five years. There are concerns that not only getting funding, but also getting regulatory approval and ethics approval to undertake research where we do not know that we can actually complete the research is going to be challenging. Finally, if, say, the research did happen, there is the question of whether it would, in fact, be unethical to recruit participants into research where there is a chance that that research is not going to be able to be completed within that time frame.

…

We would recommend, respectfully, that [the Sunset Clause] is reconsidered.[243]

- Clinical Associate Professor David Mountain, Australian Medical Association (WA):

  We obviously have some significant issues with the current legislation as it was put in. I suppose there are four key issues that we are particularly concerned about. The amendment that was put in at the last minute—section 12A—puts in a four–year sunset clause. As far as we are aware, it becomes due on that date and stops the legislation, or removes proposed section 110ZS, which allows substitute decision–making.

  We are not quite sure why that was felt to be important. I mean, we have no problem with a review of the legislation, which is already written into the legislation at one year and every three years subsequently. I do not know why it would stop at four–years, unless you are substituting it with better legislation in the meantime. But it would be disastrous, frankly, for research to go back to the previous situation again after four–years and have everything go back to square one. That would really put us a long way behind the rest of the world.[244]

- Professor Gary Geelhoed, Executive Director, Western Australian Health Translation Network:

  To have a sunset clause is more or less saying that that is the end of it. The decision is not whether we stop it, but the decision is whether we restart it. I think that is really negative in the sense that a lot of research has not come to Western Australia because of this. In national committees and that, it is generally regarded that Western Australia is a basket case and we do not do this anymore.[245]

- Professor Jim Codde, Director, Institute for Health Research, University of Notre Dame:

  The sunset clause could impact on us planning to do that here in WA. To be totally honest with you, prior to the revisions to this act, we were seriously engaging with Victoria to shift the study there because we could not get the patient groups we wanted here. If that sunset clause had kicked in and the changes were revoked—I am not quite certain how that sunset clause will work—we could not run those studies here.[246]

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243 Dr Stephen Macdonald, Staff Specialist in Emergency Medicine, Royal Perth Hospital, Australasian College for Emergency Medicine, transcript of evidence, 30 September 2020, pp 16–17.

244 Clinical Associate Professor David Mountain, Emergency Medicine Representative, Australian Medical Association (WA), transcript of evidence, 1 October 2020, p 2.

245 Professor Gary Geelhoed, Executive Director, Western Australian Health Translation Network, transcript of evidence, 1 October 2020, p 13.

246 Professor Jim Codde, Director, Institute for Health Research, University of Notre Dame, transcript of evidence, 30 September 2020, p 13.

- Professor Antonio Celenza, Australasian College for Emergency Medicine:

> Just very briefly as an example, the minimum time to complete a PhD is three years, so if there is a sunset clause for four–years, we will not be enrolling PhD students for these sorts of studies.[247]

7.30 The Committee is of the view that the introduction of the Sunset Clause reflects a cautious approach to the introduction of the Bill and Amending Act which was appropriate in light of the urgent passage of the legislation. However, evidence suggests it may have the unintended consequence of impacting the ability of medical researchers to obtain funding. On balance, the Committee is of the view that the Sunset Clause should be repealed.

RECOMMENDATION 5

The four–year sunset clause on s 110ZS of the *Guardianship and Administration Act 1990* be repealed.

Requirement to comply with advance health directive (ss 110ZR(4), ZS(2))

7.31 Sections 110ZR and ZS require decisions about medical research to be made in accordance with a research candidate's advance health directive, if they have made one.[248]

7.32 The Department of Health explained the steps that are expected to be taken by the research decision–maker (s 110ZR) or the researcher (s 110ZS) to ascertain whether an incapacitated research candidate has an advance health directive as follows:

> A health professional would usually be expected to make inquiries with the patient's family, GP or carer to ascertain whether the patient has an advance health directive.
>
> In a time critical situation, there may be limited opportunity for the researcher to make inquiries as to whether the patient has an advance health directive. The expected steps would depend on the circumstances, for example the obligations would be different if the person was already a patient in a health care setting compared to if the urgent treatment is required in an external setting.[249]

Register of advance health directives

7.33 The submission from Hon Eric Heenan QC noted that researchers and research decision–makers may not know if an incapacitated research candidate has an advance health directive.[250] Mr Heenan noted that although the legislation introducing advance health directives in 2008 contemplated the creation of a central register of advance health directives, this has not occurred.[251]

7.34 The Committee asked the Department of Health whether any steps have been taken to create a register of advance health directives. They gave evidence that a register is anticipated to commence in late 2021 or early 2022:

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247 Professor Antonio Celenza, Professor of Emergency Medicine, St John of God, Australasian College for Emergency Medicine, transcript of evidence, 30 September 2020, p 17.

248 *Guardianship and Administration Act 1990,* ss 110ZR(4), ZS(2).

249 Dr James Williamson, Assistant Director General, Clinical Excellence Division, Department of Health, Answer to question on notice No 29 asked at hearing held 1 October 2020, dated 9 October 2020, p 7.

250 Submission 13 from Hon Eric Heenan QC, 5 June 2020, pp 19–20.

251 ibid., p 20.

> DoH is currently consulting with internal stakeholders on a number of the possible advance health directive register models, with a view to developing an options paper. A business case for the recommended option is expected to be developed in mid–2021 and the development of the AHD [advance health directive] Register is anticipated to commence in late 2021/early 2022.[252]

7.35 Ms Pauline Bagdonavicius, the Public Advocate, also gave the following update on the creation of a central register of advance health directives:

> Let me just comment that work is happening at the moment in relation to two registers—one for advance health directives, which is an outcome of the work done by the ministerial expert panel on advance health directives, which is an outcome of the government's response to the Joint Select Committee on End of Life Choices. If I can talk about the advance health directive one first, wider consultation is currently happening, and that is being led by the Department of Health with the community to develop a new advance health directive template that is consistent with the directions of the ministerial expert panel. That new template will make it clearer around what is a medical research decision being made by a person, and certainly guide people about the fact that they can make medical research decisions in their advance health directive. The committee also made recommendations around the establishment of a register, and I know that Health is currently looking at that. That work is ongoing at the moment and will be subject to consideration by the Department of Health and the Minister for Health. Given the intersection with the Guardianship and Administration Act, I am sure it is something that will also be drawn to the Attorney General's consideration in due course. Ultimately, that will be a Health decision around what happens in terms of the register, but it certainly would be advantageous because it would provide a central place that could be checked for any advance health directive.[253]

7.36 The evidence received by the Committee revealed a range of views. The following stakeholders were supportive of the creation of a central register to assist in the practical implementation of the Amending Act:

- Law Society of Western Australia:

> The importance of the advance health directive is highlighted in the above provision. However, the Law Society foresees problems arising in this area in that the availability of and access by the researcher to the candidate's advance health directive will prove to be difficult especially in urgent medical situations.
>
> This points to the need for an easily accessible register for advance health directives and also Enduring Powers of Guardianship.
>
> The provisions in the *Acts Amendment (Consent to Medical Treatment) Act 2008*, section 11 (to the extent to which they insert sections 110RA, 110ZAA, 100ZAB and 110ZAC relating to the establishment of such a register) and section 12 of that Act should be implemented as a matter of priority to make access to advance health directives readily available not only in the case of the legislation currently under review but more generally in health and aged care settings.[254]

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252 Dr James Williamson, Assistant Director General, Clinical Excellence Division, Department of Health, Answer to question on notice No 28 asked at hearing held 1 October 2020, dated 9 October 2020, p 7.

253 Pauline Bagdonavicius, Public Advocate, Office of the Public Advocate Western Australia, transcript of evidence, 30 September 2020, p 10.

254 Submission 28 from Law Society of Western Australia, 17 June 2020, p 3.

- Clinical Associate Professor David Mountain, Australian Medical Association (WA):

  > In terms of knowing people's advance care directives, that would be very useful to have on central registers so that you can actually see what their wishes are and check that they are up to date and properly documented so you can see what level of care they actually want. You certainly do not want to put patients in cardiac arrest studies and then find out that they have got an advance care directive that says they clearly did not want to be put in—certainly not in a study, but did not want to be resuscitated in that situation.[255]

- Ms Pip Brennan, Executive Director, Health Consumers' Council:

  > yes, I guess, from a consumer perspective, it is important to have this where people can get hold of it.[256]

- Hon Eric Heenan QC:

  > I certainly think there should be a register of advance health directives. The legislation already provides to that effect. The *Acts Amendment (Consent to Medical Treatment) Act 2008* at section 11 provides for a register of advance health directives, but it has never been promulgated. I gather that is something to do with cost and the problems of getting suitable software, but it is under investigation as a result of a recent report into aged health or something—Mr Millman has prepared it. As for … enduring powers of guardianship, yes. I think it would be helpful to have a register of those.
  >
  > I am informed that quite a lot of work has been going on among the state and commonwealth Attorneys General to try to form some national basis for that, but there are differences in the legislation in various states, and it is a work in progress.[257]

7.37 The Department of Justice was supportive of creating a central register but cautioned against its potential reliability:

> The Department of Justice, Office of the Public Advocate, notes that while the establishment of a register would assist health services to be aware of any advance health directive in which there is a treatment decision relating to medical research, depending upon how the register is developed it is likely that some advance health directives may not be registered. Therefore it would still be necessary for researchers to consult with appropriate people known to the person who has lost capacity to ascertain if an advance health directive is in place and its intent. People who may know about an advance health directive and its location may include the incapacitated person's enduring guardian/s, family, carers and treating medical practitioners particularly General Practitioners.[258]

7.38 The following witnesses were less enthusiastic, noting the creation of a central register would not necessarily be helpful in all cases of medical research:

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255 Clinical Associate Professor David Mountain, Emergency Medicine Representative, Australian Medical Association (WA), transcript of evidence, 1 October 2020, pp 10–11.

256 Pip Brennan, Executive Director, Health Consumers' Council (WA) Inc., transcript of evidence, 1 October 2020, p 14.

257 Hon Eric Heenan QC, transcript of evidence, 30 September 2020, p 7.

258 Dr Adam Tomison, Director General, Department of Justice, Answer to question on notice No 28 asked at hearing held 1 October 2020, dated 14 October 2020, p 6.

- Professor Gary Geelhoed, Executive Director, Western Australian Health Translation Network:

> I think with elective research where you have got time to discuss it and hear views et cetera, there is time there for the individual person to look at what their advance care directive said and so on in that individual case. I think that would be easy enough when there is no time constraint, so I do not know that particularly a register would help there, although I am not arguing against it, but I am saying in that case. In terms of the time–critical cases—the ones I am talking about, the research and the intensive care and all that—the intensive care is probably different because they have been admitted and probably they have worked out what the patient wanted and so on, but literally if they have just arrived at the emergency department or just in the intensive care unit or in an ambulance or something, the reality is that in a lot of those cases, they will be treated on their merits, because you just do not know what the advance care directive is. I am talking now just about treatment of these patients, as opposed to research. Then sometimes later you find there were advance care directives and maybe those things were not appropriate, but people always err on the assumption that you should do all the things possible, unless there is a reason not to.[259]

- Professor Jim Codde, Director, Institute for Health Research, University of Notre Dame:

> the advance care directive is of no value to us. A register is fine; I do not have a problem with it, but would it assist us in our research? No, because, in reality, that is just a pathway towards choosing how they want to die. We are trying to improve quality of life, so we are at a slightly different time point. Having a register around guardianship, particularly in the community study, as Amanda [Timler] has said, where we know that it is the spouse or it is the brother who actually is the guardian of the patient, may be of benefit to us. In a community setting, in the aged–care facility where that is probably held, we probably do not need it so much, but I can see merit in that, if that answers your question.[260]

7.39 There was general agreement that the creation of a central register would assist in the practical implementation of the requirement to ascertain if an incapacitated research candidate has an advance health directive. However, the Committee notes that some witnesses had reservations about the reliability of such a register and the benefits for urgent research and medical research in the aged care setting.

FINDING 24

The Department of Health has advised a central register of advance health directives is anticipated to commence in late 2021 or early 2022.

Discontinuing medical research when research candidate regains capacity (ss 110ZR(7), ZS(5))

7.40 Sections 110ZR(7) and ZS(5) of the *Guardianship and Administration Act 1990* require the lead researcher to discontinue medical research as soon as safely practicable if an incapacitated research candidate regains the ability to consent.[261]

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259 Professor Gary Geelhoed, Executive Director, Western Australian Health Translation Network, transcript of evidence, 1 October 2020, p 15.

260 Professor Jim Codde, Director, Institute for Health Research, University of Notre Dame, transcript of evidence, 30 September 2020, p 13.

261 *Guardianship and Administration Act*, ss 110ZR(7), ZS(5).

7.41 Practical difficulties of discontinuing medical research can arise if the research candidate intermittently regains capacity to consent. This was explained by Dr James Williamson, Assistant Director General, Clinical Excellence Division, Department of Health:

> Often in the context of the conditions we are dealing with there are complications: delirium for instance. It might be a patient in ICU [intensive care unit] recovering from an infection who goes through periods of lucidity but then lapses into periods of delirium. It is not straightforward, and people often have a stuttering course on their recovery from serious illness. Trying to pick the right time at which someone has regained that capacity is difficult to spot.[262]

7.42 The Committee received a submission from the Department of Health that the requirement to discontinue research upon a research candidate regaining capacity may impact the integrity of the research if the research candidate wishes to continue in the research:

> The requirement to stop research upon the person regaining capacity could impact the integrity of research if there is a disruption to the research activities, even if the person consents to the research at the first opportunity; for example, if continuous observation cannot be maintained.
>
> …
>
> The Department recommends that consideration be given to removing the default requirement for research to be discontinued as soon as is safely practicable if a person regains capacity, as this may impact on the integrity of the research if the person makes a decision to continue in the research.[263]

7.43 The Committee asked a number of witnesses who all agreed that discontinuing research immediately could cause difficulties should the research candidate wish to continue to be involved in the medical research.[264] Ms Pauline Bagdonavicius, the Public Advocate, explained how discontinuance might occur where a guardianship order has been made by the State Administrative Tribunal:

> I have not had any experience with the application of that provision, but as I have thought more about it I want to note that where the State Administrative Tribunal has put in place a guardianship order for a person and they are deemed to be regaining capacity, until the State Administrative Tribunal has revoked the guardianship order the person is deemed not to have the capacity to make that decision. In those sorts of cases, we could be doing quite planned approaches: if a person is enrolled in medical research, they have regained their capacity and presuming they want to continue with that medical research, it would be important to be liaising with the people undertaking that medical research to keep them informed of where things are up to in terms of the process before the State Administrative Tribunal. For instance, if it was my office, we can apply, go back to SAT for a revocation of the order, which we do frequently for many other issues, but in this specific case, if the person was deemed to have regained their capacity, we would make an application to the SAT but we would then be listed for a

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262 Dr James Williamson, Assistant Director General, Clinical Excellence Division, Department of Health, transcript of evidence, 1 October 2020, p 16.

263 Submission 25 from Department of Health, 9 June 2020, pp 9, 11.

264 Clinical Associate Professor David Mountain, Emergency Medicine Representative, Australian Medical Association (WA), transcript of evidence, 1 October 2020, p 11; Dr James Williamson, Assistant Director General, Clinical Excellence Division, Department of Health, transcript of evidence, 1 October 2020, p 15; Professor Jim Codde, Director, Institute for Health Research, University of Notre Dame, transcript of evidence, 30 September 2020, p 12; Professor Daniel Fatovich, Director of Research, Royal Perth Hospital, Department of Health, transcript of evidence, 1 October 2015, p 16.

> hearing date. It is not the sort of thing that the tribunal would routinely hear the next day; there would be a period of weeks before that hearing date was listed. That is an example of how practically you could be looking ahead to that listing date on the assumption that there is the medical evidence supporting the application for the revocation of the guardianship order and working with the lead researcher around what is happening in terms of that person's situation, and working with the person themselves.[265]

7.44 Clinical Associate Professor David Mountain from the Australian Medical Association (WA) and Professor Daniel Fatovich from the Department of Health noted that in practice the researcher would typically seek consent from the research candidate before discontinuing medical research:

- Clinical Associate Professor David Mountain, the Australian Medical Association (WA):

> I would have thought that in most situations there is time and a sensibility to say, "Let's have the initial discussion." If it is clear that the patient would be unwilling and clearly does not want to be in the study, then you stop the study as soon as possible. There might be times when it is unsafe to stop what is happening, because there is a course of treatment that has to finish and it would be dangerous to stop it. Other times you would say, "We can stop it straightaway. The patient has clearly made it obvious that they are not going to consent to have this ongoing." I think everybody would say, "That's fine, we will stop straightaway."[266]

- Professor Daniel Fatovich, Department of Health:

> A previous approach is if the research component has been complete because it was just the initial thing or something that was just starting the first 24 hours, when they regain capacity, the researcher would tend to go back to the patient and explain, "You were enrolled in this research, this is what it is about et cetera", and seek their permission, consent, to remain in the research, and use the data. Or the patient might say, "I do not give my consent. I want you to destroy all the data", or, "I'm happy for you to keep what you've got so far, but I don't want any more involvement in the research." So the research has been completed. It gets very messy and it depends on each different kind of research, but there is always the goal to try and get the consent from the patient if they regain capacity.[267]

7.45 While the obligation to discontinue medical research contemplates seeking the consent of the research candidate, it does not allow for that to occur before medical research is discontinued.

7.46 The Committee asked Mr Joshua Thomson SC, Solicitor General of Western Australia about the legal implications of medical research that continues between the time a research candidate regains capacity and medical research being discontinued. He gave the following opinion that to do so would be a civil wrong:

> I think the answer is that after the medical research decision ceases to have any effect because it has not been approved and it could have been discontinued as safely as possible, there is no further permission to carry out the medical research upon the patient, and to do so would be a civil wrong committed upon the

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265 Pauline Bagdonavicius, Public Advocate, Office of the Public Advocate Western Australia, transcript of evidence, 30 September 2020, p 8.

266 Clinical Associate Professor David Mountain, Emergency Medicine Representative, Australian Medical Association (WA), transcript of evidence, 1 October 2020, p 11.

267 Professor Daniel Fatovich, Director of Research, Royal Perth Hospital, Department of Health, transcript of evidence, 1 October 2015, p 15.

> patient. That would be characterised either as a trespass to the person or an assault, depending on the nature of the medical research. If you have in mind, for example, the idea of somebody having something put into them, as opposed to medical research in the nature of observation. That clearly might not be a civil wrong in terms of an assault or a trespass. But if we are talking about research that involves some sort of invasive procedure, once the consent to that research has expired, you are committing some form of civil wrong to the patient, because the research decision itself, if it has effect, is under the act as if it was given by the patient. That is made clear. I think it is in division 4 of part 9E.[268]

7.47 The requirement to discontinue medical research under ss 110ZR(7) and ZS(5) may unintentionally cause lead researchers to urgently discontinue medical research to avoid being held liable for trespass or assault. This may cause problems if the research candidate later wishes to continue in the medical research.

FINDING 25

Noting the importance of the goal to obtain consent from a patient if they regain capacity, the requirement to discontinue medical research as soon as safely practicable should allow an opportunity for the researcher to discuss with the research candidate if they wish to proceed before discontinuing the research.

Procedures for sterilisation and electroconvulsive therapy not permitted as medical research (s 110ZT)

7.48 Section 110ZT of the *Guardianship and Administration Act 1990* prohibits procedures for sterilisation and electroconvulsive therapy for the purpose of medical research. The explanatory memorandum for the Bill notes the following:

> The substance of section 110ZT, subsections (2) and (3) is that under no circumstances can consent be given for a research candidate to participate in medical research that is a procedure for sterilisation of the research candidate or for electroconvulsive therapy to be performed on the candidate.[269]

7.49 The Australian Psychological Society made a submission that they are reassured to see the prohibition on procedures involving electroconvulsive therapy and sterilisation however the submission did not expand on the reasoning behind this.[270]

Procedure for sterilisation

7.50 A procedure for sterilisation has the meaning given in s 56 of the *Guardianship and Administration Act 1990*.[271] The definition in s 56 is set out below:

> ***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;[272]

7.51 In *JS and CS* [2009] WASAT 90, the State Administrative Tribunal held that an application for a hysterectomy on a 23–year–old woman with an intellectual disability was not a procedure

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268 Joshua Thomson SC, Solicitor General of Western Australia, transcript of evidence, 1 October 2020, p 16.

269 Explanatory Memorandum, Legislative Council, Guardianship and Administration Amendment (Medical Research) Bill 2020, p 11.

270 Submission 20 from Australian Psychological Society, 8 June 2020, p 3.

271 *Guardianship and Administration Act 1990,* s 110ZT(1).

272 ibid., s 56.

for sterilisation because the sole purpose of the procedure was to stop symptoms associated with menstruation.

7.52 The Committee notes that a lawful procedure that is carried out for a lawful purpose other than sterilisation that incidentally results, or may result, in sterilisation may not be prohibited under s 110ZT of the *Guardianship and Administration Act 1990*. This is determined on a case by case basis.[273]

Electroconvulsive therapy

7.53 The Committee asked the Department of Health if electroconvulsive therapy has previously been used as medical research in Western Australia. It provided the following response:

> Aspects of electroconvulsive therapy have previously been the subject of medical research in WA.
>
> DoH notes that stakeholders have commented that electroconvulsive therapy should not necessarily be excluded from medical research.[274]

7.54 The Royal Australian and New Zealand College of Psychiatrists and the Australian Medical Association (WA) made submissions arguing that excluding electroconvulsive therapy perpetuates stigma around this clinically proven treatment and is unhelpful.[275] Clinical Associate Professor David Mountain expanded on the Australian Medical Association's written submission at the hearing on 1 October 2020 as follows:

> Finally, the fourth issue that we are particularly concerned about is that ECT yet again was singled out as a special case. ECT is a treatment—electroconvulsive therapy, although it is not very convulsive anymore. It is a well–regarded, well–known treatment that has been in place for over 40 years. It has a very good literature and evidence base behind it, and it is extremely important in helping people who are going through some of the worst conditions known to man. It is a living hell to be in a severe depression or a severe psychotic illness with no light at the end of the tunnel. Excessively bureaucratic processes already delay patients' access to care with this treatment. To add to that and then say that we are going to make it particularly more difficult for further research, which would actually improve the treatment and reduce its side–effect profile, seems to us a step too far. It is a treatment that always seems to be singled out for special treatment when in fact there is no good reason for it to be treated any differently from other treatments that we know are effective.[276]

FINDING 26

There is a strong body of expert opinion in favour of removing the prohibition on electroconvulsive therapy.

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273 For example, in *AD* [2007] WASAT 123 an application for a hysterectomy on a 22–year–old woman with an intellectual disability was found to be a procedure for sterilisation.

274 Dr James Williamson, Assistant Director General, Clinical Excellence Division, Department of Health, Answer to question on notice No 32 asked at hearing held 1 October 2020, dated 9 October 2020, p 8.

275 Submission 11 from Royal Australian and New Zealand College of Psychiatrists, 2 June 2020, pp 1–2; Submission 19 from Australian Medical Association (WA), 8 June 2020, pp 4–5.

276 Clinical Associate Professor David Mountain, Emergency Medicine Representative, Australian Medical Association (WA), transcript of evidence, 1 October 2020, p 3.

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.

CHAPTER 8
Part 9E Division 3—Provisions about research decisions

Introduction

8.1 This chapter considers 'Part 9E Division 3—Provisions about research decisions and urgent medical research decisions' of the *Guardianship and Administration Act 1990*.[277] Division 3 contains the following three provisions:

- s 110ZU—Assessment by independent medical practitioner of research candidate's best interests
- s 110ZV—Assessment by independent medical practitioner of likelihood of research candidate regaining ability to consent
- s 110ZW—Assessment by independent medical practitioner of risks.

8.2 In order to conduct medical research under the *Guardianship and Administration Act 1990* an independent medical practitioner is required to make an assessment of the research candidate's best interests, the likelihood they will regain the ability to consent and the risks involved pursuant to ss 110ZU, ZV and ZW. The Department of Health has prepared forms to facilitate these determinations.[278]

8.3 This chapter briefly covers the legislative requirements of each provision before considering the following issues in relation to all three provisions:

- whether the requirement for an independent medical practitioner to give their reasons in writing is helpful
- whether the establishment of panels of independent medical practitioners would be helpful
- problems with obtaining a determination from an independent medical practitioner in rural and regional areas.

Assessment of research candidate's best interests (s 110ZU)

8.4 Medical research that is conducted under the *Guardianship and Administration Act 1990* requires a determination from an independent medical practitioner that the research is either:

- in the best interests of the research candidate
- not adverse to the interests of the research candidate.[279]

8.5 In non–urgent cases the research decision–maker is only required to take the independent medical practitioner's determination into account in determining for themselves that the research is in the best interests, or not adverse to the interests, of the research candidate.[280] However, in urgent cases the researcher is not permitted to conduct medical research unless

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277 Part 9E was introduced by the *Guardianship and Administration Amendment (Medical Research) Act 2020,* s 12.

278 Attached as Appendix 5. Department of Health, *GAA Medical Research Decision Forms*, 6 October 2020 See: https://rgs.health.wa.gov.au/Pages/Document-Templates.aspx. Viewed 12 October 2020.

279 *Guardianship and Administration Act 1990,* ss 110ZR(3)(a), ZS(1)(h).

280 ibid., s 110ZR(2)(b).

an independent medical practitioner has made a positive determination that it will be in the best interests, or not adverse to, the interests of the research candidate.[281]

8.6 Pursuant to s 110ZU(1), the independent medical practitioner must take into account the following when making this determination:

(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.[282]

Prescribed matters

8.7 Section 110ZU(1)(e) allows regulations to prescribe additional matters which an independent medical practitioner must take into account in determining whether research will be in the best interests of an incapacitated research candidate. Mr Joshua Thomson SC, Solicitor General of Western Australia made the following arguments for the retention of this provision:

- The prescription of matters could not enlarge or contract the operation of the Act. It would only permit the prescription of matters which relate to whether research is in the candidate's best interests or not adverse to the interests of the candidate.
- The benefit of this provision is that it permits a checklist to be created for an independent medical practitioner of any further matters which ought to be considered. In that respect, it assists in providing practical certainty for an independent medical practitioner should there be a need to add specifically to matters which need to be considered.[283]

FINDING 27

Section 110ZU(1)(e) of the *Guardianship and Administration Act 1990* is an appropriate delegation of legislative power.

Placebos

8.8 Section 110ZU(2) states:

> The fact that medical research may involve the giving of placebos does not prevent a research decision–maker or an independent medical practitioner from

281 ibid., s 110ZS(1)(h).

282 ibid., s 110ZU(1).

283 Joshua Thomson SC, Solicitor General of Western Australia, Answer to question on notice No 27 asked at hearing held 1 October 2020, dated 1 October 2020, p 7.

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.[284]

8.9 The Public Advocate, Ms Pauline Bagdonavicius, made a submission to the 2015 Statutory Review expressing concern about the use of placebos on patients who are unable to make reasonable judgements.[285] She has since written a letter to the Attorney General reversing that view and supporting the use of placebos in medical research. A copy of this letter has been tabled in the Legislative Council and is attached as Appendix 6.

8.10 The Committee asked the Public Advocate to explain the reason behind the change in her position:

> my submission to the 2015 statutory review did indicate that it should not be possible for consent to a clinical trial in which a participant receives no treatment through a placebo rather than active treatment, as it could not be considered in their best interest and, therefore, would not be in accordance with the principles of the act. However, as we were starting to progress the drafting of the amendment act, Dr Gary Geelhoed, who was then the executive director of the Western Australian Health Translation Network and the former Chief Medical Officer of the Department of Health, came specifically to meet with myself around the issue of placebos and recommendations of the statutory review, and also in relation to urgent treatment that there had been a recommendation made about. After meeting with him, I was satisfied that, generally, placebos would provide a standard of care. I was given assurances that they would still receive the best possible existing treatment for their condition, not that they would not just receive the novel treatment being trialled in research. I also had some further correspondence from him.
>
> I would just like to say that I have seen what the Department of Health has indicated in its submission to the standing committee as well—that placebos are a standard control component of many clinical trials and to exclude their use would be against the fundamental standards of research methodology and would make it impossible to enrol people in clinical trials for drug treatments and vaccines. In my view, in terms of where we are with medical research legislation, ultimately, when a placebo is being used in a clinical drug trial, the research decision–maker is going to need to consider the research request on its merits each and every time and take into account the independent medical practitioner's recommendations regarding whether or not medical research is in the participant's best interests or not adverse to the interests and consider the various elements of the related research.[286]

8.11 The Committee received a number of submissions that were supportive of including placebos in the definition of medical research. These included the following:

- Institute for Health Research, University of Notre Dame:

  > The definition of medical research as described in Item 3AA adequately covers the topic and we are pleased to see that it enables the use of placebos within the trial.[287]

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284 *Guardianship and Administration Act 1990,* s 110ZU(2).

285 Department of the Attorney General, *Statutory Review of the Guardianship and Administration Act 1990,* November 2015, p 5.

286 Pauline Bagdonavicius, Public Advocate, Office of the Public Advocate Western Australia, transcript of evidence, 30 September 2020, pp 2–3.

287 Submission 9 from Institute for Health Research, University of Notre Dame, 25 May 2020, p 2.

- Mental Health Commission:

  The MHC accepts that when a research candidate receives a placebo, the candidate, while not receiving the trial agent, would still be receiving treatment. The MHC further accepts that in the research process, it is crucial for a placebo group, to ensure integrity in the trial.[288]

- Hon Eric Heenan QC:

  Another important and overdue innovation in this legislation is that the definition of 'placebo' has been made clear. The definition adopted is from the National Statement and the Act properly recognises that use of placebos within a trial, even where unidentifiable to the researchers or patients, is not an impediment in trials involving incapacitated patients.[289]

- Department of Health:

  Section 3AA(2) of the Act lists specific activities that fall within the definition of medical research and expressly provides that medical research includes the administration of placebos…To exclude the use of placebos would be against fundamental standards of research methodology (which also include randomisation and 'blinding') and would make it impossible to enrol people in clinical trials for drug treatment and vaccines.[290]

8.12 The Committee notes the importance of placebos in research methodology. The Committee agrees with the view expressed by the Public Advocate that the research decision–maker will need to consider the research request on its merits and take into account the independent medical practitioner's recommendations, including information about the use of placebos.

Assessment of likelihood of research candidate regaining ability to consent (s 110ZV)

8.13 Medical research that is conducted under the *Guardianship and Administration Act 1990* requires a determination from an independent medical practitioner about whether the incapacitated research candidate is likely to regain the ability to consent within the timeframe for the research approved by the HREC.[291] In making this determination the independent medical practitioner must take into account:

(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.[292]

8.14 The Committee received a number of submissions that the requirement to consider the timeframe approved by the HREC for the medical research pursuant to s 110ZV(1)(e) has led

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288 Supplementary Submission 12 from Mental Health Commission, 29 September 2020, p 1.

289 Submission 13 from Hon Eric Heenan QC, 5 June 2020, p 15.

290 Submission 25 from Department of Health, 9 June 2020, p 4.

291 *Guardianship and Administration Act 1990,* ss 110ZR(1)(c), ZS(1)(g).

292 ibid., s 110ZV(1).

to HRECs adopting an unworkable interpretation that they are required to specify a time in hours and minutes.[293]

8.15 The Department of Health recommended it may be more appropriate to adopt an interpretation where the timeframe is defined as an event occurring or milestone being reached:

> 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 required the treatment).

8.16 The Department of Health has published this interpretation in a guidance document prepared to assist researchers and health service providers:

> 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).[294]

8.17 The Committee asked the following stakeholders for their views on the interpretation suggested by the Department of Health:

- Professor Jim Codde, Director, Institute of Health Research, University of Notre Dame:

> **The CHAIR**: the submission from the Department of Health has recommended that the time frame may not necessarily be numerically defined as it may be more appropriate to define the time line as an event.
>
> **Prof. CODDE**: I agree with that. I am uncertain where that came from; I did not read their submission. Time lines are difficult. Disease follows a pathway. Through to death or recovery—whatever it is—there is a pathway. Time is quite variable. I think it is better to say you are looking for deterioration or improvement in some way, regardless of time. It makes more sense to me.[295]

- Ms Pauline Bagdonavicius, Public Advocate:

> I would support the Department of Health's interpretation and as I have turned my mind to this, trying to put forward practical situations around it, it confirmed that I think that is a good approach.[296]

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293 Submission 17 from Western Australian Health Translation Network and Health Consumers' Council (WA), 8 June 2020, pp 10–11; Submission 19 from Australian Medical Association (WA), 8 June 2020, p 5; Submission 21 from Australasian College for Emergency Medicine, 8 June 2020, pp 6 and 9.

294 Department of Health, *Guidance Document: Involving Incapacitated Adults in Health and Medical Research,* 6 October 2020, p 5. See: https://rgs.health.wa.gov.au/Documents/GAA%20Medical%20Research%20Guidance%20Document.pdf. Viewed 12 October 2020.

295 Professor Jim Codde, Director, Institute of Health Research, University of Notre Dame, transcript of evidence, 30 September 2020, p 11.

296 Pauline Bagdonavicius, Public Advocate, Office of the Public Advocate Western Australia, transcript of evidence, 30 September 2020, pp 9–10.

8.18 The Committee notes the interpretation suggested by the Department of Health is broadly supported.

FINDING 28

The guidance material published by the Department of Health regarding the assessment of a research candidate regaining the ability to consent is satisfactory.

Assessment of risks (s 110ZW)

8.19 Medical research that is conducted under the *Guardianship and Administration Act 1990* requires a determination from an independent medical practitioner of the risks involved in the medical research.[297] This determination must take into account the following:

> (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.[298]

8.20 The Committee did not receive any submissions expressing concerns about this provision.

Assessment of independent medical practitioner to be in writing (ss 110ZU, ZV, ZW)

8.21 Sections 110ZU, ZV and ZW each contain the following requirement that the independent medical practitioner provide the reasons for their determination in writing:

> 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.[299]

297 *Guardianship and Administration Act 1990,* ss 110ZR(3)(b), ZS(1)(i).

298 ibid., s 110ZV(1).

299 ibid., ss 110ZU(3), ZV(2), ZW(2).

8.22 The following stakeholders were critical of the requirement that the independent medical practitioner provide their reasons in writing:

- Western Australian Health Translation Network and Health Consumers' Council (WA):

  > to provide reasons in writing for each one … is unreasonable and unworkable in an emergency situation. It is not logical to add processes that do not add to protection of the patient but do add to the time requirements such that it delays treatment.[300]

- Australian College for Emergency Medicine:

  > The requirement for the IMP [independent medical practitioner] to provide written justification for their research decision be removed on the basis that it adds nothing to patient protection and is likely to delay care and distract health professionals from essential patient care.[301]

8.23 The Committee asked the Department of Health, the Department Justice and the Public Advocate for their views on retaining the requirement for the independent medical practitioner to provide their reasons in writing. All three were supportive of retaining this requirement on the basis that it was an important safeguard:

- Ms Pauline Bagdonavicius, the Public Advocate:

  > The provision of written determination by an independent medical practitioner, I think, is a very key document to support the research decision–maker ensure that all requirements considered in making the decision as to whether or not the research candidate is to participate, as well as providing an important record for the medical research decision. The requirements are extensive. It is really important that there is consistency of information available, and available over time as well, in terms of what the independent medical practitioner's views were. From my experience from my office, there will be more than myself involved in making such a decision. There will be a guardian; I may get a request after hours, which would be a different guardian who is the on–call guardian for that night; and managers may be involved in discussions with staff as well before the proposal comes to my attention. We will actually want a consistent source of truth in terms of what the independent medical practitioner said. There is a range of things that need to be addressed by an independent medical practitioner. The legislation does allow for where it is "practicable", and I would say a lot of the research may well be non–urgent medical research, in which case it should be practicable and should occur, but in some urgent situations, certainly as and when we progress things, I would be prepared to talk to the independent medical practitioner after hours, say, ensuring that they have covered the issues but also wanting to get from them very clearly their written documentation to support what they have said to me orally. I just think it is essential. It is a critical safeguard.[302]

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300 Submission 17 from Western Australian Health Translation Network and Health Consumers' Council (WA), 8 June 2020, p 11.

301 Submission 21 from Australasian College for Emergency Medicine, 8 June 2020, p 9.

302 Pauline Bagdonavicius, Public Advocate, Office of the Public Advocate Western Australia, transcript of evidence, 30 September 2020, p 9.

- Department of Justice:

  > Requiring the determinations of the independent medical practitioner to be in writing most certainly provides additional protections to the research candidate. Should, for example, the candidate regain capacity and want to understand what assessment was made in relation to their participation in the research, they can request to see these documents. Should an interested person apply to the State Administrative Tribunal for review under Division 5 of the Act, this may be an important record to request. The requirement to record written reasons also ensures transparent decision making in the event of any allegation of unlawful conduct giving rise to potential civil or criminal liability.[303]

- Department of Health:

  > Where a determination by an independent medical practitioner is required under section 110ZR, it is necessary for the determination to be in writing to ensure that the research decision–maker can review the determination without influence from a third party and has time to properly consider and understand the determination.
  >
  > A written confirmation of an independent medical practitioner's determination is also necessary to ensure that there are proper records of the determination.[304]

8.24 The Committee notes that requiring an independent medical practitioner to provide their determination in writing may also be an important safeguard because the determination may be:

- requested by a person who applies to the State Administrative Tribunal for a review of a decision made under Part 9E[305]
- used to determine if it was reasonable for a researcher to assume another researcher had obtained a determination from an independent medical practitioner for the purposes of s 110ZX(6).[306]

FINDING 29

The requirement for an independent medical practitioner to provide their reasons in writing is consistent with the policy of providing appropriate safeguards for incapacitated research candidates.

Establishing panels of independent medical practitioners

8.25 In its written submission, the Department of Health noted that it has considered the establishment of panels of independent medical practitioners to facilitate the requirement to obtain a determination from an independent medical practitioner:

> One option that is under consideration, is the establishment of panels of independent medical practitioners at research sites that would be required to familiarise themselves with the research protocols and make themselves available to provide a determination when necessary.[307]

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303 Dr Adam Tomison, Director General, Department of Justice, Answer to question on notice No 21 asked at hearing held 1 October 2020, dated 14 October 2020, p 5.

304 Dr James Williamson, Assistant Director General, Clinical Excellence Division, Department of Health, Answer to question on notice No 21 asked at hearing held 1 October 2020, dated 9 October 2020, p 5.

305 *Guardianship and Administration Act 1990,* s 110ZZA(3).

306 ibid., s 110ZX(6).

307 Submission 25 from Department of Health, 9 June 2020, p 8.

8.26 The Department of Health has since advised the Committee that no further steps have been taken to establish such a panel.[308]

8.27 The Committee asked the following stakeholders for their views on the establishment of panels of independent medical practitioners:

- Ms Pauline Bagdonavicius, Public Advocate:

  > Yes. I think that is a very pragmatic and sensible approach. Obviously, in each case, the independent medical practitioner will have to ensure that they do not have a conflict of interest to declare.[309]

- Australian Medical Association (WA):

  > **The CHAIR**: We have a submission from the Department of Health that refers to establishing panels of independent medical practitioners who would make themselves available. Would you be sceptical about the utility of that move?
  >
  > **Prof. MOUNTAIN**: If they had enough of them and they were able to provide the resource. I am not sceptical per se, but concerned, I suppose, that if they were not able to keep those panels topped up or were not able to find enough practitioners in the first place, we would be back in a situation where research would be either delayed, stopped or unable to progress because there were not enough people on the panels, and if they needed to be paid, to make sure there were enough people on the panels, again I would be concerned where that funding would come from. I do not know whether the Department of Health said it was happy to fund those sorts of panels but I would be concerned that that would be one of the major stumbling blocks to it.[310]

- Professor Jim Codde, Director, Institute for Health Research, University of Notre Dame:

  > **The CHAIR**: The submission from the Health Department refers to establishing panels. I think you have already indicated that you are in favour of the establishment of those panels based on your empirical experience.
  >
  > **Prof. CODDE**: In principle, yes. From my previous experience, I can see benefit in that. I think, in reality, if some patient came in unconscious and immediately needed to undergo treatment, it will be who is on call rather than a panel, if you need to find somebody.[311]

- Professor Gary Geelhoed, Executive Director, Western Australian Health Translation Network:

  > **The CHAIR**: I do not know whether you are familiar with the suggestion from the Health Department about establishing panels of independent medical practitioners… Do you think there is any merit in that? …
  >
  > **Prof. GEELHOED**: Yes and no, for all the reasons I said before. I just do not think it is necessary to have anyone, but, clearly, if you had panels and I would hope—making the point here about the real practicalities around this time–critical stuff—

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308 Dr James Williamson, Assistant Director General, Clinical Excellence Division, Department of Health, Answer to question on notice No 22 asked at hearing held 1 October 2020, dated 9 October 2020, p 5.

309 Pauline Bagdonavicius, Public Advocate, Office of the Public Advocate Western Australia, transcript of evidence, 30 September 2020, p 9.

310 Clinical Associate Professor David Mountain, Emergency Medicine Representative, Australian Medical Association (WA), transcript of evidence, 1 October 2020, p 7.

311 Professor Jim Codde, Director, Institute for Health Research, University of Notre Dame, transcript of evidence, 30 September 2020, p 9.

> but if it was for other ones or if in fact it was something like we could convince you to do something post the event where each case is reviewed by an independent practitioner, it would make sense, then, to have it—not just willy–nilly—but you would have appropriately qualified and interested people to look at these things. So, yes.[312]

8.28 The Committee notes the evidence in this inquiry largely supports the creation of a panel of independent medical practitioners.

FINDING 30

The establishment of a panel of independent medical practitioners would help to facilitate the operation of the *Guardianship and Administration Act 1990*.

Independent medical practitioners in rural and regional areas

8.29 In their written submission, the Australasian College for Emergency Medicine expressed concern that the requirement to obtain a determination from an independent medical practitioner will disadvantage research candidates in rural and regional hospitals.[313]

8.30 The Committee asked the Department of Health if they have considered any measures to avoid research candidates outside metropolitan areas being disadvantaged in this way. It provided the following response:

> Many rural hospitals only have one medical practitioner on site at a time, so this requirement for an independent medical practitioner is extremely problematic for rural communities. At this stage, the DoH is not aware of any steps that have or can be taken to avoid this disadvantage.[314]

FINDING 31

The requirement to obtain a determination from an independent medical practitioner when performing medical research under the *Guardianship and Administration Act 1990* is problematic for many rural and regional communities.

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*.

312 Professor Gary Geelhoed, Executive Director, Western Australian Health Translation Network, transcript of evidence, 1 October 2020, p 12.

313 Submission 21 from Australasian College for Emergency Medicine, 8 June 2020, p 5.

314 Dr James Williamson, Assistant Director General, Clinical Excellence Division, Department of Health, Answer to question on notice No 26 asked at hearing held 1 October 2020, dated 9 October 2020, p 6.

CHAPTER 9
Part 9E Division 4—Effect of research decisions and urgent medical research decisions

Introduction

9.1 This chapter considers 'Part 9E Division 4—Effect of research decisions and urgent medical research decisions' of the *Guardianship and Administration Act 1990*.[315] Division 4 contains the following two provisions:

- s 110ZX—Reliance by researcher on research decision or urgent medical research decision
- s 110ZY—Validity of certain research decisions or urgent medical research decisions.

9.2 When these provisions are satisfied a researcher is taken to have acted in accordance with a valid decision to commence, not commence, continue or discontinue medical research involving a research candidate.[316] These provisions have been modelled on the existing provisions governing medical treatment.[317]

Reliance by researcher on research decisions and urgent medical research decisions (s 110ZX)

9.3 There can be legal consequences for a researcher who fails to obtain a research candidate's consent or comply with the provisions in Part 9E of the *Guardianship and Administration Act 1990* before performing medical research. This may include exposure to legal claims including trespass to the person, assault or negligence.[318]

9.4 The potential liability of people performing medical treatment was explained to a previous Standing Committee on Legislation by the State Solicitor's Office in 2007 when Parts 9C and 9D were inserted into the *Guardianship and Administration Act 1990*:

> The current law, in essence, is that a health professional may provide medical treatment to a patient only if the patient personally consents to that treatment or, as in the case of emergencies, consent is implied. Treatment without consent exposes the health professional to civil or criminal proceedings for trespass or assault.[319]

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315 Part 9E was introduced by the *Guardianship and Administration Amendment (Medical Research) Act 2020,* s 12.

316 *Guardianship and Administration Act 1990*, s 110ZX(1).

317 ibid., ss 110ZK, ZL.

318 *Rogers v Whitaker* (1992) 175 CLR 479 per Mason CJ, Brennan, Dawson, Toohey and McHugh JJ; *Secretary, Department of Health and Community Services v JWB and SMB* (Marion's Case) (1992) 175 CLR 218 at 310–11 per McHugh J; *Dean v Phung* [2012] NSWCA 223. See also Department of Health of Western Australia, *WA Health Consent to Treatment* Policy, 2016, p 4. See: https://healthywa.wa.gov.au/~/media/Files/Corporate/Policy%20Frameworks/Clinical%20Governance%20Safety%20and%20Quality/Policy/WA%20Health%20Consent%20to%20Treatment%20Policy/Supporting/WA-Health-Consent-to-Treatment-Policy.pdf. Viewed 2 November 2020.

319 Western Australia, Legislative Council, Standing Committee on Legislation, report 10, *Acts Amendment (Consent to Medical Treatment) Bill 2006*, October 2007, p 40. Sue Le Souef, Senior Assistant State Solicitor, State Solicitor's Office, letter, 28 September 2007, pp 11–12.

9.5 The *Guardianship and Administration Act 1990* provides protection for researchers who comply with the provisions of Part 9E from civil or criminal liability.[320]

9.6 Under s 110ZX of the *Guardianship and Administration Act 1990*, the decision of a researcher who complies with the provisions of Part 9E to commence, not commence, continue or discontinue medical research is treated as though:

- the decision was made by the research candidate
- the research action was taken with the research candidate's consent
- the research candidate had full legal capacity.[321]

9.7 This has the effect of protecting a researcher from a civil action in trespass or a criminal action for assault. The Committee notes that this provision does not provide a defence to actions in negligence.

Legislative requirements of s 110ZX

9.8 Section 110ZX will only apply in this way if the researcher's decision was made:

- while reasonably believing the research candidate is unable to make reasonable judgments and relying in good faith on what is purportedly a decision to consent, or refuse consent, to medical research under ss 110ZR (non–urgent medical research) or ZS (urgent medical research)
- while reasonably believing that another researcher has ascertained the decision is made in accordance with ss 110ZR (non–urgent medical research) or ZS (urgent medical research) in circumstances where it is reasonable to do so.[322]

9.9 The question of whether the researcher acted reasonably is an objective standard determined according to the standards of how a reasonable researcher would have acted in the circumstances.[323]

Comparison with existing medical treatment provisions

9.10 Section 110ZX is largely consistent with the existing provisions governing medical treatment.[324] The only difference is that under s 110ZX the researcher's decision to commence or discontinue medical research also has effect as if this decision was taken with the research candidate's consent. A comparison of the two provisions is set out in Table 1:

320 *Guardianship and Administration Act 1990*, s 110ZX.

321 ibid., s 110ZX(4).

322 ibid., s 110ZX.

323 Western Australia, Legislative Council, Standing Committee on Legislation, report 10, *Acts Amendment (Consent to Medical Treatment) Bill 2006*, October 2007, pp 50–2, 58.

324 *Guardianship and Administration Act 1990,* s 110ZK(2).

Table 1. *Comparison with existing medical treatment provisions: reliance on research decisions*

Medical treatment	Medical research
s 110ZK(2): … the health professional is taken for all purposes to take the treatment action in accordance with a treatment decision that has effect as if— (c) it had been made by the patient; and (d) the patient were of full legal capacity.	s 110ZX(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.

[Source: *Guardianship and Administration Act 1990*, ss 110ZK(2) and 110ZX(4).]

Reliance on another researcher

9.11 The Law Society of Western Australia made the following recommendation:

> The Law Society considers that the section should be amended so that the reliance of the researcher should be on the lead researcher, not simply another researcher, having ascertained responsibility for checking that the research action is in accordance with the research decision.[325]

9.12 The Committee notes the Law Society's view.

Validity of certain research decisions or urgent medical research decisions (s 110ZY)

9.13 Under s 110ZY of the *Guardianship and Administration Act 1990*, a researcher who commences or discontinues medical research in accordance with ss 110ZR (non–urgent medical research) or ZS (urgent medical research) is taken to have done so in accordance with a valid decision even if the effect of doing so is to worsen the candidate's condition or prognosis.

Legislative requirements of s 110ZY

9.14 The researcher's liability is not limited in this way if the medical research:

- was inconsistent with the research candidate's advance health directive[326]
- was not discontinued as soon as practicable after the research candidate regaining capacity[327]
- involved electroconvulsive therapy or a procedure for sterilisation.[328]

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325 Submission 28 from Law Society of Western Australia, 17 June 2020, p 3.

326 *Guardianship and Administration Act 1990,* ss 110ZR(4), ZS(2).

327 ibid., ss 110ZR(7), ZS(5).

328 ibid., s 110ZY(2)(b).

Comparison with existing medical treatment provisions

9.15 This provision is similar to the equivalent provision in relation to medical treatment. A comparison of the two provisions is set out in Table 2:

Table 2. *Comparison with existing medical treatment provisions: validity of research decisions*

Medical treatment	**Medical research**
s 110ZL: the health professional is taken for all purposes to have done so in accordance with a valid treatment decision, even if an effect of doing so is to hasten the death of the patient.	s 110ZY: 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

[Source: *Guardianship and Administration Act 1990,* ss 110ZL and ZY.]

CHAPTER 10
Part 9E Division 5—Jurisdiction of the State Administrative Tribunal

Introduction

10.1 This chapter explains the jurisdiction of the State Administrative Tribunal to consider guardianship matters. It begins with a short explanation of that jurisdiction before considering 'Part 9E Division 5—Jurisdiction of the State Administrative Tribunal' of the *Guardianship and Administration Act 1990*.[329] Division 5 contains the following three provisions:

- s 110ZZ—Applying for review of decision made under this Part
- s 110ZZA—Procedure on review
- s 110ZZB—Effect of State Administrative Tribunal's decision under this Division.

10.2 These provisions apply to applications made to the State Administrative Tribunal to review decisions made under Part 9E. Division 5 has been modelled on the existing provisions governing medical treatment.[330]

10.3 Division 5 supplements Parts 2 and 3 of the *Guardianship and Administration Act 1990* which govern the jurisdiction of the State Administrative Tribunal for the purpose of the Act.

Jurisdiction of the State Administrative Tribunal

10.4 The State Administrative Tribunal of Western Australia has jurisdiction to make guardianship and administration orders.[331] This jurisdiction includes:

- considering applications for guardianship and administration orders
- appointing a guardian or administrator
- declaring the capacity of a person to vote
- reviewing guardianship and administration orders
- giving or withholding consent to sterilisation of persons in respect of whom guardianship orders are in force
- certain powers in relation to powers of attorney.

10.5 The *Guardianship and Administration Act 1990* sets out principles to be observed by the State Administrative Tribunal. These include:

- the primary concern is the best interests of any represented person, or of a person in respect of whom an application is made
- every person shall be presumed to be capable of looking after their own health and safety, making reasonable judgements and managing their own affairs until the contrary is proven
- an order shall not be made if it could be met by other less restrictive means

329 Part 9E was introduced by the *Guardianship and Administration Amendment (Medical Research) Act 2020,* s 12.

330 *Guardianship and Administration Act 1990,* ss 110ZM, ZN.

331 ibid., s 13.

- the State Administrative Tribunal should, as far as possible, seek to ascertain the views and wishes of the person concerned.[332]

Applying for review of a decision (s 110ZZ)

10.6 Section 110ZZ of the *Guardianship and Administration Act 1990* allows a person to apply to the State Administrative Tribunal for review of a decision made under Part 9E. The person must be someone who, in the opinion of the State Administrative Tribunal, has an interest in such a decision.

10.7 This provision is the same as the equivalent provision governing medical treatment.[333]

Procedure on review (s 110ZZA)

10.8 Section 110ZZA of the *Guardianship and Administration Act 1990* sets out the procedures to be followed for an application to review a decision made under Part 9E. It allows the original decision–maker to vary or cease their decision even if it is the subject of a review application.

10.9 The original decision–maker in relation to a review commenced under Division 5 may include:

- a researcher who has commenced, not commenced, continued or discontinued urgent medical research
- a research decision–maker who has consented, or refused consent, for a research candidate to be involved in medical research.

Provisions excluded from *State Administrative Tribunal Act 2004*

10.10 Section 110ZZA(1) states that the following provisions of the *State Administrative Tribunal Act 2004* do not apply in relation to an application for review under Division 5:

(a) section 20 ['Notice of decision and right to have it reviewed to be given by decision–maker'];

(b) subject to subsection (4)—sections 21 ['Statement of reasons for decision, request for etc.'], 22 ['Tribunal may order decision–maker to provide reasons'] and 23 ['Exceptions to what has to be provided'];

(c) sections 26(e) ['After review commenced, decision–maker's powers restricted'] and 31 ['Tribunal may invite decision–maker to reconsider decision'];

(d) section 29(3)(c)(ii) ['Tribunal's powers in review jurisdiction'];

(e) section 29(5)(b) ['Tribunal's powers in review jurisdiction'].[334]

10.11 Among other things these provisions:

- require the original decision–maker to provide written reasons
- require the original decision–maker to give notice of a right to have the decision reviewed by the State Administrative Tribunal
- allow the State Administrative Tribunal to send the decision back to the original decision–maker for re–consideration.

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332 ibid., s 4.

333 ibid., s 110ZM.

334 ibid., s 110ZZA(1).

10.12 Mr Joshua Thomson SC, Solicitor General of Western Australia gave the following explanation for these provisions being excluded:

- They were excluded, as a matter of practicality. The purpose of a review is so that any decision upon a review only operates prospectively, rather than retrospectively. That is to protect a researcher who has acted upon a decision to carry out research before a review decision operates. Hence, the review is effectively a rehearing and applies from the point when it takes effect. There is no need to go into the previous decision.
- The exclusion of these provisions was the subject of consultation with the President of the State Administrative Tribunal.[335]

10.13 The Committee agrees the exclusion of these provisions is appropriate.

Expedited review

10.14 Hon Charles Smith MLC commented on the ability of a decision under Part 9E of the *Guardianship and Administration Act 1990* to be resolved by the State Administrative Tribunal in a timely manner:

> the role of tribunals may perhaps be useless given how rapidly a person's health can turn, unless cases can be expedited, which I have not seen in this legislation.[336]

10.15 Although the Amending Act does not introduce specific provisions allowing for cases to be expedited, the State Administrative Tribunal does have the ability to consider urgent applications and interim injunctions.[337]

10.16 Mr Joshua Thomson SC, Solicitor General of Western Australia gave the following evidence regarding the ability of the State Administrative Tribunal to consider urgent applications:

- To the extent that the Committee's concern is directed to whether the SAT [State Administrative Tribunal] will have the resources to deal with urgent applications under the new amendments, the President of the SAT has indicated that the SAT will always make sure it responds to urgent applications.
- The increasing concern of the President is dealing with the very large number of ordinary GAA [*Guardianship and Administration Act 1990*] applications which are steadily increasing year on year but for which the SAT has not had any additional resources funding since the SAT was established.
- The SAT will need to seek more resources to deal with its GAA jurisdiction in the near future.[338]

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335 Joshua Thomson SC, Solicitor General of Western Australia, Answer to question on notice No 46 asked at hearing held 1 October 2020, dated 1 October 2020, p 8.

336 Hon Charles Smith MLC, Western Australia, Legislative Council, *Parliamentary Debates (Hansard)*, 2 April 2020, p 2039.

337 *State Administrative Tribunal Act 2004,* s 90. See also, State Administrative Tribunal, *Urgent and interim applications,* 1 May 2019. See: https://sat.justice.wa.gov.au/U/urgent_and_interim_applications.aspx. Viewed 12 October 2020.

338 Joshua Thomson SC, Solicitor General of Western Australia, Answer to question on notice No 46 asked at hearing held 1 October 2020, dated 1 October 2020, p 9.

10.17 The Committee notes that while the State Administrative Tribunal is currently able to respond to urgent applications, it may need to seek more resources to adequately deal with its jurisdiction of guardianship matters in the near future.

Effect of State Administrative Tribunal's decision (s 110ZZB)

10.18 Under s 110ZZB of the *Guardianship and Administration Act 1990*, a decision by the State Administrative Tribunal:

- takes effect on the day that the decision is made
- will not affect the validity of anything done by a researcher in reliance upon the decision prior to the decision.

10.19 According to the explanatory memorandum of the Bill this provision protects a researcher acting upon the basis of a research decision while allowing the State Administrative Tribunal to correct research decisions.[339]

[339] Explanatory Memorandum, Legislative Council, Guardianship and Administration Amendment (Medical Research) Bill 2020, p 2.

CHAPTER 11
Part 9E Division 6—Reporting

Introduction

11.1 This chapter considers 'Part 9E Division 6—Reporting' of the *Guardianship and Administration Act 1990*.[340] Division 6 contains the following two provisions:

- s 110ZZC—Researcher to report medical research conducted under this Part to Health Minister
- s 110ZZD—Health Minister to report to Parliament on medical research carried out under this Part.

11.2 These provisions require all medical research that is conducted under Part 9E of the *Guardianship and Administration Act 1990* to be reported to the Minister for Health; and for the Minister for Health to annually report all such medical research to Parliament.

Researcher required to report medical research to Health Minister (s 110ZZC)

11.3 Section 110ZZC of the *Guardianship and Administration Act 1990* requires a researcher who conducts medical research under Part 9E to provide written notice to the Minister for Health. The notice is to be provided in a form approved by the Minister for Health stating:

- the researcher is conducting research in relation to the person
- whether the research is carried out pursuant to s 110ZR (non–urgent medical research) or ZS (urgent medical research)
- the type of medical research being conducted
- the purpose of the research
- any other information required by the approved form.

11.4 The statutory forms required under s 110ZZC were made publically available on 9 October 2020 following approval from the Minister for Health.[341]

Health Minister required to report medical research to Parliament (s 110ZZD)

11.5 Section 1110ZZD of the *Guardianship and Administration Act 1990* requires the Minister for Health to report any medical research that has been conducted under Part 9E to Parliament as soon as practicable after 7 April of each year.[342] Section 110ZD requires the following details of the medical research to be reported to Parliament:

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

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340 Part 9E was introduced by the *Guardianship and Administration Amendment (Medical Research) Act 2020,* s 12.

341 Attached as Appendix 5. Department of Health, *GAA Medical Research Decision Forms*, 6 October 2020 See: https://rgs.health.wa.gov.au/Pages/Document-Templates.aspx. Viewed 12 October 2020.

342 *Guardianship and Administration Act 1990*, s 110ZZD(1).

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

(i) a research decision by the research decision–maker for the candidate under section110ZR; 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 the Health Minister considers appropriate.[343]

11.6 As of 9 October 2020, nobody had been enrolled in medical research under Part 9E of the *Guardianship and Administration Act 1990.*[344]

[343] ibid., s 110ZZD.

[344] Dr James Williamson, Assistant Director General, Clinical Excellence Division, Department of Health, Answer to question on notice No 42 asked at hearing held 1 October 2020, dated 9 October 2020, p 12.

CHAPTER 12
Part 9E Division 7—Reviews

Introduction

12.1 This chapter considers 'Part 9E Division 7—Reviews' of the *Guardianship and Administration Act 1990*.[345] Division 7 contains one provision:

- s 110ZE—Review of this Part.

12.2 This provision requires the Attorney General to periodically report on the operation and effectiveness of Part 9E.

Review of Part 9E (s 110ZZE)

12.3 Section 110ZE of the *Guardianship and Administration Act 1990* requires the Attorney General to review the operation and effectiveness of Part 9E and prepare a report based on the review after the first anniversary of it coming into operation. After that, the Attorney General is required to report at intervals of not more than three years.

12.4 The first anniversary of Part 9E coming into operation is 7 April 2021.

12.5 The Committee is of the opinion that the following issues should be considered by the Attorney General under the statutory review required by s 110ZZE once there has been an opportunity to assess the practical implementation of these measures:

- the requirement for a researcher to obtain a determination from an independent medical researcher for:
    - medical research conducted under s 110ZR
    - urgent medical research conducted under s 110ZS
    - medical research conducted in rural and regional communities
- the prohibition on medical research involving electroconvulsive therapy.

[345] Part 9E was introduced by the *Guardianship and Administration Amendment (Medical Research) Act 2020,* s 12.

CHAPTER 13
Conclusions on achieving policy objectives

Introduction

13.1 This chapter summarises the extent to which the Committee considers the Amending Act achieves its policy objectives.

13.2 The policy of the Amending Act is set out in full in paragraph 1.6. It includes providing:

- legislative authorisation for the involvement of incapacitated research candidates in medical research
- appropriate safeguards for incapacitated research candidates to ensure their best interests are upheld and their freedoms and individual rights are protected.

Achieving legislative authorisation for medical research

13.3 The Committee is satisfied that the Amending Act achieves the policy of providing legislative authorisation for the involvement of incapacitated research candidates in medical research. It does so by introducing a comprehensive legislative framework for medical research based on the existing provisions governing medical treatment of incapacitated patients.

13.4 In doing so, the Amending Act addresses the gap that was found to exist in the *Guardianship and Administration Act 1990* in 2018 by providing a legislative framework that enables the involvement of incapacitated research candidates in medical research to resume in Western Australia.

Implementing appropriate safeguards

13.5 The Amending Act has introduced a number of safeguards for incapacitated research candidates involved in medical research. These include:

- a lead researcher must be a medical practitioner (see paragraphs 6.5–6.25)
- medical research is to be conducted in accordance with a research candidate's advance health directive, if the candidate has one (see paragraphs 7.31–7.38)
- a research decision–maker must provide consent on behalf of an incapacitated research candidate when performing medical research in non–urgent circumstances (see paragraphs 7.6–7.13)
- a hierarchy is to be followed when appointing a research decision–maker (see paragraphs 6.27–6.32)
- a researcher must obtain a determination from an independent medical practitioner when performing urgent medical research and it is not practicable to obtain a decision from a research decision–maker (see paragraphs 7.18–7.23)
- a lead researcher is required to discontinue medical research as soon as safely practicable if a research candidate regains the ability to consent (see paragraphs 7.40–7.47)
- medical research must not involve procedures for sterilisation or electroconvulsive therapy (see paragraphs 7.48–7.54)
- applications can be made to the State Administrative Tribunal to review decisions about medical research (chapter 10)

- all medical research on incapacitated research candidates is to be reported to the Minister for Health; and the Minister for Health is to annually report all such medical research to Parliament (chapter 11)
- the Attorney General is required to periodically review the operation of these particular medical research laws and report to Parliament (chapter 12).

Recommendations

13.6 The Committee is of the view that the Amending Act introduces important safeguards that will protect incapacitated research candidates involved in medical research in Western Australia. The Committee has also made several recommendations to improve the current laws. These include:

- amend the definition of 'independent medical practitioner' to provide clarity that an incapacitated research candidate's treating doctor may satisfy this definition provided they are not associated with medical research being performed under Part 9E of the *Guardianship and Administration Act 1990*
- amend the definition of 'lead researcher' to allow nurses, psychiatrists, paramedics and other allied health professionals to be the lead researcher
- repeal the four–year sunset clause that will delete the provision governing the involvement of incapacitated research candidates in medical research.

Hon Dr Sally Talbot MLC
Chair

APPENDIX 1

TEMPORARY ORDERS

TEMPORARY ORDER

COVID-19 RELATED BUSINESS

BY RESOLUTION OF THE HOUSE ON 31 MARCH 2020

If, following agreement with the party leaders or Members deputed, the Leader of the House or the Member deputed by the Leader advises the House that it is necessary to introduce a Government Bill or undertake any other immediate business arising from or in connection to COVID-19, the following Temporary Order shall apply in respect of those matters:

1) Any business then before the House, other than formal business, a matter of privilege, or a motion subject to SO 67 shall be adjourned to a later hour;

2) Any such Bill may be introduced without notice and shall proceed through its stages at dates and times determined by the House;

3) Any such Bill the subject of a Message from the Legislative Assembly may be taken into consideration on the day on which it is received;

4) On any sitting day, and after first consulting with the party leaders or Members deputed, the President may order that one or more of the following items of business in the order of business for that day be dispensed with:

   (a) Non-Government Business;

   (b) Private Members' Business; and

   (c) Consideration of Committee Reports.

5) If ordered, the Council shall sit beyond the following times on the days specified until Members' Statements are called by the President and, in such case, SO 5(5) applies:

   Tuesday 9.45pm;

   Wednesday 6.20pm;

   Thursday 5.20pm.

6) After first consulting with the party leaders or their representatives, the Leader of the House or a Member deputed may set maximum time limits for each stage of a Bill or a motion and on the expiry of that maximum time limit all questions relating to the stage of a Bill or motion, including any amendment, shall be put and determined *seriatim*.

7) A requirement for notice to be given in respect to any motion to be moved by the Leader of the House or a Minister is dispensed with;

8) That, in the event that a scheduled sitting day of the House does not take place, the usual process for Questions on Notice that would have occurred on that day, shall still occur.

9) Standing Orders are suspended accordingly to the extent necessary to effect these arrangements; and

10) This Temporary Order to apply until 27 November 2020 or the lifting of the state of emergency declared in Western Australia arising from the COVID-19 pandemic, whichever occurs first.

TEMPORARY ORDER

IN RELATION TO COVID-19

Adopted by the Assembly on 19 March 2020

That if, following agreement with the party leaders or members deputed, the Premier or one member deputed advises the House that it is necessary to pass urgent legislation or undertake any other immediate business arising from or in connection to Covid-19, the following Temporary Order shall apply:

(1) bills to be introduced without notice and to proceed without delay between the stages;

(2) Messages from the Legislative Council to be taken into consideration on the day on which they are received;

(3) on any sitting day, and after first consulting with the party leaders or their representatives, the Speaker may dispense with:

  (a) the requirement for giving notice for a motion;

  (b) Private Members' Business;

  (c) MPIs;

  (d) Grievances; and

  (e) Members' Statements;

(4) after first consulting with the party leaders or their representatives, the Leader of the House or a member deputed may set time limits for debates on bills and motions;

(5) Standing Orders are suspended accordingly to the extent necessary to effect these arrangements; and

(6) this Temporary Order will expire when the Premier or a member deputed advises the House it is no longer required.

APPENDIX 2

STAKEHOLDERS CONTACTED, SUBMISSIONS AND PUBLIC HEARINGS

Stakeholders contacted

Number	From
1.	Australian Medical Association
2.	Australian Medical Association (WA)
3.	Uniting Care West
4.	Medical Board of Australia
5.	Aboriginal and Torres Strait Islander Health Practice Board
6.	Nursing and Midwifery Board of Australia
7.	Fiona Stanley Hospital
8.	Royal Perth Bentley Group
9.	Sir Charles Gairdner Osborne Park Health Care Group
10.	St John of God Health Care
11.	Peel Health Campus
12.	Joondalup Health Campus
13.	Armadale Health Service
14.	Rockingham Peel Group
15.	Hollywood Private Hospital
16.	Mount Hospital
17.	Public Health Association of Australia
18.	Public Health Advocacy Institute of Western Australia
19.	National Health and Medical Research Centre
20.	Centre for Health Services Research, University of Western Australia
21.	Australian Institute of Health and Welfare
22.	Aboriginal Health Council of Western Australia
23.	Law Society of Western Australia
24.	Law Reform Commission of Western Australia
25.	Australian Human Rights Commission

Number	From
26.	Office of the Public Advocate of Western Australia
27.	State Administrative Tribunal

Submissions received

Number	From
1.	Private citizen
2.	Private citizen
3.	Leonie Holland
4.	Karina Egitto
5.	Nicholas Ruston
6.	Grant Van Heerden
7.	Private citizen
8.	Private citizen
9.	Institute for Health Research, University of Notre Dame
10.	Sharon Dawson
11.	Royal Australian and New Zealand College of Psychiatrists (WA)
12.	Mental Health Commission
13.	Hon Eric Heenan QC
14.	South Metropolitan Health Service
15.	Western Australian Country Health Service Human Research Ethics Committee and Sir Charles Gairdner Hospital and Osborne Park Group Human Research Ethics Committee
16.	Office of the Public Advocate Western Australia
17.	Western Australian Health Translation Network and Health Consumers' Council (WA)
18.	Research Governance Pathwest
19.	Australian Medical Association (WA)
20.	Australian Psychological Society
21.	Australasian College for Emergency Medicine WA Faculty
22.	St John of God Murdoch ICU Research Group
23.	Elizabeth Pinna

Number	From
24.	Dr Sue Ashford
25.	Western Australian Department of Health
26.	Sir Charles Gairdner Osborne Park Health Care Group
27.	Department of Communities
28.	The Law Society of Western Australia

Public hearings

Date	Participants
30 September 2020	• Hon Eric Heenan QC
	• Office of the Public Advocate of Western Australia o Pauline Bagdonivicius, Public Advocate
	• Institute for Health Research, University of Notre Dame o Professor Jim Codde, Director o Dr Amanda Timler, Research Officer
	• Australasian College for Emergency Medicine WA Faculty o Dr Stephen Macdonald, Staff Specialist in Emergency Medicine, Royal Perth Hospital o Professor Tony Celeza, Professor of Emergency Medicine • St John of God Murdoch ICU Research Group o Professor Bart De Keulenaer, Director o Professor Adrian Regli, Intensive Care Specialist
1 October 2020	• Western Australian Health Translation Network o Professor Gary Geelhoed, Executive Director o Professor Steve Webb • Health Consumers' Council (WA) o Pip Brennan, Executive Director
	• Australian Medical Association (WA) o Clinical Associate Professor David Mountain, Emergency Medicine Representative

Date	Participants

	• Department of Health
	  ○ Dr James Williamson, Assistant Director General
	  ○ Jodie Hegarty, Manager, Research Development Unit
	  ○ Professor Daniel Fatovich, Director of Research, Royal Perth Hospital
	• Department of Justice
	  ○ Subhan Dellar, Acting Principal Policy Officer
	  ○ Joshua Thomson SC, Solicitor General of Western Australia

APPENDIX 3

FUNDAMENTAL LEGISLATIVE PRINCIPALS

Does the Bill have sufficient regard to the rights and liberties of individuals?

1. Are rights, freedoms or obligations, dependent on administrative power only if sufficiently defined and subject to appropriate review?
2. Is the Bill consistent with principles of natural justice?
3. Does the Bill allow the delegation of administrative power only in appropriate cases and to appropriate persons?
4. Does the Bill reverse the onus of proof in criminal proceedings without adequate justification?
5. Does the Bill confer power to enter premises, and search for or seize documents or other property, only with a warrant issued by a judge or other judicial officer?
6. Does the Bill provide appropriate protection against self–incrimination?
7. Does the Bill adversely affect rights and liberties, or impose obligations, retrospectively?
8. Does the Bill confer immunity from proceeding or prosecution without adequate justification?
9. Does the Bill provide for the compulsory acquisition of property only with fair compensation?
10. Does the Bill have sufficient regard to Aboriginal tradition and Island custom?
11. Is the Bill unambiguous and drafted in a sufficiently clear and precise way?

Does the Bill have sufficient regard to the institution of Parliament?

12. Does the Bill allow the delegation of legislative power only in appropriate cases and to appropriate persons?
13. Does the Bill sufficiently subject the exercise of a proposed delegated legislative power (instrument) to the scrutiny of the Legislative Council?
14. Does the Bill allow or authorise the amendment of an Act only by another Act?
15. Does the Bill affect parliamentary privilege in any manner?
16. In relation to uniform legislation where the interaction between state and federal powers is concerned: Does the scheme provide for the conduct of Commonwealth and State reviews and, if so, are they tabled in State Parliament?

APPENDIX 4

GUIDANCE FROM THE DEPARTMENT OF HEALTH—DECEMBER 2018

RESEARCH INVOLVING INCAPACITATED ADULTS

Overview

The *Guardianship and Administration Act 1990* (the Act) enables a substitute decision-maker to be appointed to make decisions in the best interests of an adult with a decision-making disability.

It has been recognised that the Act supports consent (or refusal of consent) by substitute decision-makers with regards to the provision of treatment but not for participation in research projects.

Amendment of the Act to enable the participation of incapacitated adults in research was previously endorsed by Cabinet in line with recommendations from the 2015 *Statutory Review of the Guardianship and Administration Act 1990* (Act Review).

Following concerns raised by the WA research community with regards to the Act Review recommendations, in particular the use of placebos and research in emergency situations, the Minister for Health and the Attorney General placed the drafting of the amendments on hold and the Department of Health was asked to provide policy options to address concerns. The Minister for Health has now provided the Department of Health recommendations paper to the Attorney General for his consideration.

Pending amendment of the Act, Health Service Provider researchers, ethics and governance offices have expressed the need for clarification of the current legislative environment.

The following **statement** has been endorsed by the State Solicitor's Office and provides guidance for the current legislative environment.

- **Attachment 1** provides a visual summary of this guidance in the context of research activities undertaken within the WA health system.
- **Attachment 2** provides an overview of the proposed legislative environment based on the Department of Health recommendations for amendment of the Act. The actual legislative environment, following amendment of the Act, will be subject to consultation undertaken by the Department of Justice (which will include the Public Advocate) and Cabinet approval, if appropriate.

Please note that the Department has written to the National Health and Medical Research Council (NHMRC) to advise them of the current legislative situation and has requested their continued support of researchers while amendments are progressed.

Current legislative environment statement

The requirements for consent to medical treatment are outlined in the *WA Health Consent to Treatment Policy 2016*, which is a mandatory policy under the Clinical Governance, Safety and Quality Policy Framework.

There appears to be some misconception that a person who is authorised by the Act to make a "treatment decision" that they consider to be in the best interests of the incapacitated patient may also consent to the patient's participation in any research that includes an element of "treatment".

A decision to participate in a research project, and all that it entails, is not a "treatment decision" for the purposes of the Act.

There are two separate and distinct obligations for participation in a research project. The first is ethical and scientific approval. The second is compliance with legal obligations (including consent of participants).

Ethical and scientific approval provided by a Human Research Ethics Committee (HREC), in accordance with the *National Statement on Ethical Conduct in Human Research 2007* (National Statement), ***does not*** override the legal position regarding requirements for consent, and it is still the responsibility of institutions to consider the specific legal requirements for research conducted on their sites. The National Statement makes it clear that it is intended to address *ethical* considerations only and that the consideration of *legal* obligations, which vary between States, is outside the scope of the National Statement.

To support consistent application of the current legislative framework, the following business rules have been confirmed by the State Solicitors Office (SSO):

- consent to treatment by an authorised substitute decision-maker does not imply consent to participation in a research project;
- a substitute decision-maker is not presently authorised by the Act to consent to an incapacitated patient's full participation in a research project, even though they may consent to a proposed treatment that is the subject of the research project;
- a "waiver of consent" by a HREC expresses a view that it is unobjectionable from an *ethical* perspective to waive a requirement for consent, but it does not affect the *legal* requirements for consent to treatment, consent to participate in a research project, or consent to disclose confidential information – the term "waiver of consent" is inappropriate for the purposes of governance decision making, for incapacitated patients or patients with capacity, and consent is still required;
- "deferred consent" or "delayed consent" (for incapacitated or capacitated patients) are terms that obfuscate the fact that there is *no* consent prior to involvement in research – those concepts are not appropriate and should be discarded.

If an existing research activity is impacted by the business rules above then the following applies:

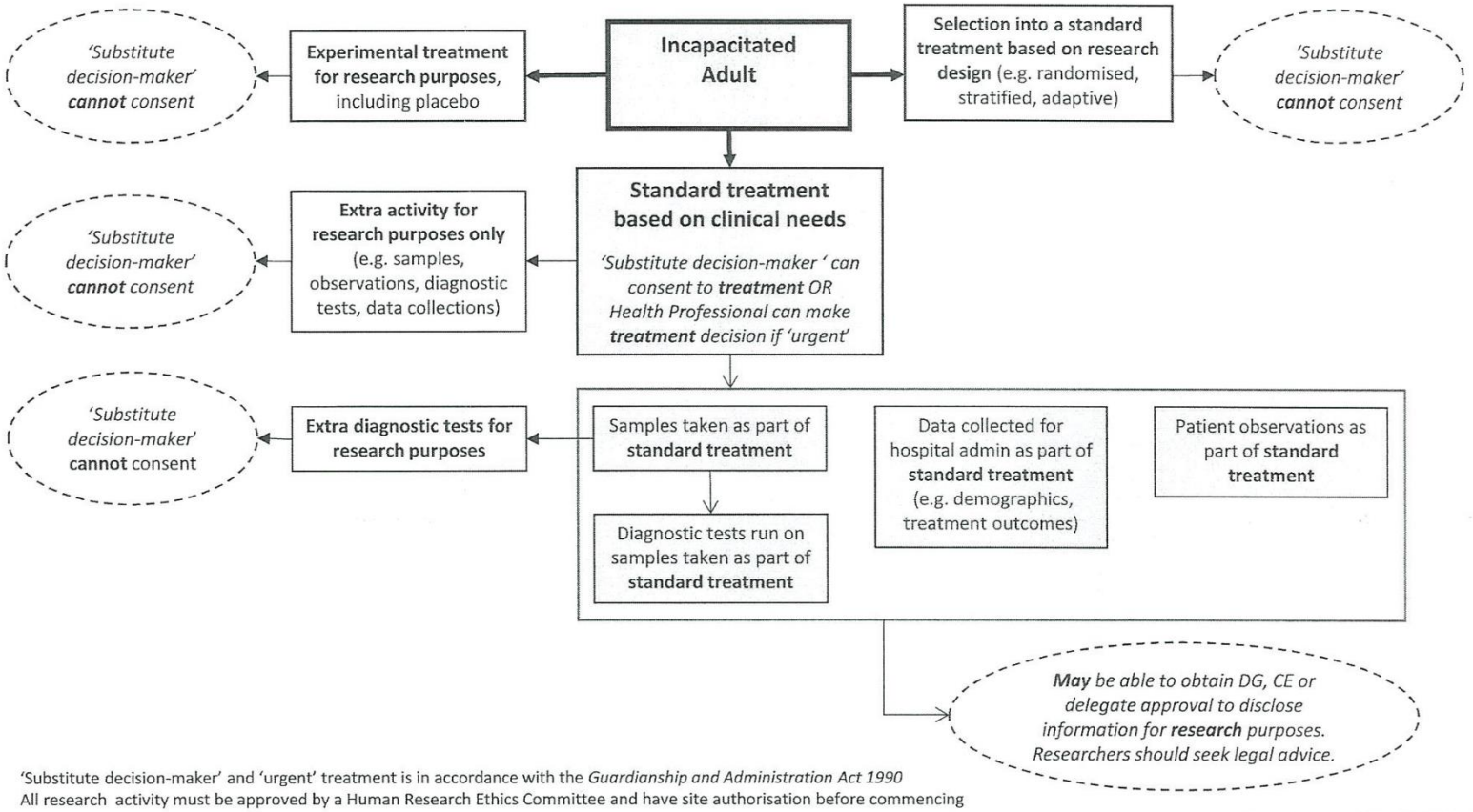
- if involving patients unable to consent to research then suspend activity in relation to those patients (where research entails only the examination of patients' medical record, an alternative mechanism of authorisation may be available to seeking consent of a substitute decision-maker);
- to the extent that guidance is needed in relation to a particular research trial the appropriate officer at the relevant Health Service Provider may be contacted;
- if involvement of patients unable to consent is complete but data/tissue have been collected from these patients then SSO advice can be sought on a case by case basis prior to the use of this data/tissue.

The importance of health and medical research in generating benefits to individuals and the community is appreciated but it is essential that clinical researchers, WA Health individuals, and institutions are not exposed to any legal risk or professional or public criticism.

Attachment 1

Current Legislative Environment: Consent Pathways for Research Involving Incapacitated Adults

The below flowchart presents consent pathways for research under the Guardianship and Administration Act 1990. It is intended as a guide only and researchers and ethics/governance offices should seek further legal advice if uncertain.



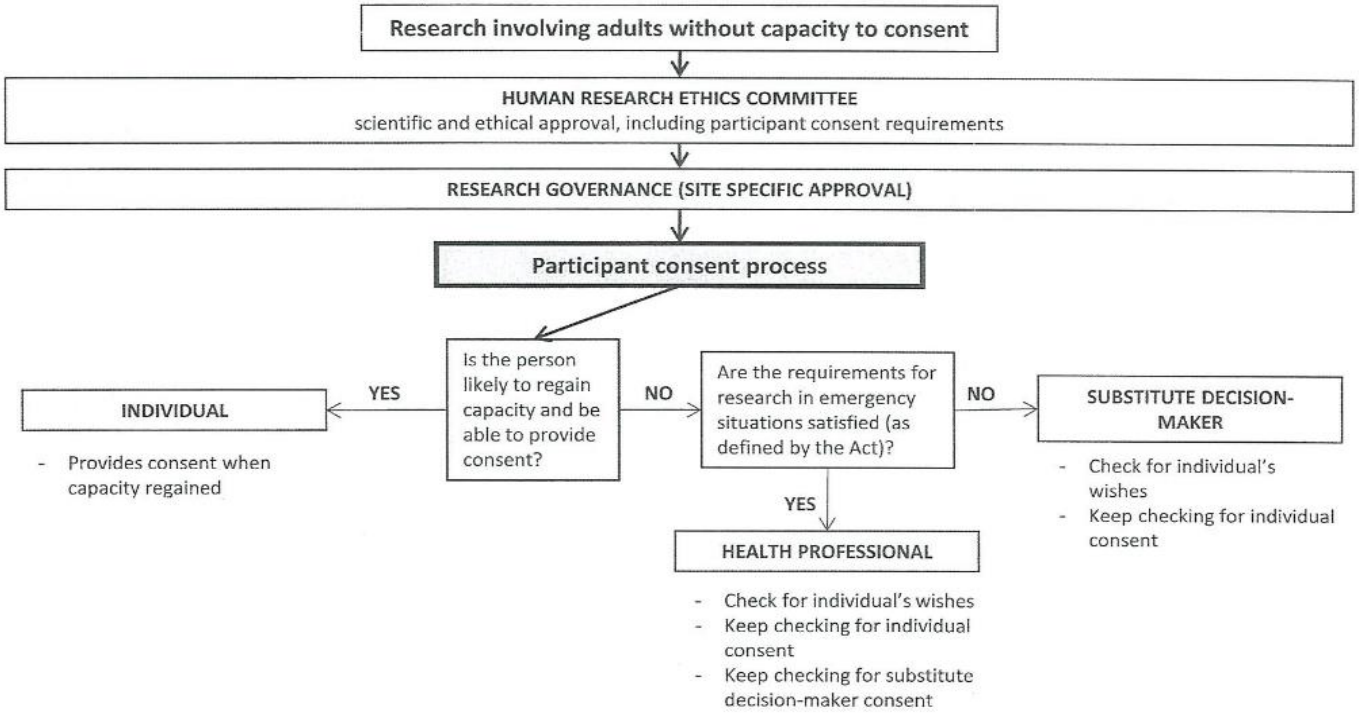
'Substitute decision-maker' and 'urgent' treatment is in accordance with the *Guardianship and Administration Act 1990*
All research activity must be approved by a Human Research Ethics Committee and have site authorisation before commencing

Department of Health WA, 2018

Attachment 2

Proposed Legislative Environment Following Act Amendment: Consent Pathways for Research Involving Incapacitated Adults

The below flowchart is an overview of the Department of Health proposed consent pathways for research under the Guardianship and Administration Act 1990. The Department's recommendations for amendment of the Act are under the consideration of the Department of Justice and will be subject to Cabinet approval.



Department of Health WA, 2018

APPENDIX 5

STATUTORY FORMS

Government of **Western Australia**
Department of **Health**

GAA Medical Research Decision Form – Urgent Treatment

This form must be used to document the decision when enrolling an incapable person in health and medical research with the consent of a research decision-maker; OR without consent if approved by a HREC.

Patient label/details

Decisions must comply with the *Guardianship and Administration Act 1990 (GAA)*.

Refer to the Department of Health Research Governance Service (RGS) for guidance and forms.

RESEARCH PROJECT DETAILS	
Title	
Project Reference No. *WA public health: use RGS No.* *Other: use HREC Reference No.*	
Protocol No.	
HREC	
Site	
Site Lead Researcher	
Researcher	
Independent Medical Practitioner	

RESEARCHER DECLARATION		
1.	The research candidate is eligible to be included in this research based on the inclusion/exclusion criteria and unable to make reasonable judgements in relation to their participation in the research.	☐
2.	I am not aware of, and would not reasonably be expected to be aware of, any current advance health directive that is inconsistent with this research.	☐

INDEPENDENT MEDICAL PRACTITIONER (IMP) DECLARATION		
3.	I am not currently involved in treatment of the research candidate which is related to this research.	☐
4.	I am not involved in, nor connected to, the research, other than having a professional interest in the area of the research. Note: Investigators on this research project and persons who have vested interests in whether the research candidate is or is not enrolled in the research would not meet this criterion.	☐
5.	I am not a spouse, de facto partner parent, grandparent, sibling, child or grandchild of the research candidate.	☐
6.	I am not a member of the HREC that approved the research.	☐

Version date: 06 October 2020

INDEPENDENT MEDICAL PRACTITIONER (IMP) DETERMINATION		
7.	The research candidate is **not likely to regain the ability** to be able to make reasonable judgements within the timeframe for the research approved by the HREC. The IMP must take into account: (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; and (e) the nature of, and the timeframe approved by the HREC for, the medical research in which the research candidate is to participate.	☐
	Reasons: ***(please address each point and explain the resulting determination)***	
8.	The research candidate's participation in the research will be in accordance with one of following **risk** categories: (i) will only involve observing the candidate or carrying out another non-invasive examination, treatment or procedure; or (ii) if (i) does not apply - will not involve any known substantial risks to the candidate; or (iii) if (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 (i), (ii) and (iii) do not apply - will not involve substantial risks to the candidate greater than if the candidate did not participate in the research. The IMP must take into account: (a) whether the research candidate's participation in the 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 – • whether there are substantial risks to the candidate involved in the existing treatment available to the candidate; • if there are substantial risks involved in the existing treatment – whether those risks are greater than the risks involved in participating in the research; (d) if there is no existing treatment available – whether the risks involved in participating in the research are greater than not participating in the research.	☐
	Reasons: ***(please address each point and explain the resulting determination including the risk category)***	
9.	Participation in this research is in the **best interests** of the research candidate or will not be adverse to the interests of the research candidate. The IMP must take into account: (a) the wishes of the person (to the extent they can be ascertained) as the paramount consideration; (b) the likely effects of research participation, including: • the existence, likelihood and severity of any potential risks; • 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; and (d) any alternative treatments available to the research candidate.	☐

Version date: 06 October 2020

	Reasons: ***(please address each point and explain the resulting determination)***	
10.	I have an appropriate understanding of the research protocol (including the timeframe for the research approved by the HREC) and the circumstances relevant to the research candidate to make the above determinations.	☐
11.	It was not practicable to provide the determinations in writing before the research commenced therefore the determinations were provided orally. Note: Oral determinations (in lieu of written determinations) should only apply if the research candidate is being enrolled into Urgent Medical Research without consent.	☐

Date of Determination		**Time of Determination**	
IMP Signature		**Date**	

RESEARCHER ACTIONS		
12.	It has been determined by the IMP that the research candidate is not likely to be able to make reasonable judgements within the timeframe for the research approved by the HREC (point 7).	☐
13.	***Please select <u>either</u> (a) <u>or</u> (b):*** **(a) Medical Research with consent of research decision-maker:** I confirm that the IMP determinations regarding risk (point 8) and best interests (point 9) have been provided to the RDM and they understand the determinations. The RDM has confirmed that the research is not inconsistent with any current advance health directive. The RDM has provided informed consent for enrolment of the research candidate in the research. ***OR*** **(b) Urgent Medical Research without consent:** I have enrolled the research candidate without consent and confirm that: (i) this enrolment pathway has been approved by the HREC; (ii) the candidate requires urgent treatment; (iii) there is no existing research decision for the research candidate; (iv) it is not practicable to obtain a research decision from a RDM within the timeframe for the research approved by the HREC; and (v) the IMP has determined that the research is in an appropriate risk category (point 8) and is in the candidate's best interests or not adverse to their best interests (point 9). 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.	☐ ☐

Version date: 06 October 2020

Government of **Western Australia**
Department of **Health**

GAA Medical Research Decision Form

This form must be used to document the decision when enrolling an incapable person in health and medical research with the consent of a research decision-maker.

Decisions must comply with the *Guardianship and Administration Act 1990 (GAA)*.

Patient label/details

Refer to the Department of Health Research Governance Service (RGS) for guidance and forms.

RESEARCH PROJECT DETAILS	
Title	
Project Reference No. *WA public health: use RGS No.* *Other: use HREC Reference No.*	
Protocol No.	
HREC	
Site	
Site Lead Researcher	
Researcher	
Independent Medical Practitioner	

RESEARCHER DECLARATION		
1.	The research candidate is eligible to be included in this research based on the inclusion/exclusion criteria and unable to make reasonable judgements in relation to their participation in the research.	☐
2.	I am not aware of, and would not reasonably be expected to be aware of, any current advance health directive that is inconsistent with this research.	☐

INDEPENDENT MEDICAL PRACTITIONER (IMP) DECLARATION		
3.	I am not currently involved in treatment of the research candidate which is related to this research.	☐
4.	I am not involved in, nor connected to, the research, other than having a professional interest in the area of the research. Note: Investigators on this research project and persons who have vested interests in whether the research candidate is or is not enrolled in the research would not meet this criterion.	☐
5.	I am not a spouse, de facto partner parent, grandparent, sibling, child or grandchild of the research candidate.	☐
6.	I am not a member of the HREC that approved the research.	☐

Version date: 06 October 2020

INDEPENDENT MEDICAL PRACTITIONER (IMP) DETERMINATION		
7.	The research candidate is **not likely to regain the ability** to be able to make reasonable judgements within the timeframe for the research approved by the HREC. The IMP must take into account: (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; and (e) the nature of, and the timeframe approved by the HREC for, the medical research in which the research candidate is to participate.	☐
	Reasons: ***(please address each point and explain the resulting determination)***	
8.	The research candidate's participation in the research will be in accordance with one of following **risk** categories: (i) will only involve observing the candidate or carrying out another non-invasive examination, treatment or procedure; or (ii) if (i) does not apply - will not involve any known substantial risks to the candidate; or (iii) if (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 (i), (ii) and (iii) do not apply - will not involve substantial risks to the candidate greater than if the candidate did not participate in the research. The IMP must take into account: (a) whether the research candidate's participation in the 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 – • whether there are substantial risks to the candidate involved in the existing treatment available to the candidate; • if there are substantial risks involved in the existing treatment – whether those risks are greater than the risks involved in participating in the research; (d) if there is no existing treatment available – whether the risks involved in participating in the research are greater than not participating in the research.	☐
	Reasons: ***(please address each point and explain the resulting determination including the risk category)***	
9.	Participation in this research is in the **best interests** of the research candidate or will not be adverse to the interests of the research candidate. The IMP must take into account: (a) the wishes of the person (to the extent they can be ascertained) as the paramount consideration; (b) the likely effects of research participation, including: • the existence, likelihood and severity of any potential risks; • 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; and (d) any alternative treatments available to the research candidate.	☐

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	Reasons: ***(please address each point and explain the resulting determination)***	
10.	I have an appropriate understanding of the research protocol (including the timeframe for the research approved by the HREC) and the circumstances relevant to the research candidate to make the above determinations.	☐

Date of Determination		**Time of Determination**	
IMP Signature		**Date**	

RESEARCHER ACTIONS		
11.	It has been determined by the IMP that the research candidate is not likely to be able to make reasonable judgements within the timeframe for the research approved by the HREC (point 7).	☐
12.	I confirm that the IMP determinations regarding risk (point 8) and best interests (point 9) have been provided to the RDM and they understand the determinations. The RDM has confirmed that the research is not inconsistent with any current advance health directive. The RDM has provided informed consent for enrolment of the research candidate in the research.	☐
13.	I will ensure that written notice is provided to the Department of Health within 15 calendar days using the Department of Health report template, to meet my obligation to report to the Minister for Health of any enrolments under the GAA.	☐

Participant Study ID ***(mandatory)*****:**			
Comments ***(optional):***			
Researcher Signature		**Date**	

SITE LEAD RESEARCHER RESPONSIBILITIES		
14.	If the RDM withdraws consent or the person regains capacity, I will ensure that the research is discontinued as soon as is safely practicable; and the research is not recommenced unless consent is provided to continue in the research.	☐

Site Lead Researcher Signature		**Date**	

Version date: 06 October 2020

APPENDIX 6

LETTER FROM THE PUBLIC ADVOCATE—APRIL 2020

Government of Western Australia
Department of Justice

Office of the Public Advocate

Our Ref: F2020/00985

Hon. John Quigley MLA
Attorney General; Minister for Commerce
Office of the Attorney General
Level 5, Dumas House
2 Havelock Street
WEST PERTH WA 6005

Dear Attorney General

GUARDIANSHIP AND ADMINISTRATION AMENDMENT (MEDICAL RESEARCH) BILL 2020

This letter is to confirm my support for the Guardianship and Administration Amendment (Medical Research) Bill 2020.

The Office of the Public Advocate was a key stakeholder in the Statutory Review of the *Guardianship and Administration Act 1990* (the Act), the report of which was tabled in the Parliament on 2 December 2015. Both my office and the Department of Health, specifically requested medical research be considered in the Terms of Reference of the review, as it has been an ongoing issue for guardians and there is a lack of clarity in the Act.

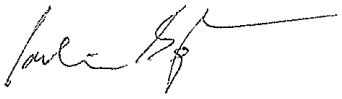
I met with Professor Gary Geelhoed, Executive Director, Western Australian Health Translation Network, on 18 June 2018 who addressed the concerns I raised in the Statutory Review regarding the provision of placebos in medical research. I was assured that, should a person receive a placebo during medical research, they would still receive the best possible existing treatment for their condition, they would just not receive the novel treatment being trialled in the research. I understand placebos to be an important part of medical research, and am confident that, should a person receive a placebo during medical research, they will still be receiving the best available treatment for their condition.

I am supportive of the amendments in the Bill which will enable myself, as the Public Advocate, to consent to medical research on behalf of a represented person, where that research is in the person's best interests and will have no detrimental impact on the person. I note that the assessment by an independent medical practitioner of the research candidate's best interests provides a key safeguard which assist guardians and other research decision-makers in making their decision about the participation of a represented person in medical research.

Level 23 David Malcolm Justice Centre 28 Barrack Street Perth Western Australia 6000
PO Box 6293 East Perth Western Australia 6892
Telephone Advisory Service 1300 858 455 Facsimile (08) 9278 7333
Email: opa@justice.wa.gov.au
ABN 70 598 519 443
For information on guardianship and administration go to www.publicadvocate.wa.gov.au

I have viewed all drafts of the Bill as it has developed, and am confident that the Bill ensures that the best interests of the person remain central in the amendments. As is required in the *Guardianship and Administration Act 1990,* the amendments ensure that all medical research decisions are made in the best interests of the person, and regard the wishes of the person as the paramount consideration.

Yours sincerely



Pauline Bagdonavicius
PUBLIC ADVOCATE

1 April 2020

GLOSSARY

Term	Definition
Bill	Guardianship and Administration Amendment (Medical Research) Bill 2020
Amending Act	*Guardianship and Administration Amendment (Medical Research) Act 2020*
Committee	Standing Committee on Legislation
FLP	Fundamental legislative principles
HREC	Human research ethics committee
Incapacitated research candidate	An individual who is unable to make reasonable decisions about their involvement in medical research
National Statement	National Statement on Ethical Conduct in Human Research
NHMRC	National Health and Medical Research Council
Statutory Review	Statutory review of the *Guardianship Administration Act 1990* conducted by Department of Justice in 2015.
Sunset Clause	Provisions which activate the lapsing of the provisions governing urgent medical research and introduce transitional provisions: *Guardianship and Administration Amendment (Medical Research) Act 2020,* ss 2, 13, 15.
UNCRPD	United Nations Convention on the Rights of Persons with Disabilities

Standing Committee on Legislation

Date first appointed:

17 August 2005

Terms of Reference:

The following is an extract from Schedule 1 of the Legislative Council Standing Orders:

'4. Legislation Committee

4.1 A *Legislation Committee* is established.

4.2 The Committee consists of 5 Members.

4.3 The functions of the Committee are to consider and report on any Bill referred by the Council.

4.4 Unless otherwise ordered, any amendment recommended by the Committee must be consistent with the policy of the Bill.'

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