GOVERNMENT OF WESTERN AUSTRALIA

Department of Justice

Review of the *Guardianship and Administration Amendment (Medical Research) Act 2020* (WA)

Final Report

Contents

Executive Summary

1. The Department of Justice (Department) has prepared this report for the Attorney General on the operation and effectiveness of the *Guardianship and Administration Amendment (Medical Research) Act 2020* (WA) (Amendment Act). Section 110ZZE(2) of the Amendment Act requires the Attorney General to table the report on the first review of the Amendment Act (Final Report) no later than 12 months after the first anniversary of the legislation's commencement: that is, by 7 April 2022.

2. The Attorney General is the Minister responsible for the administration of the *Guardianship and Administration Act 1990* (WA) (GAA) and the Department is the agency in the public sector principally assisting the Attorney General in its administration.

3. The Department has canvassed the views of key stakeholders during the review and has investigated how the Amendment Act has been operating in practice since it commenced. The Department invited 63 stakeholders to make a submission during the consultation phase of the review and received 27 submissions in response. Several stakeholders have also provided case studies on how the Amendment Act has been operating in practice, which have informed the findings and recommendations in the Final Report.

4. Stakeholders from both the medical research community and advocacy groups have raised problems with the 'lead researcher' definition in section 110ZO of the Amendment Act. There is consensus amongst stakeholders that the requirement for a lead researcher to have medical qualifications excludes many researchers who may not be medical practitioners, but are instead allied health professionals involved in important medical research. For example, practitioners in the fields of nursing, paramedicine, physiotherapy or psychology are not permitted to be the lead researcher in a medical research project conducted under the auspices of the Amendment Act. The Department has found that this limitation should be removed, as this would benefit both researchers and research candidates.

5. The definition of 'medical research' has been raised by some stakeholders as being so broad that it results in observational or comparative effectiveness studies being subject to the requirements of the Amendment Act. These types of studies are often viewed as low risk by medical researchers and stakeholders have recommended that the definition of medical research be narrowed to apply only to high risk or invasive research procedures. Stakeholders have submitted that the requirements of the Amendment Act are so onerous that they should apply where the level of risk to a incapacitated person has been assessed as being more than merely low risk. The Department has found that this approach does not take into account the purpose of the Amendment Act, which is to ensure that there are sufficient safeguards in place, regardless of the level of risk, to protect incapacitated persons who may be enrolled in medical research.

6. The definition of 'independent medical practitioner' (IMP) and the importance of this person's role in the enrolment process for incapacitated persons has emerged as a key issue among stakeholders. Some stakeholders have submitted that the

IMP definition should be broadened along the same lines as the lead researcher definition, to allow other health professionals to make determinations according to the Amendment Act. The Department does not support this proposal, as the IMP role is a crucial safeguard in the enrolment process and adheres to the principles of the GAA.

7. The Department has found that there appears to be uncertainty amongst the medical research community as to how the requirement for an IMP operates in practice, despite guidance that has been provided by the Department of Health on the approval processes established by the Amendment Act. The Department of Health has provided this clarity through its Research Governance Service website, and the review has highlighted the importance of this valuable resource.

8. The Department has considered the recommendations of the Standing Committee on Legislation's (Standing Committee) review of the Amendment Act and has sought feedback from stakeholders on the issues raised. The conclusions within this Final Report are broadly in line with the Standing Committee's recommendations, with the exception of the recommendation to consider removing the current prohibition on electroconvulsive therapy in the GAA. The Department has found that stakeholders largely do not have a view on the prohibition and only one stakeholder supported the prohibition being abolished.

9. Stakeholders have unanimously indicated that the sunset clause that will result in the repeal of section 110ZS (Urgent medical research without consent) should be removed from the Amendment Act. Sections 13 and 15 of the Amendment Act will take effect from the day after four years have passed since assent day (8 April 2024) and will remove the ability for incapacitated persons to be enrolled in medical research from that date onwards, excluding ongoing research permitted by transitional arrangements. The nature of medical research is such that a period of four years (at the time of this review, less than two years) is not adequate for researchers to obtain all required approvals, finalise their trial's parameters and recruit participants.

10. The Standing Committee observed that the Amendment Act disadvantages medical researchers in rural or remote, or out-of-hospital settings. Difficulties already faced in these domains (such as availability of medical staff or recruitment of research participants) are exacerbated by the Amendment Act's IMP and lead researcher requirements. The Department has considered the Standing Committee's recommendation that the Minister for Health advise if telehealth could be used in regional and remote communities to overcome difficulties with complying with the IMP determination requirement, but makes no conclusions on this issue.

Findings and Recommendations

The Department's findings and recommendations arising out of the review are extracted here:

Finding 1: The Department finds that the definition of 'medical research' in section 3AA of the *Guardianship and Administration Act 1990* (WA) is appropriate and has been operating effectively in practice since the provision commenced.

Finding 2: The Department finds that the definition of 'lead researcher' in section 110ZO of the *Guardianship and Administration Act 1990* (WA) has adversely impacted medical research that may be conducted on incapacitated persons, particularly for paramedical and community-based research.

Recommendation 1: The definition in section 110ZO of the *Guardianship and Administration Act 1990* (WA) of 'lead researcher' should be amended to change the reference to 'medical practitioner' to 'health practitioner.' A new definition of 'health practitioner' should be inserted into section 110ZO which has the meaning given in the *Health Practitioner Regulation National Law (Western Australia)*.

Finding 3: The Department finds that the safeguard offered by the definition of 'independent medical practitioner' in section 110ZO of the *Guardianship and Administration Act 1990* (WA) has been operating appropriately, despite the fact that some health professionals involved in medical research who are not medical practitioners have been unable to enrol incapacitated persons in their research projects.

Recommendation 2: Notwithstanding the access issues discussed in Finding 3, the Department recommends that the definition of 'independent medical practitioner' in section 110ZO of the *Guardianship and Administration Act 1990* (WA) not be amended.

Finding 4: The Department finds that the requirement to obtain a determination from an independent medical practitioner in sections 110ZR and 110ZS of the *Guardianship and Administration Act 1990* (WA) is, on balance, an appropriate safeguard to protect incapacitated persons.

Finding 5: The Department finds that the administrative processes, including forms, established by the Department of Health to support the practical implementation of the *Guardianship and Administration Amendment (Medical Research) Act 2020* (WA) are appropriate and effective.

Recommendation 3: Notwithstanding Finding 5, as it may be of some assistance to incapacitated persons, the Department suggests that the Department of Health, in consultation with its key stakeholders, consider amending its 'GAA Medical Research Decision Form – Urgent Treatment' to include a field whereby the research decision-maker's name and the capacity in which they are providing their consent is recorded on the form.

Finding 6: The Department finds that the *Guardianship and Administration Amendment (Medical Research) Act 2020* (WA) has been effective in codifying processes regarding medical research which had been routine prior to 2018 to enable medical research to be safely conducted on incapacitated persons.

Finding 7: The Department finds that the *Guardianship and Administration Amendment (Medical Research) Act 2020* (WA) has provided a means by which medical research may be safely conducted on patients who may be incapacitated as a result of COVID-19 symptoms.

Finding 8: The Department finds that the *Guardianship and Administration Amendment (Medical Research) Act 2020* (WA) has put in place processes and safeguards to enable incapacitated persons to be enrolled in medical research.

Finding 9: The Department finds that there has been a significant increase in the number of incapacitated persons enrolled in medical research according to sections 110ZR and 110ZS of the *Guardianship and Administration Act 1990* (WA) since the *Guardianship and Administration Amendment (Medical Research) Act 2020* (WA) commenced operation.

Finding 10: The Department finds that the sunset clause that will result in the repeal of section 110ZS of the *Guardianship and Administration Act 1990* (WA) on 8 April 2024 is causing detrimental impacts to the medical research community in a way that is disproportionate to the protection that the legislation offers incapacitated persons.

Recommendation 4: The Department recommends the repeal of sections 2(b), 13 and 15 of the *Guardianship and Administration Amendment (Medical Research) Act 2020* (WA).

Finding 11: The Department finds that the prohibition on the use of electroconvulsive therapy as medical research in section 110ZT of the *Guardianship and Administration Act 1990* (WA) is appropriate and should not be removed.

Recommendation 5: The Department recommends that the prohibition on electroconvulsive therapy being performed on a research candidate in section 110ZT(2) of the *Guardianship and Administration Act 1990* (WA) remain in place.

1 Introduction

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

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

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

The Department has assisted the Attorney General in the preparation of this final report on this, the first review of the Amendment Act (Final Report). According to section 110ZZE(2) of the Amendment Act, the Attorney General must cause the Final Report to be laid before each House of Parliament as soon as practicable after the report is prepared, but not later than 12 months after the first anniversary or the expiry of the period of three years for the recurrent reviews required thereafter, as the case may be.

1.1 Structure of this report

This introductory chapter provides background information on the Department's review and the terms of reference that have guided the drafting of the Final Report.

Chapter 2 summarises the methodology used during the Department's review of the Amendment Act and information about case studies and stakeholder consultation.

Chapter 3 explains the Amendment Act's origins and clarifies important definitions and concepts used throughout the Final Report.

Chapter 4 considers the ethics and principles that underpin medical research, with a focus on Australia's ethics governance regime, including the use of Human Research Ethics Committees (HREC).

Chapter 5 outlines the practical implications of the Amendment Act's operation on medical research and presents the views of key stakeholders in the medical research field.

Chapter 6 explores how the Amendment Act provides protection to incapacitated persons who may be enrolled in medical research in Western Australia and any unintended consequences of the legislation on this cohort of research participants.

Chapter 7 examines the recommendations contained in the Standing Committee's report on the Amendment Act. Three of the seven recommendations were explicitly

directed towards this review, but the Department has taken the opportunity in this review to consider the implications of all seven of the Standing Committee's recommendations, with the help of feedback received from stakeholders during the review.

1.2 Terms of Reference

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

> *The Minister must review the operation and effectiveness of* [Part 9E] *and prepare a report based on the review –*
>
> *(a) as soon as practicable after the 1st anniversary of the day on which the Guardianship and Administration Amendment (Medical Research) Act 2020 section 12 comes into operation; and*
> *(b) after that, at intervals of not more than 3 years.*

The review of the Amendment Act's operation has involved objective consideration of how the Amendment Act is being implemented and the consequences of that implementation in practice. This aspect of the review required data on the number of incapacitated persons enrolled in medical research since the Amendment Act commenced and the circumstances of their participation. The Department has also relied on case studies provided by medical researchers to examine the practical effects of participants and/or their representatives being enrolled in medical research without consent.

The review of the Amendment Act's effectiveness has involved an examination of whether Part 9E of the GAA has met the desired policy objectives since it came into force in 2020. The policy behind the legislation was outlined in the Second Reading Speech when it was introduced by the Minister for Health.[1]

One of the Amendment Act's aims was to put into legislation those procedures which had been routine prior to the Department of Health receiving legal advice which put the lawfulness of those procedures in doubt. The measurement of the Amendment Act's effectiveness has involved consultation with stakeholders to consider the current process of enrolment of incapacitated persons in medical research, compared to the process that occurred prior to the suspension of this type of medical research in 2018.

The Department has also considered the recommendations made by the Legislative Council's Standing Committee on Legislation (Standing Committee) during its review of the Amendment Act.

[1] See further, paragraph 3.3.

2 Methodology

The Department has conducted this review using mixed methods: primarily, broad consultation with stakeholders, together with a brief review of previous relevant inquiries (including the Standing Committee's inquiry and report) and a jurisdictional comparison.

Data analysis was expected to form a significant part of the review but, due to the low numbers of incapacitated people initially enrolled in medical research when the Amendment Act first commenced, the Department has instead supplemented available data with the analysis of stakeholder submissions and case studies to inform the review.[2]

The Department established a Project Reference Group (PRG) to guide and facilitate the review, comprising of representatives from the:

- Department of Health, Office of Medical Research and Innovation (OMRI);
- Office of the Public Advocate; and
- Western Australian Office of Crime Statistics and Research.

Project management support was provided to the PRG by the Department's Legislative Services Directorate within the Strategic Reform Division.

2.1 Consultation with stakeholders

The Department consulted very widely, ensuring that key stakeholders from those sectors that may be affected by the Amendment Act were contacted. This included organisations in the fields of:

- disability advocacy;
- mental health advocacy;
- First Nations health and advocacy;
- culturally and linguistically diverse communities health and advocacy;
- medical researchers and practitioners, including emergency medicine (in both the public and private sectors); and
- relevant agencies/authorities at the State and Commonwealth Government level.

A list of all stakeholders who were invited to provide a submission is attached to this report at Appendix 1.

The Department provided stakeholders with a Discussion Paper during the consultation phase. The Discussion Paper contained the terms of reference for the review, background information on the Amendment Act and information about other jurisdictions with legislation in place governing medical research and guided questions based on the review's terms of reference.

[2] The Minister for Health's first report under section 110ZZD of the GAA, tabled in 2021, revealed that only nine incapacitated people had been enrolled in medical research during the Amendment Act's first year of operation. Data in the 2021-22 reporting period have revealed much higher enrolment figures: see paragraph 6.3 for further discussion.

The guided questions were intended to assist stakeholders in preparing their submission and were neither prescriptive nor mandatory. The guided questions that were provided to stakeholders are attached at Appendix 2.

The Department received 27 submissions as part of its consultation on the review. The list of submitters is attached at Appendix 3. The Department thanks all stakeholders who provided a submission to the review.

During consultation, the WA Health Translation Network – Consumer and Community Involvement Program (CCI Program) and the Health Consumer's Council WA jointly hosted an online survey of consumers and community members, based on the guided questions provided to stakeholders. Despite the small response rate to the survey, the responses are an indication of the views of people with lived experience as either a person with a disability or chronic condition, or a carer.

2.2 Case studies

During the consultation phase of this review, the PRG facilitated the collation of case studies from medical researchers to illustrate any practical implications of the Amendment Act on their clinical studies. Researchers were advised to de-identify any examples provided to the review to preserve confidentiality. Case studies used throughout have been reproduced with permission.

The boxed case studies throughout this report have also been extracted from submissions received from other key stakeholders, as indicated below.

> [Silver Chain is] *commencing a research project that explores the use of smart glasses technology for the remote orientation of experienced palliative care nurses who have recently joined Silver Chain in NSW. The outcome of this piece of innovative research will build critical evidence to inform our models of care in these difficult times of COVID-19. Our consent approach has been informed by the evidence-based MORECare Capacity Statement for research in adults with impaired mental capacity nearing the end-of-life. We will obtain written consent at study recruitment from the Research Candidate, their substitute decision-maker or both, informed by a validated cognitive screening tool appropriate to the research context. Additionally, research participants will be asked to nominate a substitute decision-maker at the start of the project in the event that they lose their capacity to provide ongoing consent (temporarily or permanently) during the research project … it would be extremely challenging, if not altogether impossible, to conduct this research in WA due to Part 9E of Guardianship and Administration Act 1990.*
> ***Source: Silver Chain Group Ltd, Submission 21***

The Department thanks all submitters for the case studies provided during this review.

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

3.1 Review of the Act in 2015

A statutory review of the GAA commenced in 2013 and was tabled in Parliament in 2015 (2015 Review) under a previous State Government.[3] The topic of consent to medical research for people with decision-making difficulties emerged as a major issue in the 2015 Review and several recommendations were made to address it.

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

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

3.2 Medical research before 2018

In 2018, the Department of Health sought legal advice from the State Solicitor's Office (SSO) regarding the legality of medical treatment provisions in the GAA still being relied upon to enrol incapacitated persons in medical research. The advice distributed to all Health Service Provider Chief Executives confirmed that 'consent to treatment by an authorised substitute decision-maker does not imply consent to participation in a research project' and 'a substitute decision-maker is not presently authorised by the [GAA] to consent to an incapacitated patient's full participation in a research project'.[4]

A consequence of the legal advice from SSO was that all existing research activity that involved patients who were unable to provide consent was suspended, with the Department of Health and SSO offering further advice on a case-by-case basis for affected medical research projects.[5]

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

3.3 The Bill and the Amendment Act

It was several years after the 2015 Review that the Bill for the Amendment Act was introduced into the Parliament and the process for enrolling incapacitated persons in medical research was clarified.

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

In April 2020, the then Minister for Health, Hon Roger Cook MLA, introduced the Guardianship and Administration Amendment (Medical Research) Bill 2020 (Bill) into Parliament, as the emerging COVID-19 emergency meant that the ability to conduct medical research trials had become crucial. The Bill introduced a new Part 9E into the GAA to enable medical research to be carried out in respect of persons who do not have the capacity to consent to it. The Bill also included a review clause that required the operation and effectiveness of Part 9E to be reviewed as soon as practicable after one year from the date that Part 9E commenced, followed by recurrent three-yearly reviews thereafter.[6]

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

The Government supported the insertion of the sunset clause and the amendment was passed by the Legislative Council. A transitional provision was also inserted into the Bill to ensure that those existing research decisions for individuals that would be affected by the operation of the sunset clause could continue, despite the research project not being able to proceed.[7]

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

3.4 What does the Amendment Act do?

The Amendment Act provides authorisation and includes appropriate safeguards to enable an incapacitated person (through their nominated representative) to provide consent for their participation in medical research.

There are two circumstances in which an incapacitated person may be enrolled in medical research: with the consent of their decision-maker, or in urgent circumstances where that consent is not obtained prior to their participation.

3.4.1 Definitions inserted

The Amendment Act inserted several new defined terms to support the operation of Part 9E, including ‘independent medical practitioner’ (IMP), ‘lead researcher’, ‘medical research’, ‘research decision-maker’, and ‘urgent medical research decision.’

The Amendment Act also changed the definition of ‘treatment’ in section 3 of the GAA to extend it to include medical research in Part 9B Advance Health Directives (AHD)

[6] A late drafting change to the Bill as a result of the Opposition’s request changed the review period from its original 24 month period to 12 months: Hon Roger Cook MLA, Minister for Health, Legislative Assembly, *Parliamentary Debates (Hansard)*, 1 April 2020, p 2004.

[7] Section 15 of the Amendment Act will commence on the same day as the sunset clause (8 April 2024) and will insert a new clause 8 to Schedule 5 of the GAA: ‘Effect of repealed s. 110ZS on continuing urgent medical research after repeal day.’

and Part 9E.[8] The effect of this broadening of the term is that a research decision-maker cannot make a decision about medical research that is contrary to a decision made in an AHD. If a person's AHD has already set out their decisions about participating in medical research, the decision-making hierarchies put in place by Part 9E of the GAA do not need to operate if/when the person loses capacity.

3.4.2 New processes

Sections 110ZR and 110ZS are the key operational provisions that the Amendment Act inserted into the GAA. The provisions provide authorisation for an incapacitated person's enrolment in medical research with a decision-maker's consent, or without that consent, respectively. The wording used in section 110ZS is consistent with existing provisions governing urgent medical treatment decisions in Division 2 of Part 9D of the GAA. Section 110ZS is subject to a sunset clause and will automatically expire four years after its commencement date: that is, on 8 April 2024.

In situations where the research is not urgent and a research decision-maker is involved, they are required to only take into account the determination of an IMP according to the Amendment Act when making their own decision on the incapacitated person's behalf. According to section 110ZR(2), the IMP's determination is only one factor that a research decision-maker must consider when deciding whether to consent to an incapacitated person being enrolled in medical research. The situation may therefore arise where the research decision-maker makes a decision contrary to the IMP's determination and does not consent to the medical research.

The determination made by an IMP prior to an incapacitated person being enrolled in medical research (in both urgent and non-urgent cases) is a key safeguard included in the Amendment Act. The requirement arises in section 110ZR in relation to research conducted with the consent of the incapacitated person's decision-maker and in section 110ZS for urgent medical research where consent is not obtained.

The IMP's determination involves a multi-faceted assessment of:

- the incapacitated person's best interests (in section 110ZU);
- the likelihood of the incapacitated person regaining their ability to consent (in section 110ZV); and
- a risk assessment (in section 110ZW).

The IMP must take into account the wishes of an incapacitated person, to the extent that they can be ascertained, as the paramount consideration when making their determination. This is an effective safeguard to ensure that the welfare of an incapacitated person is protected.

Other important provisions in the Amendment Act include the following:

- section 110ZT describes the types of medical research for which a research decision-maker cannot give their consent: research that involves sterilisation of the candidate, or electroconvulsive therapy;
- sections 110ZU-ZW outline the role of the IMP and the matters that they must take into account during their determinations under sections 110ZR or 110ZS;

[8] An Advance Health Directive is a legal document in which a person outlines their decisions about their future health care treatment, and will come into effect only if the person loses capacity.

- sections 110ZX and 110ZY explain the effect of actions taken by a researcher with regard to medical research on a research candidate and the types of research actions that are deemed reasonable when undertaken by a researcher in good faith;
- sections 110ZZ-110ZZB establish the jurisdiction of the State Administrative Tribunal to review decisions made in accordance with the provisions in Part 9E;
- sections 110ZZC and 110ZZD set out the reporting requirements of researchers and the Minister for Health; and
- section 110ZZE requires a review of the operation and effectiveness of Part 9E, which provides the authorisation for this review.

Other Australian jurisdictions have differing provisions to deal with an incapacitated person being enrolled in medical research, whether with the consent of a decision-maker or without consent. See Appendix 5 for further detail.

3.5 Report of the Standing Committee on Legislation

The Legislative Council took the unusual step of passing the Amendment Act and referring it to its Standing Committee for inquiry and report after the legislation had already commenced.[9]

The Standing Committee reported to the Parliament on the Amendment Act on 25 November 2020 and made seven recommendations in its report.[10] Three of the Standing Committee's recommendations suggested that certain clauses of the Amendment Act be considered during the review: Recommendations 3, 4 and 6.

Chapter 7 of this report examines the recommendations that were made by the Standing Committee in detail, and outlines the views of stakeholders on each recommendation. The Department has made findings for the Attorney General's consideration in relation to the Standing Committee's recommendations and, where appropriate, recommendations for amendments.

3.6 Administrative procedures to support the Amendment Act

The Amendment Act commenced in April 2020, however, administrative processes and forms were not publicly released until October 2020.

The Department of Health maintains a comprehensive package of guidance documents and information for researchers via its Research Governance Service (RGS) website.[11] OMRI is responsible for providing policy advice and guidance documents to medical researchers and health service providers (HSP).

[9] After the Third Reading stage of the Bill, the Hon Michael Mischin MLC moved a motion without notice in the Legislative Council to refer the Bill to the Standing Committee, which was supported by the Government and triggered the committee inquiry into the Amendment Act.
[10] Legislative Council, Standing Committee on Legislation, *Guardianship and Administration Amendment (Medical Research) Bill 2020 and amendments made by the Guardianship and Administration Amendment (Medical Research) Act 2020*, Report 48, 25 November 2020.
[11] Department of Health, Research Governance Service: https://rgs.health.wa.gov.au/Pages/Home.aspx (viewed on 7 April 2022).

The RGS provides the following template documents for research involving incapacitated persons according to the Amendment Act:

- GAA Medical Research Guidance Document;
- GAA Medical Research Decision Form;
- GAA Medical Research Decision Form – Urgent Medical Research; and
- GAA Medical Research Decision Report.[12]

Figure 1 outlines the process for enrolling incapacitated adults in medical research and is included in the guidance material provided to medical researchers by the Department of Health.

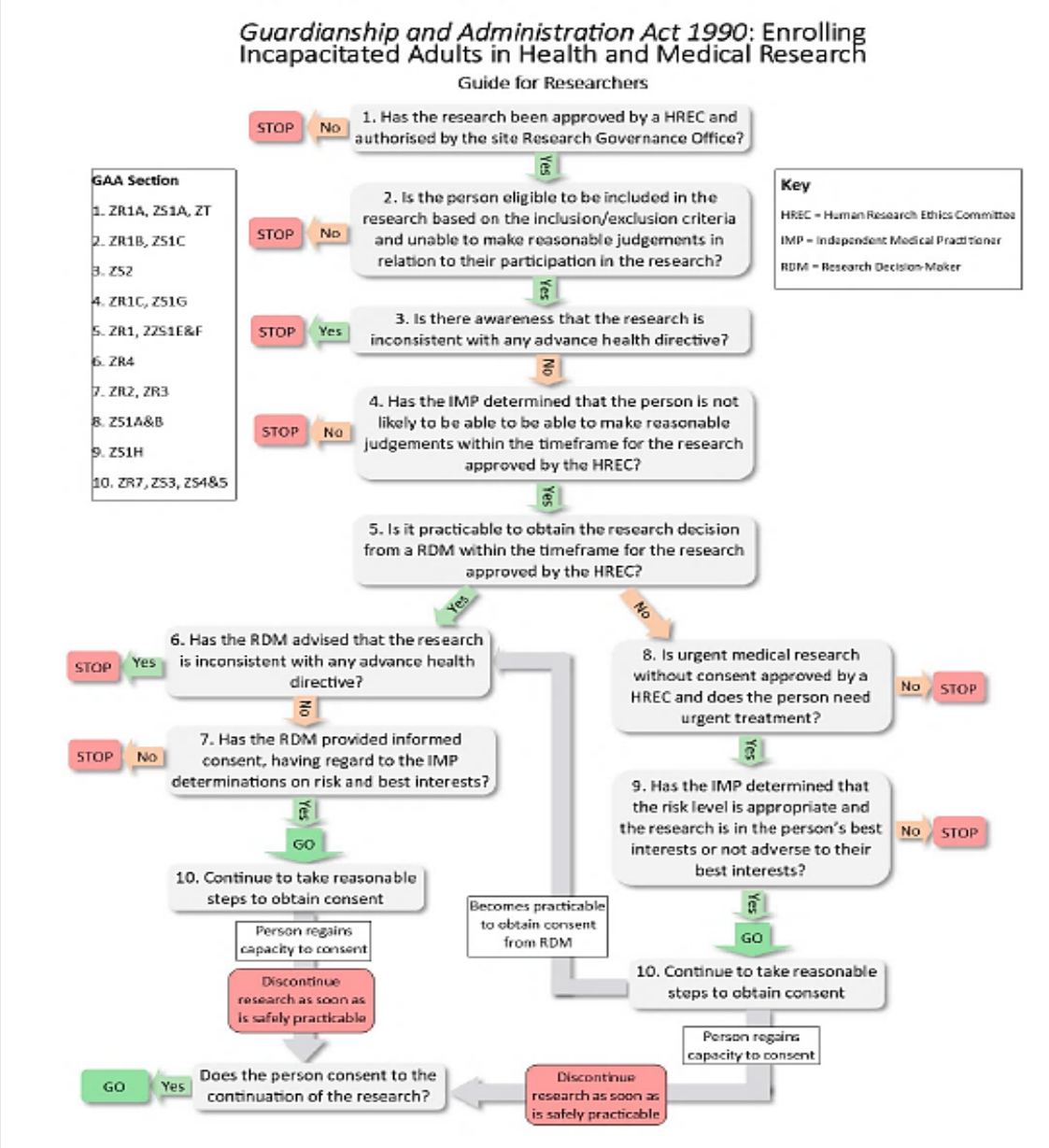

Figure 1 - Enrolling Incapacitated Adults in Health and Medical Research, October 2020, Department of Health

[12] Forms and guidance documents available from: RGS - Document Templates (health.wa.gov.au) (viewed on 7 April 2022).

4 Ethics of conducting medical research on humans

4.1 Introduction

This chapter outlines the ethical framework that underpins all medical research that is conducted on humans in Australia. The history of medical ethics can be traced back to the post-World War Two Nuremberg Code, but has been codified by the international community through the Declaration of Helsinki, which was drafted and amended by the World Medical Association.

In Australia, HRECs have a fundamental role in the approval of all medical research that occurs, including that which is conducted under the provisions of the Amendment Act.

4.2 Declaration of Helsinki

The World Medical Association first developed the Declaration of Helsinki (Declaration) in 1964 as a statement of ethical principles for medical researchers to apply to research involving human subjects. The Declaration is one of the World Medical Association's key standards documents regarding ethics in medicine and has been amended several times since it was first drafted.[13]

The Declaration outlines the responsibilities of medical researchers when conducting trials on human subjects and ethical issues that should be considered when commencing medical research.

The Declaration notes that medical progress is based on research and acknowledges that this must ultimately include studies that involve human subjects (Principle 5). The primary purpose of medical research is to generate new knowledge, but this can never take precedence over the rights and interests of individual research subjects (Principle 8). The Declaration refers to all medical research that involves human subjects requiring assessment by a research ethics committee before the research begins, with the right to ongoing monitoring of the study (Principle 23). For further discussion of the role of HRECs in Australia, see paragraph 4.4.

There are many principles in the Declaration whose influence can be seen in the safeguards for incapacitated persons being enrolled in medical research that the Amendment Act has established. Refer to Appendix 4 for an extract of the relevant Declaration principles.

4.3 National Statement on Ethical Conduct in Human Research

The National Health and Medical Research Council (NHMRC) is an independent statutory body established by federal legislation: the *National Health and Medical Research Council Act 1992* (Cth). The NHMRC is the Commonwealth Government's lead agency for funding health and medical research and issues health and policy guidelines to support research and the delivery of health care in Australia.

[13] World Medical Association, *Declaration of Helsinki*, 1964. Available from: World Medical Association, Current Policies: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/ (viewed on 7 April 2022).

The NHMRC first released its definitive guidance on research ethics, the 'National Statement on Ethical Conduct in Human Research' (National Statement), in 2007.[14] The National Statement is intended as a guide for researchers conducting research on human participants, human ethics committees, research governance bodies and the potential participants themselves. Whilst the National Statement is not a legislative instrument and therefore not binding, it represents best practice for ethical conduct in human trials and is therefore widely regarded as the keystone document for medical researchers and ethics committees.

In 2020, the NHMRC commenced a review of the sections of the National Statement that outline ethical considerations specifically in relation to participants (Section 4) and research governance and ethical review processes (Section 5). The public consultation phase of the NHMRC's review concluded in late 2020 and the NHMRC advises that it has no fixed timeline for the release of any updates to the sections under review.[15]

The participation of incapacitated persons in medical research is discussed in Chapters 4.4 and 4.5 of the National Statement: 'People highly dependent on medical care who may be unable to give consent' and 'People with a cognitive impairment, an intellectual disability, or a mental illness', respectively. The National Statement makes it clear that research conducted in emergency or intensive care, or the care of unconscious people raises 'significant ethical issues' and requires review and approval through the HREC process, rather than any internal processes that an institution may develop.[16]

According to the National Statement, a HREC must review and approve any research that may be conducted on the following categories of participants:[17]

- women who are pregnant and the human foetus;
- people highly dependent on medical care who may be unable to give consent;
- people with a cognitive impairment, an intellectual disability or a mental illness;
- Aboriginal and Torres Strait Islander Peoples; and
- some categories of research on people who may be involved in illegal activities.[18]

The processes outlined in the National Statement for enrolling people who may be unable to give consent in medical research (Chapters 4.4 and 4.5), explicitly refer to the safeguards that should be implemented to ensure that the 'distinctive vulnerabilities' of this broad cohort of potential participants are taken into account.[19]

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[14] National Health and Medical Research Council and Australian Research Council, *National Statement on Ethical Conduct in Human Research*, 2007. Available from: https://www.nhmrc.gov.au/research-policy/ethics/national-statement-ethical-conduct-human-research (viewed on 7 April 2022).

[15] National Health and Medical Research Council, *Public consultation on National Statement content*, available on National Statement homepage, footnote 14, above.

[16] National Statement, paragraph 5.1.6.

[17] Except where the research uses collections of non-identifiable data and involves negligible risk, and therefore meets the requirements for a review exemption under paragraphs 5.1.22-23 of the National Statement.

[18] National Statement, paragraph 5.1.6.

[19] This term is used to describe people with a cognitive impairment, intellectual disability or a mental illness: National Statement, Chapter 4.5, Introduction.

The Amendment Act reflects the National Statement's approach by requiring a HREC to have approved medical research that an incapacitated person may be enrolled in, either with the consent of their research decision-maker or, in the case of urgent medical research, without consent.[20]

4.4 Role of human research ethics committees in Australia

The National Statement contains detailed guidance for institutions that establish HRECs, either individually or jointly with another institution, and outlines the requirements for a HREC's:

- terms of reference;
- composition;
- appointment; and
- internal governance procedures.[21]

There are over 200 HRECs in Australia which are hosted by organisations that must register with the NHMRC. A HREC may be hosted by a hospital in the public or private system (or multiple hospitals), a university or by a private organisation. The HREC is an independent body in relation to its host organisation.

The National Mutual Acceptance scheme (NMA) allows for publicly-funded health services to access a single ethical and scientific review of human research projects. Under the NMA, a multi-centre human research project is reviewed once only. Western Australia is a participating jurisdiction in the NMA and the Department of Health's RGS provides information and oversight for researchers.

The Honourable Eric Heenan QC submitted to the review that:

> *It is important to appreciate the authority, membership and continuing scrutiny of HRECs. No clinical trial or medical research may be conducted in a hospital or institution unless the trial or study is first approved in detail by the HREC's scientific sub-committee for evaluation of the potential justification of the study. The HREC itself will consist of a membership of leading clinicians, nurses, psychologists, hospital administrators, ethicists and a legal representative*.[22]

[20] Amendment Act, ss 110ZR, 110ZS.
[21] National Statement, Section 5: Processes of research governance and ethical review.
[22] The Hon Eric Heenan QC, Submission 7, 16 February 2022, p 6. The Hon Eric Heenan is currently the legal member of the St John of God Health Care Inc HREC.

5 Implementation of the Amendment Act and implications of its use in practice

The Department consulted with medical research institutions, HSP and heard from experts in the fields of emergency medicine and research during this review. Consumer advocates and community groups who provided a submission also provided feedback regarding how the Amendment Act was being used in practice.

Stakeholders raised a broad range of concerns with the Amendment Act's practical effects on medical research, but the following issues emerged as being of particular importance to understanding the practical effects of the legislation:

- definitions in the Amendment Act are causing difficulties for medical researchers;
- the IMP requirements are difficult to comply with; and
- administrative processes and paperwork are a burden.

5.1 Definitions in the Amendment Act are causing difficulties for researchers

There are several defined terms in the Amendment Act, but the following three definitions have been identified by stakeholders as being of most concern:

- 'medical research' in section 3AA;
- 'lead researcher' in section 110ZO; and
- 'independent medical practitioner' in section 110ZO.[23]

The Department has examined this feedback provided by stakeholders in the context of the legislative scheme in which the Amendment Act operates and provides the following information and views.

5.1.1 Medical research definition is too broad

According to section 3AA of the GAA, 'medical research' means research conducted with or about individuals or their data or tissue, in the fields of medicine or health. It also includes an 'activity undertaken for the purposes of that research.'

The Explanatory Memorandum to the Amendment Act explains that the types of medical research included in the definition were modelled on the definition of 'medical research procedure' in the *Medical Treatment Planning and Decisions Act 2016* (Vic).

Victoria's definition provides that a medical research procedure includes the administration of pharmaceuticals or the use of equipment or a device, but does not include:

- any non-intrusive examination including visual examination of the mouth, throat, nasal cavity, eyes or ears or measuring a person's height, weight or vision;
- observing a person's activities;
- undertaking a survey; or
- collecting or using a person's personal or health information, as defined in Victorian legislation.[24]

[23] See paragraph 3.4 for further discussion of the Amendment Act's provisions.
[24] *Medical Treatment Planning and Decisions Act 2016* (Vic), s 3.

The definition used in the Amendment Act differs from Victoria's legislation as it does not exclude the procedures above; these are explicitly included in section 3AA:

- any non-intrusive examination, including a visual examination of the mouth, throat, nasal cavity, eyes or ears or measuring an individual's height, weight or vision;
- observing an individual;
- undertaking a survey, interview or focus group;
- collecting, using or disclosing information, including personal information; and
- a comparative assessment of health care, which may include experimental health care.[25]

The only exception to the medical research definition in section 3AA is research that is conducted about individuals or their data/tissue that only involves analysing data, does not result in any disclosure or publication of personal information and any other activity that is prescribed by regulation. No additional activities have been prescribed by regulation.

The Department observes that, while the Amendment Act's definition of medical research is based on the Victorian model, it does not follow that the two are comparable. The Amendment Act captures a wide range of medical procedures that may be conducted for the purposes of medical research.

Stakeholders to the review submitted that the definition of medical research should not cover research that only includes simple or low risk procedures:

> *Ear Science believes there is scope to narrow the definition of "medical research" as defined in section 3AA of the Act such that it only covers invasive procedures*.[26]
>
> *Simple observational studies and comparative effectiveness studies should be excluded from being considered medical research*.[27]

The School of Medicine at the University of Western Australia submitted that 'all research is treated the same whether it is experimental testing of a novel therapy, solely observational, or comparative effectiveness testing between two standard of care therapies'.[28] The submission also recommends that the requirement for an IMP determination be removed for research that is 'low/negligible risk.'

The Australasian College for Emergency Medicine also submitted that the requirement to obtain a determination from an IMP should be removed for research that has been classified by the relevant HREC as low or negligible risk.[29]

[25] Section 3AA(2)(c) and (d) of the GAA refer to 'heath care that has not yet gained the support of a substantial number of practitioners in that field of health care' (that is, experimental health care) and carrying out a comparative assessment of the procedure above against health care which would not be considered experimental.
[26] Ear Science Australia Institute Australia, Submission 2, 3 February 2022, p 2.
[27] Australian and New Zealand Intensive Care Society, Submission 11, 17 February 2022, p 3 and North Metropolitan Health Service, Submission 18, 22 February 2022, p 3.
[28] UWA School of Medicine, Submission 5, 15 February 2022, p 3.
[29] Australasian College for Emergency Medicine, Submission 13, 18 February 2022, p 3.

The Department notes that 'low/negligible risk' and 'high risk' medical research is not defined in the Amendment Act, and what may be low risk for one patient may be high risk for another. For example, what may be assumed to be a low risk observational study of a patient with an acute mental health condition, such as paranoid schizophrenia, may actually be high risk for them and may affect their recovery. The Amendment Act takes a cautious approach because the provisions are contained in legislation that is designed to protect the best interests of vulnerable people.

The National Statement is the paramount document setting out best practice for medical research in Australia and its provisions must always inform any medical research decisions made under the auspices of the Amendment Act. The National Statement defines 'low risk research' as any research in which the only foreseeable risk is one of discomfort, while 'negligible risk research' has no foreseeable risk of harm or discomfort, and any foreseeable risk is no more than 'inconvenience'.[30]

Few stakeholders working in medical research submitted that the definition of medical research in the Amendment Act has detrimentally impacted their work; many described it as 'satisfactory' or 'appropriate', or reported no issues in its operation.[31] In this context, the broad wording is an important legislative safeguard and the Department makes the following finding regarding the definition.

Finding 1: The Department finds that the definition of 'medical research' in section 3AA of the *Guardianship and Administration Act 1990* (WA) is appropriate and has been operating effectively in practice since the legislation commenced.

5.1.2 Lead researcher must be a medical practitioner and this is too restrictive

Section 110ZO of the Amendment Act defines the 'lead researcher' as a medical practitioner who has sole or joint overall responsibility for conducting the research. This wording therefore permits more than one person to fulfil the role of lead researcher.

The key requirement, however, is that they be a medical practitioner, which is defined as a person registered under the *Health Practitioner Regulation National Law (Western Australia)* (Health Practitioner National Law) in the medical profession who is not a student.[32]

There is broad consensus among stakeholders that restricting the definition of lead researcher in the Amendment Act to medical professionals has severely affected medical research in Western Australia:

> [The] *requirement in s. 110ZO that the lead researcher must be a medical practitioner has limited the capacity of the PA* (Public Advocate) *to approve a represented person to participate in medical research. For example, the PA has been asked to approve represented persons to be recruited into medical research and the lead researchers*

[30] National Health and Medical Research Council and Australian Research Council, *National Statement on Ethical Conduct in Human* Research, 2007, p 13.
[31] For example: Harry Perkins Institute and Centre for Clinical Research in Emergency Medicine, Submission 3, Australasian College of Emergency Medicine, Submission 13, WA Country Health Service, Submission 14, Office of the Public Advocate, Submission 24.
[32] The Health Practitioner Regulation National Law is a Schedule to the *Health Practitioner Regulation National Law (WA) Act 2010* (WA).

> *were allied health practitioners. As the lead researchers in these cases were not medical practitioners the request could not be considered*.[33]
>
> *The requirement in the amended legislation for the lead researcher to be a medical practitioner … a number of researchers* [commented] *that there is a range of health-focussed research that may be best led by an allied health practitioner with a more relevant qualification to the research being conducted. This is particularly the case given that the broad definition of "medical research" means that community-based, non-invasive allied health and social research falls within legislation*.[34]
>
> *Many College members undertake collaborative research which may be led by non-medical personnel such as paramedics, nursing and allied health professionals. At present, a research study of an allied health intervention is required to have a medical practitioner as the lead researcher even if the project is outside their training and expertise … This issue has particularly impacted paramedic-led prehospital research in WA*.[35]

Stakeholders proposed various ways to amend the definition, such as broadening the definition to include: other allied health professionals, non-medical clinicians, health professionals who are registered with the Australian Health Practitioner Regulation Authority (AHPRA), or nursing and allied health staff. Paramedical research, which often occurs in an ambulance and is frequently urgent in nature, is also excluded from the definition, resulting in adverse effects, such as the following case study.

The NHMRC funded EXACT study would have seen St John Ambulance paramedics randomise adults experiencing out of hospital cardiac arrest to one of two blood oxygen saturation levels (100% vs >92%). The aim was to compare the comparative effectiveness of the different oxygen treatment protocols at improving survival to hospital discharge, as well as assessing secondary outcomes such as long-term quality of life and neurological functioning. Both oxygenation levels are used in the routine clinical care of patients but high-quality data on their comparative effectiveness is lacking, resulting in a pressing need for a randomised clinical trial to more definitively guide treatment. EXACT cannot be conducted in WA (but was in Vic & SA) under Part 9E due to the need for very urgent randomisation in the field by paramedics. The lack of a medical practitioner and insufficient time to obtain a determination from an independent medical practitioner and/or the consent of a research decision maker (if present) preclude compliance with Part 9E. EXACT could be conducted in WA if Part 9E is amended to (1) permit nurses, allied health professionals and paramedics to be Lead Researchers and (2) the requirement to obtain a determination from an IMP is removed for urgent low risk or comparative effectiveness research. Patients would still receive care that is within current routine practice administered under a strict protocol.
Source: East Metropolitan Health Service, Case Studies, 18 March 2022

The Department notes that a definition of health professional which is aligned with the Health Practitioner National Law will ensure that health professionals involved in medical research are subject to the AHPRA regulatory regime.

APHRA has the ability to sanction registered health professionals for professional misconduct or unprofessional conduct under the Health Practitioner National Law, which can include an offence under another statute, such as the GAA. AHPRA can

[33] Office of the Public Advocate, Submission 24, 4 March 2022, p 2.
[34] Office of the Deputy Vice-Chancellor, Research, Curtin University, Submission 27, 16 March 2022, p 2.
[35] Australasian College for Emergency Medicine, Submission 13, 18 February 2022, p 4.

also make decisions on a health professional's continuing registration, such as imposing conditions or training on the individual, if it has been satisfied of unsatisfactory professional performance.

The Standing Committee recognised that the requirement for the lead researcher to be a medical practitioner was intended as a safeguard for incapacitated persons in some cases, but ultimately recommended that the definition be amended to include 'nurses, psychiatrists, paramedics and allied health professionals'.[36]

Finding 2: The Department finds that the definition of 'lead researcher' in section 110ZO of the *Guardianship and Administration Act 1990* (WA) has adversely impacted medical research that may be conducted on incapacitated persons, particularly for paramedical and community-based research.

Part 9D of the GAA permits urgent treatment decisions to be made in relation to incapacitated persons without consent. Section 110ZH within Part 9D uses the term 'health professional' as the relevant person who may provide urgent treatment in such circumstances.

'Health professional' is defined by referring to section 5PA of the *Civil Liability Act 2002* (WA), which includes the same list of 16 health professions from the Health Practitioner National Law, plus 'any other person who practises a discipline or profession in the health area that involves the application of a body of learning.' The definition of 'health profession' in the Health Practitioner National Law is broad and includes recognised specialities in the following professions:

- Aboriginal and Torres Strait Islander health practice;
- Chinese medicine;
- chiropractic;
- dental (including the profession of a dentist, dental therapist, dental hygienist, dental prosthetist and oral health therapist);
- medical;
- medical radiation practice;
- midwifery;
- nursing;
- occupational therapy;
- optometry;
- osteopathy;
- paramedicine;
- pharmacy;
- physiotherapy;
- podiatry; and
- psychology.[37]

[36] See further, paragraph 7.1. Note that the reference to 'psychiatrists' is in error, as psychiatrists are medical doctors with specialised training, so are already within the definition of 'medical practitioner.'
[37] A 'health practitioner' in the Health Practitioner National Law means an individual who practises a health profession, as defined above.

The Department has considered the various proposals in submissions on this issue and agrees with stakeholders that the definition of lead researcher in its current form is affecting the practical implementation of the Amendment Act. The Department observes that limiting the definition to medical practitioners only has also adversely affected research that takes place in the community, which often involves incapacitated persons, such as people with dementia:

> *Since the Amendment Act commenced my work has been with people living with dementia in the community and working with their carers also … Our work centres on assisting people living with dementia in the community to remain living at home, through preventative health interventions, to avoid admission into a residential aged care facility. The Amendment Act appears to have been written predominately with hospitalised patients in mind … and does not appear to consider how research within the community (in people's homes) is undertaken … For example, one current project we are undertaking is teaching people with dementia (if they have had a fall or are unsteady on their feet) to use a walking aid … we are allied health practitioners on this grant (predominantly physiotherapists because they are the most qualified health professionals to teach people how to use a walking aid). Under the Amendment Act we had to include a medical practitioner as the lead researcher, which we have done, but we are greatly concerned why this is a requirement because we would never recommend a person with dementia go to a medical practitioner to learn how to use a walking aid because that is not a large part of their training.*
> ***Source: Comments provided by a researcher in Submission 27, Office of the Deputy Vice-Chancellor, Research, Curtin University***

In line with Finding 2, the Department makes the following recommendation in relation to the definition of lead researcher.

Recommendation 1: The definition in section 110ZO of the *Guardianship and Administration Act 1990* (WA) of 'lead researcher' should be amended to change the reference to 'medical practitioner' to 'health practitioner'. A new definition of 'health practitioner' should be inserted into section 110ZO which has the meaning given in the *Health Practitioner Regulation National Law (Western Australia)*.

5.1.3 Independent medical practitioner definition is unclear and should be improved

Stakeholders have raised concerns during this review regarding the wording used in the IMP definition in section 110ZO of the Amendment Act:

> [In] *the acute care setting (eg Intensive Care, Emergency Department), the treating doctor (not the IMP) best knows the patient's acute medical condition that causes incapacity and the likely duration of the incapacity. Furthermore, the treating doctors in the critical care setting generally know the patient's wishes better than an IMP who had no current contact with the patient and the next of kin*.[38]

The concerns above relate to the wording used in section 110ZO(a) and (b) to describe the 'arm's length' relationship that must exist between an IMP and an incapacitated person who is a potential research candidate. That is, the IMP definition requires the individual to be a medical practitioner who:

> *(a) is not involved in providing treatment under this Part* [9E] *to the research candidate whose participation is sought in the research; and*

[38] North Metropolitan Health Service and Australia and New Zealand Intensive Care Society, Submission 18, 22 February 2022, p 4.

(b) is not involved in, nor connected to, the research, other than having a professional interest in the area of the research. [emphasis added]

The Department notes that the wording in section 110ZO(a) may be interpreted as excluding an incapacitated person's usual treating doctor from fulfilling the IMP role if the words 'under this Part' are not taken into account. According to the words of the provision, an incapacitated person's treating doctor is only prevented from acting as IMP if they are providing treatment to the person that is also part of the medical research: this is a subtle, yet important distinction. Some stakeholders were concerned that this distinction was not sufficiently clear:

> *The definition of IMP has confused some doctors when they are asked to declare that "I am not currently involved in the treatment of the research candidate which is related to the research." … Asking for a doctor not involved in the treatment of the patient appears counter-intuitive and time intensive*.[39]

> *Despite clarification by the Department of Health and the Standing Committee, several of the requirements to qualify as an IMP are ambiguous and, therefore, difficult to implement when designating IMPs:*
> - *There is uncertainty as to whether a research candidate's treating doctor can be an IMP…*
> - *It is unclear what constitutes being 'involved in or connected to the medical research' (s 110ZO) and, therefore, the degree of connection that disqualifies a person from being an IMP*. [40]

The Department of Health's OMRI provides essential information as part of its service to HSP and has advised that it regularly assists researchers with their requests for information regarding the Amendment Act and other statutory obligations. In 2020, the Department of Health published guidance to HSP to clarify this issue, advising that:

> *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 Medical Research*.[41]

The Department notes that, while this information is helpful and correct, it is contained as a footnote within a 24-page document, and may therefore be overlooked by medical researchers or other parties seeking information about the IMP role.

Stakeholders have also advised that the use of the word 'medical' in the IMP definition can exclude other health practitioners who may fulfil the role:

> *The definition of the Independent Medical Practitioner does not recognise the research that is undertaken by other AHPRA registered health professionals such as nurses, psychologists, paramedics and other allied health professionals. The terminology for the IMP should be changed to Independent Health Practitioner*.[42]

[39] Harry Perkins Institute and Centre for Clinical Research in Emergency Medicine, Submission 3, 9 February 2022, p 3.
[40] East Metropolitan Health Service, Submission 23, 4 March 2022, p 5.
[41] Department of Health, Research and Innovation Office, 'Guidance document: Involving Incapacitated Adults in Health and Medical Research', 6 October 2020, p 5.
[42] Australasian College for Emergency Medicine, Submission 13, 18 February 2022 , p 4.

The following case study also illustrates the impact on incapacitated persons of the difficulties that a community-based study may face when complying with the IMP requirement.

> [Silver Chain is] *currently undertaking an evaluation of a new overnight, in-home palliative care respite service in WA. To this end, we commissioned an Australian academic group at the forefront of person-centred palliative care research. Currently, Silver Chain and the research team are grappling with the dilemma of whether to include or exclude incapacitated Research Candidates, due to the logistical challenges of engaging at least two medical practitioners. This has significantly delayed commencement of the project, the outcome of which will inform funder decision-making about future continuation of the service. In addition, if we are unable to include incapacitated clients in this study, we lose the opportunity to contribute knowledge about the potential benefits of in-home palliative care respite for a high risk group and their carers.*
> ***Source: Silver Chain Group Ltd, Submission 21***

In line with the observations made in paragraph 5.1.2 on the definition of 'lead researcher', the Department makes the following finding and recommendation for amendments to the IMP definition in the Amendment Act.

Finding 3: The Department finds that the safeguard offered by the definition of 'independent medical practitioner' in section 110ZO of the *Guardianship and Administration Act 1990* (WA) has been operating appropriately, despite the fact that some health professionals involved in medical research who are not medical practitioners have been unable to enrol incapacitated persons in their research projects.

Recommendation 2: Notwithstanding the access issues discussed in Finding 3, the Department recommends that the definition of 'independent medical practitioner' in section 110ZO of the *Guardianship and Administration Act 1990* (WA) not be amended.

5.2 Requirement to obtain an IMP determination is challenging in emergency situations

Most stakeholders who provided a submission to this review were not supportive of the requirement to obtain an IMP's determination before enrolling an incapacitated person in medical research, in any circumstances. Extensive feedback was received, including the following concerns:

> *Researchers have found training IMPs about their role under Part 9E and the administrative processes for obtaining and documenting their determinations, as well as ensuring they are fully briefed on the background, aims and eligibility criteria for specific research projects, to be time-consuming and burdensome on researchers and coordinators*.[43]

> *In some circumstances, the lack of availability of an IMP can mean that the patient cannot be enrolled in the research even though the RDM* [research decision-maker] *agrees that the participant would wish to participate*.[44]

[43] East Metropolitan Health Service, Submission 23, 4 March 2022, p 6.
[44] Australasian College for Emergency Medicine, Submission 13, 18 February 2022, p 3.

> *The process of briefing the IMP and them subsequently completing the* [GAA Medical Research Decision] *form is time consuming, very challenging to achieve in the setting of an ED* [Emergency Department] *where there is significant time pressure on medical staff. This is a significant obstacle to recruiting patients*.[45]

When urgent treatment[46] is required and the consent of an incapacitated person's decision-maker is not obtained, the researcher must not conduct the research unless they have received a determination from an IMP. The IMP must assess various matters in relation to the incapacitated person's participation, according to the process outlined in section 110ZS(1)(g), (h) and (i).[47]

This process is complex and involves many steps, and the Department has heard that this requirement can be difficult to comply with, particularly during an emergency:

> *The requirement to obtain a determination from an IMP before an incapacitated person may be enrolled in medical research has proven extremely problematic. I work in a time critical environment, where literally every second counts. Previous research on this requirement has found that complex consent processes: are anti-therapeutic; result in avoidable mortality and probably morbidity; and the delay in starting research can obscure a real treatment benefit from the administration of a time critical therapy*.[48]

> [Researchers] *specifically working in the areas of intensive care, anaesthesia and stroke … have indicated that it is often challenging to obtain a determination from an Independent Medical Practitioner (IMP) in a timely way … Finding someone who is appropriately qualified, on call, understands the condition, the patient's status (but is not involved in the administration of the research), and the risks of the research can be difficult in most contexts*.[49]

Dr Matthew Anstey at Sir Charles Gairdner Hospital provided the following case study to illustrate the challenges faced by incapacitated persons in intensive care settings.

[45] Dr Stephen Macdonald, Submission 12, 17 February 2022, p 9.
[46] 'Urgent treatment' is defined in section 110ZH of the GAA and was not part of the Amendment Act. It means treatment that is urgently needed to save the patient's life, prevent serious damage to their health or to prevent them from suffering or continuing to suffer significant pain or distress. It does not include psychiatric treatment or sterilisation.
[47] See further, paragraph 3.4.2.
[48] Harry Perkins Institute and Centre for Clinical Research in Emergency Medicine, Submission 14, 9 February 2022, p 6.
[49] South Metropolitan Health Service, Submission 4, 14 February 2022, p 4.

The Guardianship and Administration Act offers an option for incapacitated patients to participate in research in Western Australia. Patients who are critically unwell in Intensive Care are often unable to participate in decision making about their care, including research. Treatments being examined are often time-critical and delays to their administration can potentially reduce the efficacy of the treatment. One example of the effect of these delays is illustrated by the following case:

A patient with septic shock and multi-organ failure (from a severe infection causing low blood pressure and impairment of critical organs) was admitted to the Intensive Care Unit at 9pm on a Friday night. He met the inclusion criteria for a randomised controlled trial comparing high dose intravenous Vitamin C or placebo, in addition to standard care. Vitamin C is a low risk medication that is being studied to see if it may reduce the inflammation in severe infections. Furthermore, there is some evidence to suggest that earlier administration may lead to better outcomes. As he was so unwell, the only way to gain approval for participation was through the GAA/IMP pathway as he did not have capacity. For this trial at Sir Charles Gairdner Hospital, this requires contacting the medical executive on call for them to make a determination. Due to other factors happening in the hospital on that weekend, there was a delay of over 18 hours until the medical executive was able to review the case, by which time it was no longer possible to enrol the patient and unfortunately they missed out.

Source: Dr Matthew Anstey, Case Study, 16 March 2022

The East Metropolitan Health Service (EMHS) submitted that it has implemented several risk-stratified solutions to deal with the 'practical challenges' of the IMP requirements in the Amendment Act:

> *For low-risk projects the researchers identify and train colleagues within their Department. For example, the RPH Emergency Department designate their 'EPIC' (Emergency Physician in Charge) as an on-duty IMP for research projects. However, if the EPIC happens to be an investigator on a specific project, another medical practitioner on the ward must take on the role.*
>
> *For higher risk interventional and invasive studies, the designated IMP is the EMHS Director of Clinical Services DCS … While this ensures a single contact point, the DCS may be unavailable if attending to other urgent patters, potentially delaying or preventing an enrolment*.[50]

EMHS noted that neither of these options are 'ideal' and 'each has strengths and weaknesses.'

The Department acknowledges the burden that the IMP requirement may impose on medical researchers in certain situations, such as emergency medicine or paramedicine, and in regional, rural or community settings.

The Department also notes that removing the IMP requirement for medical research in the Amendment Act means that the research has only been approved by a HREC before the research has commenced. This would not therefore include an assessment of individual patient differences, particularly in relation to incapacitated persons who may be enrolled in the research.

The consequences of this are that an incapacitated person's research decision-maker must make a potentially untrained decision as to whether there would be any risks to that particular patient with their particular conditions or combination of symptoms at

[50] East Metropolitan Health Service, Submission 23, 4 March 2022, p 5.

that point in time. This would not align with the policy objectives of the Amendment Act, nor the GAA more generally, and may undermine the protection that the legislation is intended to provide to incapacitated persons.

The inclusion of an IMP determination for incapacitated research candidates ensures an individualised assessment of best interests and risks, in addition to the general ethics approval provided by the HREC.

Finding 4: The Department finds that the requirement to obtain a determination from an independent medical practitioner in sections 110ZR and 110ZS of the *Guardianship and Administration Act 1990* (WA) is, on balance, an appropriate safeguard to protect incapacitated persons.

5.3 Administrative processes and forms are a burden for medical researchers

The requirement for the IMP and medical researchers to complete research decision forms emerged as a contentious issue amongst stakeholders during this review. Stakeholders from the medical research community expressed their view that the content and format of these forms was onerous and too complex:

> *The four page governance form (GAA Medical Research Decision Form) is strongly disliked as it is overengineered and is a disincentive to enrolment*.[51] [emphasis in original]

> *The completion of a handwritten 4-page document by the IMP prior to recruitment is logistically prohibitive … we consider the requirement to provide written statements in support of every criterion to be unnecessary and call for substantial simplification*.[52]

Other stakeholders submitted that the administrative assistance provided to medical researchers was valuable:

> *The WA Department of Health staff have been excellent at explaining things and providing advice within their scope. We realise how this Amendment Act was written was nothing to do with them and they are only trying to assist with its implementation, it is very beneficial to have them available though to answer questions we as researchers may have*.[53]

The Department has examined the relevant IMP determination forms (GAA Medical Research Decision Form and GAA Medical Research Decision Form–Urgent Medical Research) and notes that the majority of the required information is provided by ticking a box to acknowledge or confirm statements on the form.[54] These statements are based on the requirements in Part 9E of the GAA and contain extracts of the relevant legislation, where applicable.

[51] Harry Perkins Institute of Medical Research and Centre for Clinical Research in Emergency Medicine, Submission 3, 9 February 2022, p 3.
[52] University of Western Australia, School of Medicine, Submission 5, 15 February 2022, p 3.
[53] Office of the Deputy Vice-Chancellor Research, Curtin University, Submission 27, 14 March 2022, p 10.
[54] The 'GAA Medical Research Decision Report' requires information about the research project only (selected from drop-down lists) and contact details of the researcher.

There are three sections in the forms where an IMP must provide written reasons for their determination as to the:

- likelihood of the research candidate regaining the ability to be able to make reasonable judgments within the timeframe for the research approved by the HREC;
- applicable risk category in which the research candidate's participation falls; and
- assessment of how participating in the research will be in the best interests of the research candidate, or not adverse to their interests.

The Department notes that, of the 14 and 15 fields on the form for an IMP to complete for the non-urgent and urgent medical research, respectively, it does not seem onerous for an IMP to provide substantive information on the three topics above in cases where a potential candidate cannot provide consent on their own behalf. Given the importance of ensuring that a rigorous process is followed for incapacitated persons in particular, it is entirely appropriate to require a record of this information.

Question 11 of the 'GAA Medical Research Decision Form–Urgent Medical Research' provides an option for an IMP to confirm that 'it was not practicable to provide the determinations in writing before the research commenced therefore the determinations were provided orally.' The Amendment Act permits an IMP to provide their determination orally before the medical research commences, but it must be provided in writing after the candidate has commenced their participation.[55] There is no specified timeframe in which the written determination must be completed. The Department notes that this gives an added element of flexibility in time-sensitive situations.

The Department also notes that the Standing Committee made a finding in its report on the Amendment Act that:

> *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*.[56]

In light of the above, the Department does not agree that the administrative processes that support the operation of the Amendment Act are onerous or excessive, either for medical researchers or for IMPs who provide determinations in support of medical research.

The forms developed by the Department of Health reflect the requirements of the Amendment Act and ensure that an incapacitated person's enrolment in medical research meets the reporting requirements in the legislation. The requirement for an IMP to inform the research decision-maker or the researcher of the reasons for their determination (using the form) creates an audit trail and provides additional protections to an incapacitated medical research candidate.

[55] The requirement to follow up an oral determination with written reasons applies in sections 110ZU, 110ZV and 110ZW.
[56] Legislative Council, Standing Committee on Legislation, *Guardianship and Administration Amendment (Medical Research) Bill 2020 and amendments made by the Guardianship and Administration Amendment (Medical Research) Act 2020*, Report 48, 25 November 2020, Finding 29.

The flow of information that is created by the Department of Health's forms assists researchers in meeting their reporting obligations according to the Amendment Act and, in turn, the obligation of the Minister for Health to report to Parliament.

If an incapacitated person regains capacity and wants to understand what assessment was made in relation to their participation in medical research, they may request the documentation to see the decision-making process that occurred. This is an appropriate safeguard to protect their interests and should be viewed as an integral part of medical research, rather than an administrative burden.

Finding 5: The Department finds that the administrative processes, including forms, established by the Department of Health to support the practical implementation of the *Guardianship and Administration Amendment (Medical Research) Act 2020* (WA) are appropriate and effective.

Recommendation 3: Notwithstanding Finding 5, as it may be of some assistance to incapacitated persons, the Department suggests that the Department of Health, in consultation with its key stakeholders, consider amending its 'GAA Medical Research Decision Form – Urgent Treatment' to include a field whereby the research decision-maker's name and the capacity in which they are providing their consent is recorded on the form.

6 Effectiveness of the Amendment Act in protecting incapacitated persons

6.1 The purpose of the Amendment Act is to protect vulnerable people

The Department notes that one of the policy objectives of the Amendment Act is to 'provide the authorisation and appropriate safeguards to enable enduring guardians, guardians and next of kin to consent to medical research for people under legal incapacity'.[57] At the time that the Bill was introduced into the Parliament, the COVID-19 pandemic was emerging as a health emergency for Western Australia and legislative changes across a wide range of portfolios were introduced in response to the pandemic. The aims of the Bill were to:

- codify processes in legislation which had been routine prior to the Department of Health receiving legal advice in 2018 which put the lawfulness of those processes in doubt;
- provide a means for medical research to be conducted on patients who may be incapacitated as a result of COVID-19 symptoms[58]; and
- put in place processes and safeguards to enable incapacitated persons to be enrolled in medical research for other reasons.

The focus of the legislation was therefore those incapacitated persons who may be enrolled in medical research either with the consent of their research decision-maker or, in urgent circumstances, without consent. According to the GAA, the primary concern in all decisions involving an incapacitated person must be that individual's best interests, rather than the advancement of medical research generally.[59]

Experts in the law regarding capacity to consent acknowledge that including incapacitated persons in medical research is important:

> *Specifically, cognitively impaired adults have an equitable right to research being conducted in areas relevant to their treatment and care, and should be given an equitable opportunity to participate in such research, even if they lack capacity*.[60]

During the review of the Amendment Act, it has become apparent that there is an inherent tension that exists between:

- the desire to permit medical research on incapacitated persons which could advance medical knowledge and result in positive outcomes for patients, either as individuals or particular cohorts; and
- the need to have sufficiently robust safeguards in place to protect those vulnerable patients who are unable to provide consent on their own.

[57] Legislative Assembly, Guardianship and Administration Amendment (Medical Research) Bill 2020, *Explanatory Memorandum*, p 1.
[58] See further: paragraph 6.2.
[59] Section 4 of the GAA sets out principles that the State Administrative Tribunal must observe when dealing with proceedings commenced under the Act.
[60] Nick O'Neill & Carmelle Peisah, *Capacity and the Law: 2021 Edition*, Sydney University Press and AustLII, December 2021, Chapter 16.

Several stakeholders from the medical research community expressed the view that the requirements in the Amendment Act are stifling the important research work that they conduct, with little benefit otherwise:

> *The significant administrative and practical hurdles imposed by the amendments are … disproportionate and serve no purpose other than to impede the resolution of important treatment uncertainties … Given the current impediments, I would discourage anyone who was interested in pursuing a career as a clinical researcher in emergency medicine or a related discipline which is likely to involve patients who lack capacity to provide consent from doing so in WA until such time that these difficulties are resolved.*[61]

> *It can be very challenging to develop high level evidence in critically ill and/or incapacitated patients due to the time critical nature … Unnecessary obstacles to ethically approved research results in patients continuing to be exposed to unproven and even potentially harmful 'routine' care without the regulatory oversight and monitoring inherent if they were enrolled in clinical research*.[62]

The following case study is also indicative of the challenge in protecting vulnerable people (including their right to privacy) while obtaining the information necessary for the purpose of medical research.

An ever-increasing number of novel psychoactive substances, such as stimulants, hallucinogens and cannabinoid drugs, are being detected worldwide. There is an urgent need to monitor their use and conduct research into their effects in order to reduce harm and mortality. However, this is challenging due to the social context of their use and their illegality. One method is to monitor patients presenting to Emergency Departments who are suspected of being intoxicated having taken one of these drugs and where blood tests are required for their routine clinical care. A single additional research blood sample could be collected and used to conduct mass spectrometry analysis to identify the presence and concentration of any psychoactive drugs, which would improve diagnostic testing. This could be linked to clinical data, providing comprehensive information on current drugs of abuse and creating an early warning system for emerging drugs of concern. Despite the public health benefits and compelling public interest in a project of this kind, it is not clear if it could be effectively conducted under Part 9E due to the violation of privacy for patients. For example, if a patient was enrolled urgently without consent, Part 9E requires the lead researcher to 'continue to take reasonable steps' to obtain a decision from a research decision maker. This would require a discussion of the purpose of the medical research, resulting in disclosure of the patient's illicit drug use that might not have been necessarily had if the patient only received routine treatment.
Source: East Metropolitan Health Service, Case Studies, 18 March 2022

Other stakeholders recognised the tension that exists when medical research is conducted on patients whose capacity may be in question:

> *A legislative pathway that supports the ongoing access to improve outcomes for these vulnerable patients through HREC-approved research is essential … Any additional legislated administrative requirements must be carefully considered with respect to their potential impact on the care of incapacitated patients. Such administrative requirements should therefore be reasonable, clinically feasible and practicable. The incapacitated should not be disadvantaged in their opportunities to participate in medical research*.[63]

[61] Dr Stephen Macdonald, Submission 12, 17 February 2022, pp 7 and 12.
[62] University of Western Australia, School of Medicine, Submission 5, 15 February 2022, p 2.
[63] Australian and New Zealand Intensive Care Society, Submission 11, 17 February 2022, p 2.

> *PWdWA acknowledges the long history of abuse and exploitation that people with disabilities have experienced under the label of medical research and understands the need for safeguarding processes to be in place regarding medical research. Furthermore, we recognise the right of all people with disabilities to have access to the same range, quality, and standards of health care as other persons. It is discriminatory to deny healthcare and health services on the basis of disability. This includes being able to participate in medical research*.[64]

Stakeholders did not raise concerns during this review with the requirements in sections 110ZR and 110ZS to discontinue medical research involving an incapacitated person as soon as safely practicable when the person regains the ability to consent or where a research decision-maker makes a decision to refuse consent to the medical research. The Department observes that this may be the result of low enrolments in medical research involving incapacitated persons during the first year of the Amendment Act's operation (see further, paragraph 6.3), or may be because this safeguard has been working effectively. Future reviews of the Amendment Act will be better placed to identify any trends in the number of enrolments and measure the effectiveness of this requirement.

Finding 6: The Department finds that the *Guardianship and Administration Amendment (Medical Research) Act 2020* (WA) has been effective in codifying processes regarding medical research which had been routine prior to 2018 to enable medical research to be safely conducted on incapacitated persons.

Finding 7: The Department finds that the *Guardianship and Administration Amendment (Medical Research) Act 2020* (WA) has provided a means by which medical research may be safely conducted on patients who may be incapacitated as a result of COVID-19 symptoms.

Finding 8: The Department finds that the *Guardianship and Administration Amendment (Medical Research) Act 2020* (WA) has put in place processes and safeguards to enable incapacitated persons to be enrolled in medical research.

6.2 The Amendment Act was intended to respond to urgent research that may be required during a pandemic

The Department notes that the Amendment Act's intent was to, among other things, codify the procedures that had been occurring prior to legal advice being received by the Department of Health regarding the reliance on treatment provisions in the GAA for incapacitated persons being enrolled in research. In this sense, the Amendment Act has been effective in meeting its policy objectives as it has clarified the legal authority and processes by which medical researchers may conduct research on incapacitated persons.

However, the statement by the then Minister for Health that the Amendment Act would provide 'critical legislative amendments that [would] enable our doctors to join the

[64] People with Disabilities (WA) Inc., Submission 6, 15 February 2022, p 1.

global effort to trial new and emerging treatments for COVID-19' does not appear to have been borne out in practice, according to stakeholders.[65]

The Department observes that feedback from stakeholders during the review and case studies provided did not raise concerns with the Amendment Act's impact on medical research relating to COVID-19 management or treatment. This does not mean that the provisions in the Amendment Act have not been used to conduct research on incapacitated persons with COVID-19, particularly when noting the effect of closed State borders on the numbers of people infected with COVID-19 during 2020 and 2021.

However, it is not possible to identify if the incapacitated persons enrolled in medical research are being provided with care specifically for COVID-19-related illness, as the reports that are required to be tabled in Parliament are de-identified: see below, paragraph 6.3. The Department accordingly cannot make a finding regarding this particular aspect of the Amendment Act's effectiveness in this report.

6.3 Few incapacitated people were enrolled in medical research when the Amendment Act first commenced, but numbers have increased dramatically since then

Evidence is emerging that the number of incapacitated people enrolled in medical research according to the provisions in the Amendment Act is increasing since it commenced in 2020. The Department has examined data on the number of incapacitated persons enrolled in medical research and questioned stakeholders on the difficulties (if any) that the Amendment Act was causing.

For advocacy groups, the Department sought feedback on how their clients may have been affected by the legislation. The Department also sought comment through those advocacy groups from clients who may have been enrolled in medical research according to the Amendment Act's powers.

The Public Advocate submitted that she has been requested to act as the research decision-maker for persons for whom she has been appointed as guardian, but on every occasion the lead researcher was not a medical practitioner so consideration could not be given to the request.[66]

The Mental Health Law Centre advised that it has not provided representation to any incapacitated persons according to the Amendment Act since it commenced. People with Disabilities (WA) Inc. also submitted that the organisation has not been approached by anyone to seek support with decisions made under the Amendment Act.

The State Administrative Tribunal (SAT) submitted that since the Amendment Act's enactment, it has not received any applications for the appointment of a guardian (or additional powers for an existing guardian) with authority to consent to medical research on behalf of a represented person. SAT also advised that it has not received any applications under section 110ZZ of the GAA for the review of a decision made to enrol a represented person in medical research.[67]

[65] Legislative Assembly, Hon Roger Cook MLA, Minister for Health, *Parliamentary Debates (Hansard)*, 1 April 2020, p 1975.
[66] Office of the Public Advocate, Submission 24, 4 March 2022, p 2.
[67] State Administrative Tribunal, Submission 26, 15 March 2022, pp 1-2.

The President of SAT has advised that, since the date of its submission, the SAT has made one order granting a limited guardian the power to make research decisions in relation to a represented person, subject to section 45(4A) and sections 110ZR and 110ZT of the GAA. That authority was included as part of a suite of guardianship powers conferred on a limited guardian, rather than in response to an immediate need for a guardian to make a medical research decision.[68]

The Minister for Health is required to report on the number of incapacitated persons enrolled in medical research, according to the requirement in section 110ZZD of the GAA. At the time of this report's tabling, the Minister for Health has tabled two such reports: for the 2020-2021 period and for 2021-22: these are extracted at Figure 2 and Appendix 6, respectively.

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

Figure 2 - Research Candidates enrolled under Part 9E - Medical Research of the Guardianship and Administration Act 1990 – 7 April 2020 to 6 April 2021

The data in the Minister for Health's reports are sourced from the written notices that researchers must provide according to section 110ZZC of the GAA, including details regarding the manner in which the research candidate was enrolled (that is, with their research decision-maker's consent or urgently, without consent) and what the research entails.

[68] State Administrative Tribunal, Email to Department of Justice, 15 August 2022.

During the first reporting period (Figure 2), nearly all incapacitated persons were enrolled in medical research with their research decision-maker's consent: 89 per cent, or eight of the nine total enrolments. Of those eight enrolments, the purpose of the medical research varied, including:

- two instances of comparative assessment of health care practices for rehabilitation and therapy at Royal Perth Hospital;
- three survey, interview or focus group enrolments in the category of 'Care for Disabled' at Curtin University; and
- one case where pharmaceuticals or a placebo was administered at Fiona Stanley Hospital.

The only occasion where an incapacitated person was enrolled in medical research in an urgent circumstance occurred at Fiona Stanley Hospital and involved the collection of either blood, tissue or fluids from the individual in the field of emergency medicine.

Between the first reporting period and the period ending 6 April 2022 (the most recent reporting period), the Department notes that there has been almost a thirteen-fold increase in the number of medical research enrolments: from nine to 115. The total of 115 for the 2021-2022 reporting period includes 100 enrolments with the research decision-maker's consent (87 per cent), and 15 without consent for urgent medical research (13 per cent): see Figure 3. The Department of Health's guidance document reiterates that the use of section 110ZS of the Amendment Act (research without consent) is to be a measure of last resort for medical researchers:

> *It is expected that the majority of people enrolled into research under the Act will be enrolled via this* [non-urgent] *pathway …*
>
> [The urgent medical research without consent] *pathway can only be used if the 'Medical Research with consent of Research Decision-Maker' pathway is not available*.[69]

Figure 3 shows that the majority of research decisions made in 2021-22 using the Amendment Act's powers were for the purpose of providing treatment to an incapacitated person.

The Department observes that the majority of enrolments under the Amendment Act have been in three main types of medical research: intensive care, neurology and neuromuscular diseases, and clinical microbiology: see Figure 4. In these three types of medical research, overwhelmingly the enrolment was consented to by a research decision-maker.

Several stakeholders raised concerns about the Amendment Act's detrimental effects on medical researchers in emergency medicine and intensive care: for example, UWA School of Medicine, Australian and New Zealand Intensive Care Society, Dr Stephen Macdonald, Australasian College for Emergency Medicine, North Metropolitan Health Service, EMHS and the Australian Medical Association (WA).

[69] Department of Health, *GAA Medical Research Guidance Document*, Version date: 01 June 2022, p 8.

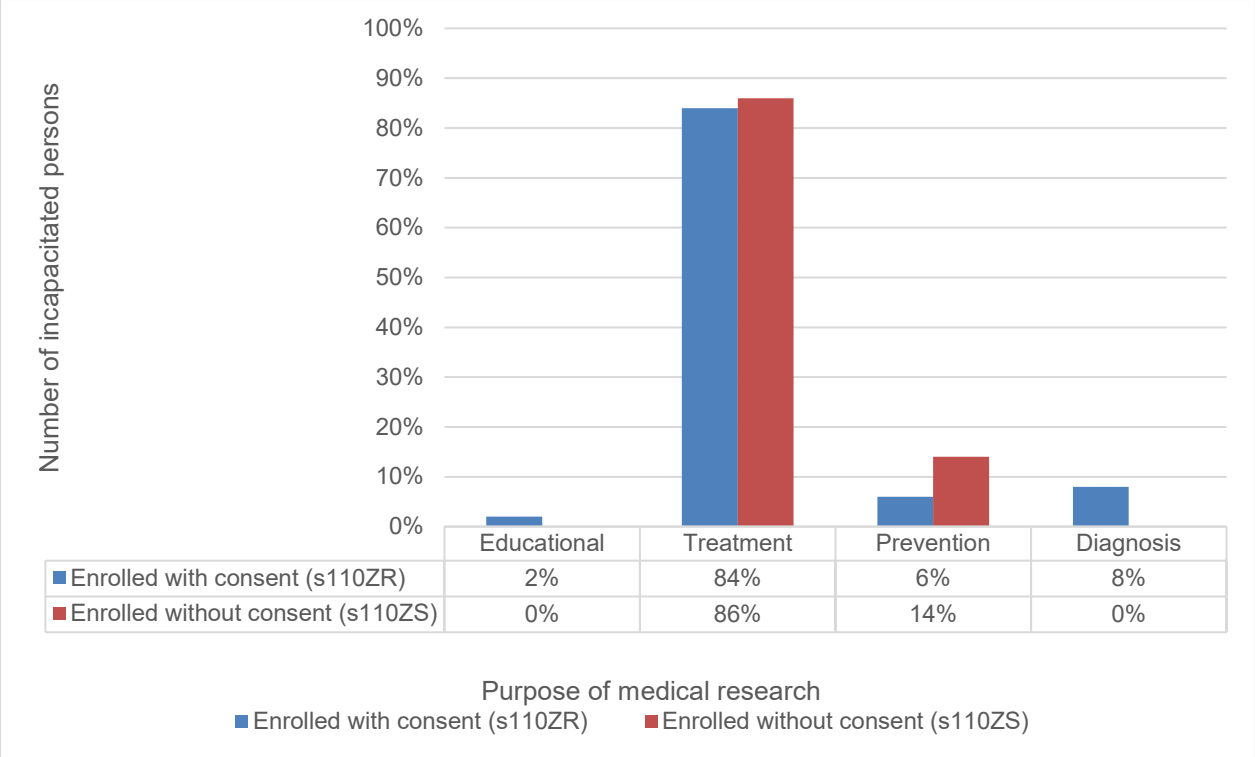

Figure 3 Purpose of enrolment for incapacitated medical research candidates 7 April 2021-6 April 2022

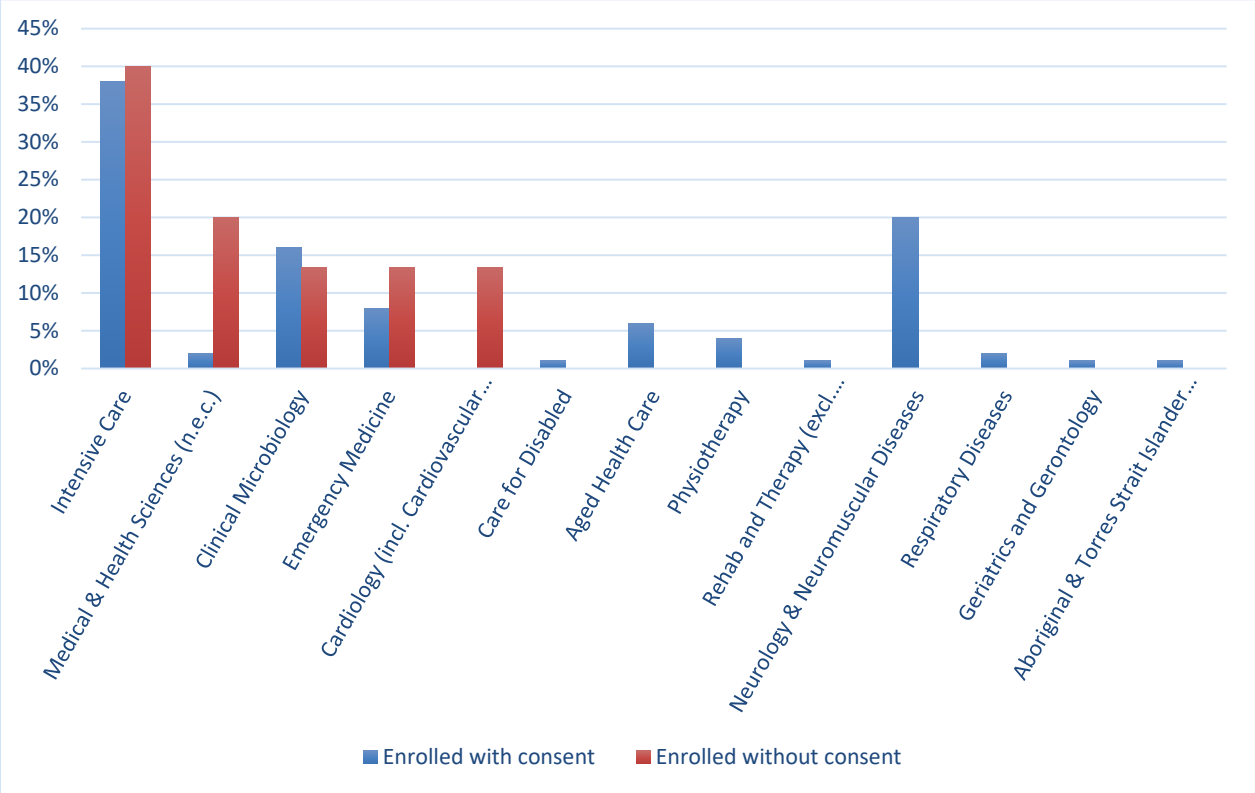

Figure 4 Type of medical research for incapacitated medical research candidates 7 April 2021-6 April 2022

The Minister for Health's report also notes that two-thirds of enrolments occurred within the WA health system at Royal Perth, Fiona Stanley or Sir Charles Gairdner Hospitals.

Several stakeholders from the medical research community submitted that the onerous requirements of the Amendment Act and the impending repeal of section 110ZS have resulted in medical researchers preferring to conduct research that may involve incapacitated people in jurisdictions other than Western Australia:

> *Since the passage of the Amendment* [Act] *in April 2020 the number of participants enrolled in research under its provisions is currently only a small fraction of the number prior to 2018 … One low-risk observational research study involving patients with Critical Illnesses presenting to Emergency Departments that was previously recruiting 8-10 patients a month has slowed to 1-2 per month, with eight in total being recruited under the provisions of Part 9E … prior to 2018, Western Australia had a vibrant and internationally recognised program of research in prehospital care*.[70]
>
> *The Amendment Act has had a massive negative impact on the capacity to conduct ICU research compared with the research undertaken prior. West Australian patients no longer contribute to national and international ICU research projects. This is to the detriment of the care of present and future patients*.[71]
>
> *The amendments to the* [GAA] *have created barriers that put WA researchers at a substantial competitive disadvantage* [compared to] … *the Eastern states and other countries*.[72]

It may be too soon to be able to assess the extent of the Amendment Act's impact on the number of incapacitated persons participating in medical research, given the huge variance in the data from the legislation's first year of operation to now.

Finding 9: The Department finds that there has been a significant increase in the number of incapacitated persons enrolled in medical research according to sections 110ZR and 110ZS of the *Guardianship and Administration Act 1990* (WA) since the *Guardianship and Administration Amendment (Medical Research Act) 2020* (WA) commenced operation.

[70] Australasian College for Emergency Medicine, Submission 13, 18 February 2022, p 3.
[71] Australia and New Zealand Intensive Care Society, Submission 11, 17 February 2022, p 3.
[72] University of Western Australia, School of Medicine, Submission 5, 15 February 2022, p 2.

7 Recommendations of the Standing Committee on Legislation

The Department has considered the recommendations made by the Standing Committee during its inquiry into the Amendment Act and the changes made by the Bill to the GAA.

The recommendations contained in the Standing Committee's report were directed towards particular aspects of the Amendment Act and the Bill, and these issues are discussed in detail in Chapter 5 of this report.

Where relevant and appropriate, the Department has formed a view on each of the recommendations in the Standing Committee's report. Where a particular recommendation of the Standing Committee has not already been considered in this Final Report, the Department has made its own recommendation to the Attorney General in this Chapter.

7.1 Recommendations made regarding the Amendment Act's definitions

The Standing Committee recommended that the definitions in section 110ZO of:

- 'independent medical practitioner' be amended 'to provide clarity to stakeholders'; and
- 'lead researcher' be amended to allow 'nurses, psychiatrists and allied health professionals to be lead researchers'.[73]

The Department sought feedback from stakeholders on the effectiveness and appropriateness of these definitions during this review and has made findings and recommendations: see paragraph 5.1 in this report.

7.2 Recommendations made regarding the independent medical practitioner's determination

The Standing Committee recommended that this review consider the requirement to obtain a determination from an IMP for medical research according to sections 110ZR and 110ZS of the Amendment Act 'after there has been an opportunity to review its implementation in practice': Recommendations 3 and 4 of the Standing Committee report.

The Department consulted extensively with stakeholders on the requirement for an IMP determination and has made findings and recommendations in this regard: see paragraphs 5.1.3 and 5.2.

7.3 Recommendation made regarding the sunset clause

During its inquiry, the Standing Committee explored the effect of the transitional provisions in the Amendment Act and the implications of the delayed repeal of section 110ZS until four years after the Amendment Act is in operation (collectively, the 'sunset clause').

[73] Legislative Council, Standing Committee on Legislation, *Guardianship and Administration Amendment (Medical Research) Bill 2020 and amendments made by the Guardianship and Administration Amendment (Medical Research) Act 2020*, Report 48, 25 November 2020, Recommendations 1 and 2.

The Standing Committee noted that every witness who gave evidence at hearings was in favour of removing the sunset clause.[74] The Department observes that all six stakeholders referred to in relation to this comment are involved in medical research in a professional capacity.[75] The Standing Committee noted that it received one submission in support of the sunset clause from the Mental Health Commission, which submitted that the sunset clause was a 'safeguard against the misuse of section 110ZS'.[76]

The Standing Committee was of the view that, on balance, the sunset clause contained in the Amendment Act should be repealed: Standing Committee Recommendation 5.

Nine stakeholders to this review recommended that the sunset clause affecting section 110ZS of the Amendment Act be repealed:

- Harry Perkins Institute of Medical Research;
- University of Western Australia School of Medicine;
- the Hon Eric Heenan QC;
- Australian and New Zealand Intensive Care Society;
- Dr Stephen Macdonald;
- Australasian College for Emergency Medicine;
- North Metropolitan Health Service;
- EMHS; and
- Australian Medical Association (WA).

No stakeholders to this review submitted that the existence of the sunset clause was of benefit to incapacitated research candidates.

The Department has heard from stakeholders that the sunset clause is causing disadvantage to medical researchers in terms of their ability to obtain funding for longer term projects, particularly from national funding bodies. The Australian Medical Association (WA) summarised the tension between a need to review the Amendment Act, given the urgent circumstances in which it was considered by the Parliament, and the effects on ongoing clinical research:

> *Parliament accepted that the Bill was somewhat expedited as the circumstances of the day demanded. Understandably, certain members stated that they wished they had more time to review the Bill, and in lieu of a satisfactory timeframe for review … a relatively short sunset clause was preferred … However, the* [statutory review] *must consider that the sunset clause has and will affect the ability of medium and long-term research to take place in Western Australia … WA routinely receives disproportionately less medical research funding than other states … Opportunities for research also help*

[74] Legislative Council, Standing Committee on Legislation, *Guardianship and Administration Amendment (Medical Research) Bill 2020 and amendments made by the Guardianship and Administration Amendment (Medical Research) Act 2020*, Report 48, 25 November 2020, pp 72-74.
[75] The Standing Committee's report provides quotes from: the Hon Eric Heenan QC, Australian Medical Association (WA), WA Health Translation Network, Institute for Health Research University of Notre Dame and representatives from the Australasian College for Emergency Medicine.
[76] Legislative Council, Standing Committee on Legislation, *Guardianship and Administration Amendment (Medical Research) Bill 2020 and amendments made by the Guardianship and Administration Amendment (Medical Research) Act 2020*, Report 48, 25 November 2020, p 72.

> *our health system to attract and retain the best doctors in their fields. If this clause remains, it will restrict the funding of vital research in our state and make WA a less attractive location for experienced clinical researchers.*
>
> *There appears to have been a view in Parliament that because any one patient would not receive treatment for any longer than four years, that there was no harm to research programs due to a short sunset clause period … Trials include large numbers of participants – not all will be being treated at the same time or for the same length of time. The bottom line is, in essence, that extended periods of funding are necessary to complete high-quality research.*[77]

Finding 10: The Department finds that the sunset clause that will result in the repeal of section 110ZS of the *Guardianship and Administration Act 1990* (WA) on 8 April 2024 is causing detrimental impacts to the medical research community in a way that is disproportionate to the protection that the legislation offers incapacitated persons.

The Department makes the following recommendation in relation to the sunset clause.

Recommendation 4: The Department recommends the repeal of sections 2(b), 13 and 15 of the *Guardianship and Administration Amendment (Medical Research) Act 2020* (WA).

7.4 Recommendation made regarding the prohibition on electroconvulsive therapy

The Standing Committee recommended that this review consider the current prohibition on using electroconvulsive therapy (ECT) for the purposes of medical research in the GAA, 'with a view to removing the prohibition'.[78]

The Department asked all stakeholders for feedback on this recommendation during consultation for this review, but most stakeholders did not provide a view on the issue. Three stakeholders provided a response, expressing mixed views:

- RUAH/Mental Health Law Centre and the WA Country Health Service support the current prohibition on ECT[79]; but
- Professor Daniel Fatovich advised that 'all aspects of clinical practice should be available to have research conducted' and that 'excluding any aspect from research will not advance patient care in that field'.[80]

ECT is a medical treatment that can only be carried out on children (between 14-17 years) or adult involuntary patients/mentally impaired accused with the approval of the Mental Health Tribunal, according to section 409 of the *Mental Health Act 2014* (WA) (MHA). Further, section 202(2) of the MHA expressly bans the use of ECT as an

[77] Australian Medical Association (WA), Submission 25, 4 March 2022, p 3.
[78] Legislative Council, Standing Committee on Legislation, *Guardianship and Administration Amendment (Medical Research) Bill 2020 and amendments made by the Guardianship and Administration Amendment (Medical Research) Act 2020*, Report 48, 25 November 2020, p 82.
[79] RUAH Legal Services & Mental Health Law Centre, Submission 8, 17 February 2022, p 2; WA Country Health Service, Submission 14, 18 February 2022, p 3.
[80] Harry Perkins Institute of Medical Research and Centre for Clinical Research in Emergency Medicine, Submission 3, 9 February 2022, p 9.

emergency psychiatric treatment, which can otherwise be provided to a person without their consent.

The Amendment Act clarified that ECT can only be performed on a patient if they have the ability to consent to it, and a research decision-maker cannot consent to ECT on the patient's behalf.

The Mental Health Tribunal deals with applications by a patient's psychiatrist to provide ECT treatment according to the MHA, but the only parties to the proceedings are the patient and their psychiatrist, unless the Mental Health Tribunal is of the opinion that another person has a sufficient interest in the matter to be a party. A guardian or other family member could become a party to the Mental Health Tribunal's proceeding and give their views on an application to administer ECT, but only ever in relation to ECT being used as medical treatment, not for medical research.

The decision to authorise the use of ECT on a patient is always made by the Mental Health Tribunal, having regard to the 14 matters set out in section 414 of the MHA, as relevant. The Mental Health Law Centre provides legal representation under the MHA for ECT applications to the Mental Health Tribunal and it submitted that:

> *matters such as ECT approval of involuntary patients requires the additional oversight of a Tribunal. The provision of ECT requires the use of anaesthetic which results in risks to cardiovascular and respiration, in some instances, there is a risk of death to the patient. Commonly, ECT results in memory loss and cognitive difficulties. While it is accepted as a legitimate treatment for certain mental illnesses, it carries higher risks to the patient than other treatment options*.[81]

The Department has considered the views of the three stakeholders above and has observed that the majority of submitters (89 per cent) did not express a view on the prohibition on ECT for medical research and only one stakeholder opposed it. Based on the responses to this review, there does not appear to be a strong sentiment amongst stakeholders in either the medical research community nor amongst patient advocates to alter the current prohibition on ECT.

The Department therefore makes the following finding and recommendation in response to the Standing Committee's recommendation.

Finding 11: The Department finds that the prohibition on the use of electroconvulsive therapy as medical research in section 110ZT of the *Guardianship and Administration Act 1990* (WA) is appropriate and should not be removed.

Recommendation 5: The Department recommends that the prohibition on electroconvulsive therapy being performed on a research candidate in section 110ZT(2) of the *Guardianship and Administration Act 1990* (WA) remain in place.

[81] RUAH/Mental Health Law Centre, Submission 8, 17 February 2022, p 2.

7.5 Recommendation made regarding the use of telehealth as an option to obtain an independent medical practitioner's determination

During its inquiry into the Amendment Act, the Standing Committee considered the difficulties faced by medical researchers in rural and regional areas in complying with the IMP requirement. The Standing Committee heard from the Department of Health that 'the requirement for an [IMP] is extremely problematic for rural communities' and that nothing has 'at this stage' been done to address this problem.[82] Further, the Standing Committee found that the IMP requirement was 'problematic for many rural and regional communities'.[83]

The Standing Committee made a recommendation directed at the Minister for Health regarding the use of telehealth for IMP determinations and requested a response from the Minister about this option.[84] Due to the prorogation of the 40th Parliament, the Minister for Health was not required to provide a response to this recommendation and the Department has confirmed that the Standing Committee did not receive a response.[85]

The Department heard from some stakeholders that the IMP determination 'may be impossible' to obtain in situations involving low resource or regional facilities and can result in some research trials recruiting IMPs from interstate due to a lack of rural site researchers.[86]

> *Two current projects – Healing Right Way and Brain Injury Yarning Circles – involve providing community support for Aboriginal people with brain injury. Many of the relevant rehabilitation specialists and neurologists in WA are involved in the study. Hence, under the new legislation, our most practical option was to recruit the assistance of an IMP from South Australia. Finding an appropriate IMP interstate is possible but then times zones etc become an issue to communication. Because the studies were essentially trialling particular types of community support and would be considered low risk compared to other potentially invasive medical interventions, the requirement for an IMP appeared to be somewhat disproportional.*
> ***Source: Deputy Vice-Chancellor (Research), Edith Cowan University, Submission 9***

Stakeholders did not specifically refer to the use of telehealth during this review. The Department notes that, if telehealth were to be used as an option to fulfil the IMP requirement, it would depend on the nature of the project and research candidates involved, the site and the type of telehealth facilities available. Consideration of these

[82] Legislative Council, Standing Committee on Legislation, *Guardianship and Administration Amendment (Medical Research) Bill 2020 and amendments made by the Guardianship and Administration Amendment (Medical Research) Act 2020*, Report 48, 25 November 2020, p 92, quoting Dr James Williamson, Assistant Director General, Clinical Excellence Division, Department of Health, Answer to Question on Notice 26, 9 October 2020, p 6.
[83] Legislative Council, Standing Committee on Legislation, *Guardianship and Administration Amendment (Medical Research) Bill 2020 and amendments made by the Guardianship and Administration Amendment (Medical Research) Act 2020*, Report 48, 25 November 2020, Finding 31.
[84] The Legislative Council Standing Orders provide that a parliamentary committee may table a report subject to Standing Order 191(3), which requires the government to respond to the recommendations contained in a report within two months of its tabling. The Standing Committee's report did not request a government response when it was tabled on 25 November 2020. Parliament was prorogued shortly afterwards on 7 December 2020 and consideration of the report was removed from the Notice Paper.
[85] Standing Committee on Legislation, Email to the Department of Justice, 13 April 2022.
[86] Ramsay Health Care WA, Submission 15, 18 February 2022 and Harry Perkins Institute of Medical Research and Centre for Clinical Research in Emergency Medicine, Submission 3, 9 February 2022.

issues is beyond the scope of this review and is primarily a matter for the Department of Health.

The Department notes that there is nothing in either the Amendment Act nor the GAA that expressly prohibits the use of telehealth where the circumstances are appropriate and the facilities are available.

The Department does not make any further comment on the use of telehealth as per the Standing Committee's recommendation.

8 Conclusion

The Department notes that work to implement the remaining recommendations of the 2015 Review remains ongoing. The findings and recommendations in this report may inform specific aspects of that review and provide valuable feedback on stakeholder views.

Whilst all of the recommendations made in this report are intended to improve the operation and effectiveness of the Amendment Act, the Department notes that the repeal of the sunset clause that will affect section 110ZS of the Amendment Act has greater urgency due to its ongoing effect on research funding in the State and the imminent deadline of 8 April 2024, which is less than two years away.

Appendix 1 List of stakeholders contacted

1. Aboriginal and Torres Strait Islander Health Practice Board
2. Aboriginal Health Council of WA
3. Association of Australian Medical Research Institutes
4. Australian Alzheimer's Research Foundation
5. Australian Medical Association (WA)
6. Australian Psychological Society
7. Bellberry Limited
8. Black Dog Institute
9. Busselton Population Medical Research Institute
10. Charlies Foundation for Research
11. Child and Adolescent Health Service
12. Consumer and Community Involvement Program
13. Consumers of Mental Health WA
14. Coroner's Court of Western Australia
15. Curtin University
16. Dementia Australia (WA)
17. Development Disability WA
18. Ear Science Institute Australia
19. East Metropolitan Health Service
20. Edith Cowan University
21. Fiona Wood Foundation
22. First Peoples Disability Network
23. Harry Perkins Institute of Medical Research
24. Health and Disability Services Complaints Office
25. Institute for Immunology and Infectious Diseases
26. Institute for Respiratory Health
27. Keogh Institute for Medical Research
28. Kin
29. Linear Clinical Research
30. Lions Eye Institute
31. Living with Disability Research Centre (La Trobe University)
32. Mental Health Advocacy Service
33. Mental Health Commission
34. Mental Health Law Centre
35. Mental Health Matters 2
36. Murdoch University
37. National Centre for Asbestos Related Diseases
38. National Disability Services
39. National Health and Medical Research Council
40. National Mutual Acceptance Committee
41. North Metropolitan Health Service
42. Notre Dame University
43. Office of the Chief Psychiatrist
44. People with Disabilities (WA) Inc.
45. Perron Institute for Neurological and Translational Science
46. Perth Children's Hospital Foundation
47. QIMR Berghofer Medical Research Institute
48. Raine Medical Research Foundation
49. Ramsay Health
50. Rocky Bay
51. Royal Perth Hospital Research Foundation
52. South Metropolitan Health Service
53. Spinnaker Health Research Foundation

54. St John of God Healthcare
55. State Administrative Tribunal
56. Synapse
57. Telethon Kids Institute
58. Uniting Care West
59. University of Western Australia
60. WA Country Health Service
61. Western Australian Association for Mental Health
62. Western Australian Health Translation Network
63. Women and Infants Research Foundation

Appendix 2 List of guided questions provided to stakeholders

No.	Question
1	What has been your experience, if any, with incapacitated persons being involved in medical research prior to the Amendment Act commencing in 2020?
2	What is your opinion on/experience with the current process for enrolling incapacitated persons in medical research, compared with the process prior to the suspension of medical research activity that involved patients who were unable to provide consent?[87]
3	Is the definition of 'medical research' in section 3AA of the Amendment Act appropriate, according to the intention and policy of the legislation? Have there been any unintended consequences as a result of the wording of the definition?
4	**For Researchers**: Has the Amendment Act created any difficulties for your medical research projects? **For Incapacitated Persons or their Decision-Makers**: Has the Amendment Act created any difficulties for you regarding your participation in medical research? **For Advocacy Groups**: Has the Amendment Act created any difficulties for your clients or the community on whose behalf you advocate? **For Regulators/Approvers of Research:** Has the Amendment Act created any difficulties for you in reviewing, approving and monitoring medical research projects? **For all:** Please provide specific examples or (deidentified) case studies for the above if possible.
5	What is your opinion on/experience with how the in-built safeguards in the Amendment Act are working in practice, including but not restricted to the: • requirement in sections 110ZR and 110ZS of the Amendment Act to obtain a determination from an independent medical practitioner before an incapacitated person may be enrolled in medical research; and • requirement for the lead researcher to be a medical practitioner.
6	Do you think there should be different procedures in place for enrolling an incapacitated person in medical research if their lack of capacity is temporary, rather than permanent? Why or why not?
7	Do you think there should be different procedures in place for enrolling a person in medical research, depending on the nature of their incapacity; for example, an unconscious person, a person with serious mental illness, a person with an intellectual disability or a person with dementia? Why or why not?
8	What is your opinion on/experience with the current prohibition on the use of electroconvulsive therapy as medical research in section 110ZT of the Amendment Act?
9	In other Australian jurisdictions, civil and administrative tribunals are significantly involved in the process of approving/assessing medical research where an incapacitated person is involved. Do you think it is desirable to give the State Administrative Tribunal a greater role in this way? Why or why not?

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

10	What is your experience with the process through which users are given assistance to navigate forms/processes in the practical implementation of the Amendment Act's operation?
11	Do you think that there should be statutory penalties for medical researchers who do not follow the procedures outlined in the Amendment Act (for example, Victoria's penalties at paragraph 5.7 Discussion Paper)? Why or why not?

Appendix 3 Submissions received

1. Raine Medical Research Foundation
2. Ear Science Institute Australia
3. Harry Perkins Institute
4. South Metropolitan Health Service
5. UWA School of Medicine
6. People with Disabilities WA Inc.
7. The Hon Eric Heenan QC
8. Ruah Legal Services/Mental Health Law Centre
9. ECU Deputy Vice Chancellor (Research) Professor Caroline Finch
10. Health and Disability Services Complaints Office
11. Australian and New Zealand Intensive Care Society
12. Dr Stephen Macdonald
13. Australasian College of Emergency Medicine
14. WA Country Health Service
15. Ramsay Health Care
16. Telethon Kids Institute
17. Professor Judith Finn
18. North Metropolitan Health Service
19. Developmental Disability WA
20. Child and Adolescent Health Service
21. Silver Chain
22. Consumer and Community Involvement Program and Health Consumers Council
23. East Metropolitan Health Service
24. Office of the Public Advocate
25. Australian Medical Association (WA)
26. State Administrative Tribunal
27. Office of the Deputy Vice-Chancellor, Research, Curtin University

Appendix 4 Extract from *Declaration of Helsinki*

12. Medical research involving human subjects must be conducted only by individuals with the appropriate ethics and scientific education, training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional.

14. Physicians who combine medical research with medical care should involve their patients in research only to the extent that this is justified by its potential preventive, diagnostic or therapeutic value and if the physician has good reason to believe that participation in the research study will not adversely affect the health of the patients who serve as research subjects.

19. Some groups and individuals are particularly vulnerable and may have an increased likelihood of being wronged or of incurring additional harm.

    All vulnerable groups and individuals should receive specifically considered protection.

23. The research protocol must be submitted for consideration, comment, guidance and approval to the concerned research ethics committee before the study begins. This committee must be transparent in its functioning, must be independent of the researcher, the sponsor and any other undue influence and must be duly qualified. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration.

    The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No amendment to the protocol may be made without consideration and approval by the committee. After the end of the study, the researchers must submit a final report to the committee containing a summary of the study's findings and conclusions.

28. For a potential research subject who is incapable of giving informed consent, the physician must seek informed consent from the legally authorised representative. These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the group represented by the potential subject, the research cannot instead be performed with persons capable of providing informed consent, and the research entails only minimal risk and minimal burden.

29. When a potential research subject who is deemed incapable of giving informed consent is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorised representative. The potential subject's dissent should be respected.

30. Research involving subjects who are physically or mentally incapable of giving consent, for example, unconscious patients, may be done only if the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research group. In such circumstances the physician must seek informed consent from the legally authorised representative. If no such 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.

World Medical Association, Declaration of Helsinki, current edition: 2013.

Appendix 5 Medical research legislation in Australia

Victoria	Relevant statute: *Medical Treatment Planning and Decisions Act 2016* (Vic) The Victorian definition of 'medical research procedure' includes 'procedures carried out for the purposes of medical research, excluding visual examinations, measurements and observations. A decision-maker or the incapacitated person themselves may consent to participation in approved medical research. An incapacitated person may be enrolled in approved medical research without consent if a health practitioner believes, on reasonable grounds, that the medical research is necessary as a matter of urgency. There are various conditions applicable to the chosen procedure, such as it being necessary to save the person's life or prevent significant pain or distress. The medical practitioner must forward a signed certificate to the Victorian Public Advocate that confirms the procedure in the Act was correctly followed and they must take reasonable steps to ascertain if the incapacitated person has an advance health directive or decision-maker in place. Failure to take reasonable steps is deemed unprofessional conduct and the medical practitioner may be subject to financial penalties or regulatory action under the *Health Practitioner Regulation National Law (Victoria) Act 2009* (Vic). The incapacitated person's decision-maker or a person who has a special interest may apply to the Victorian Civil and Administrative Tribunal for a review of the medical research decision.
South Australia	Relevant statutes: *Guardianship and Administration Act 1993* (SA) and *Consent to Medical Treatment and Palliative Care Act 1995* (SA) South Australia does not have specific legislation that permits an incapacitated person to be enrolled in medical research. Decisions about medical treatment may be made by a decision-maker. In certain situations, emergency medical treatment may be administered to an incapacitated person without consent, but only if another medical practitioner has personally examined the incapacitated person and prepares a written opinion in support of the treatment.
New South Wales	Relevant statute: *Guardianship Act 1987* (NSW) An incapacitated person may only be enrolled in medical research with the approval of the NSW Civil and Administrative Tribunal. Medical research is referred to in NSW legislation as a 'clinical trial' and involves 'drugs or techniques being tested' and is 'intended to cure or alleviate a particular condition from which the patients suffer.' The tribunal must be satisfied that the clinical trial meets requirements set out in the Act: if so satisfied, it may provide consent for the person, or may allow the person's guardian to provide consent to participate in the trial. There is no explicit provision in NSW legislation that would allow an incapacitated person to be enrolled in urgent medical research without consent being obtained from a decision-maker.
Queensland	Relevant statute: *Guardianship and Administration Act 2000* (Qld) The terms 'special medical research' and 'clinical research' are used to describe medical research, but does not include psychological research or approved clinical research. Only the Queensland Civil and Administrative Tribunal may

	consent to an incapacitated person participating in special medical research or experimental health care, if the tribunal is satisfied of various matters set out in the Act. An incapacitated person may participate in approved clinical research if this is approved by following the legislative order of priority for dealing with a health matter. There is no explicit provision in Queensland legislation that would allow an incapacitated person to be enrolled in urgent medical research without consent being obtained from a decision-maker.
Tasmania	Relevant statute: *Guardianship and Administration Act 1995* (Tas) There is no provision in statute for an incapacitated person to be enrolled in medical research. The Act deals only with administering medical treatment, for which a decision-maker may provide consent on behalf of an incapacitated person. There is no reference to medical research in Tasmanian guardianship legislation.
Northern Territory	Relevant statutes: *Guardianship of Adults Act 2016* (NT) and *Advance Personal Planning Act 2013* (NT) Definition of 'restricted health care' includes health care that is provided for the purposes of medical research. It does not include: non-intrusive examination, observation of activities, collecting information from/about a person or health care prescribed by regulations as not being within the definition. A guardian cannot consent to an incapacitated person being subjected to restricted health care. An incapacitated person may be involved in medical research via an advance consent decision made under statute. A person who is appointed in an advance personal plan may not make decisions about enrolling a person in restricted health matters, which includes special medical research and experimental health care. There is no explicit provision in NT legislation to allow an incapacitated person to be enrolled in urgent medical research without consent being obtained from a decision-maker.
Australian Capital Territory	Relevant statutes: *Powers of Attorney Act 2006* (ACT) and *Guardianship and Management of Property Act 1991* (ACT) A 'medical research power of attorney' may be put in place by which the principal allows their attorney to exercise power in relation to participation in medical research. The medical research may include experimental health care or participation in a clinical trial. An independent doctor must assess the likelihood of the principal regaining their decision-making capacity and must provide their reasons in writing. A guardian may be appointed by the ACT Civil and Administrative Tribunal to provide consent for a research candidate to be enrolled in approved medical research. The appointed guardian has similar powers to provide consent as an attorney does, with the same requirement for an independent doctor to make a written assessment as to the likelihood of the person regaining their decision-making capacity. There is no explicit provision in ACT legislation that would allow an incapacitated person to be enrolled in urgent medical research without consent being obtained from a decision-maker.

Appendix 6 Research Candidates recruited under Part 9E – Medical Research of the Guardianship and Administration Act 1990 (WA) – 7 April 2021 to 6 April 2022

Type of Medical Research	Research Purpose	NHMRC Broad Research Category	NHMRC Field Research	Site
Research Candidates enrolled under 110ZR – Research Decision Maker (n=100)				
Survey, interview or focus group	Educational	Health Services Research	111703 Care for Disabled	Curtin University
Survey, interview or focus group	Educational	Health Services Research	111702 Aged Health Care	Curtin University
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110310 Intensive Care	Sir Charles Gairdner Hospital
Procedure or practice (e.g. physiotherapy, mental health, surgical procedure)	Treatment	Clinical Medicine and Science	110317 Physiotherapy	Royal Perth Hospital
Comparative assessment of health care practices	Treatment	Clinical Medicine and Science	110321 Rehabilitation and Therapy (excl. Physiotherapy)	Royal Perth Hospital
Procedure or practice (e.g. physiotherapy, mental health, surgical procedure)	Treatment	Clinical Medicine and Science	110317 Physiotherapy	Royal Perth Hospital
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110904 Neurology and Neuromuscular Diseases	Emerald Life, aged care facility (formally known as Kimberly Care)
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110904 Neurology and Neuromuscular Diseases	Emerald Life, aged care facility (formally known as Kimberly Care)
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110904 Neurology and Neuromuscular Diseases	Emerald Life, aged care facility (formally known as Kimberly Care)
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110904 Neurology and Neuromuscular Diseases	Emerald Life, aged care facility (formally known as Kimberly Care)
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110904 Neurology and Neuromuscular Diseases	Emerald Life, aged care facility (formally known as Kimberly Care)
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110904 Neurology and Neuromuscular Diseases	Emerald Life, aged care facility (formally known as Kimberly Care)
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110904 Neurology and Neuromuscular Diseases	Carinya on Bicton
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110904 Neurology and Neuromuscular Diseases	Carinya on Bicton
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110904 Neurology and Neuromuscular Diseases	Carinya of Bristol
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110904 Neurology and Neuromuscular Diseases	Carinya of Bristol
Procedure or practice (e.g. physiotherapy, mental health, surgical procedure)	Treatment	Clinical Medicine and Science	110310 Intensive Care	St John of God Midland Public Hospital

Type of Medical Research	Research Purpose	NHMRC Broad Research Category	NHMRC Field Research	Site
Procedure or practice (e.g. physiotherapy, mental health, surgical procedure)	Treatment	Clinical Medicine and Science	110310 Intensive Care	St John of God Midland Public Hospital
Procedure or practice (e.g. physiotherapy, mental health, surgical procedure)	Treatment	Clinical Medicine and Science	110310 Intensive Care	St John of God Midland Public Hospital
Procedure or practice (e.g. physiotherapy, mental health, surgical procedure)	Treatment	Clinical Medicine and Science	110310 Intensive Care	St John of God Midland Public Hospital
Procedure or practice (e.g. physiotherapy, mental health, surgical procedure)	Treatment	Clinical Medicine and Science	110310 Intensive Care	St John of God Midland Public Hospital
Procedure or practice (e.g. physiotherapy, mental health, surgical procedure)	Treatment	Clinical Medicine and Science	110310 Intensive Care	St John of God Midland Public Hospital
Procedure or practice (e.g. physiotherapy, mental health, surgical procedure)	Treatment	Clinical Medicine and Science	110310 Intensive Care	St John of God Midland Public Hospital
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110904 Neurology and Neuromuscular Diseases	Joseph Cook House (Southern Cross Care/Southern Plus)
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110904 Neurology and Neuromuscular Diseases	Margaret Hubery House
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110904 Neurology and Neuromuscular Diseases	Margaret Hubery House
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110904 Neurology and Neuromuscular Diseases	Margaret Hubery House
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110904 Neurology and Neuromuscular Diseases	Margaret Hubery House
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110904 Neurology and Neuromuscular Diseases	Margaret Hubery House
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110904 Neurology and Neuromuscular Diseases	Margaret Hubery House
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110904 Neurology and Neuromuscular Diseases	Margaret Hubery House
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110904 Neurology and Neuromuscular Diseases	Margaret Hubery House
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110904 Neurology and Neuromuscular Diseases	Margaret Hubery House
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110310 Intensive Care	Sir Charles Gairdner Hospital
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110310 Intensive Care	Fiona Stanley Hospital
Use of equipment or device	Treatment	Clinical Medicine and Science	110310 Intensive Care	Royal Perth Hospital
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110203 Respiratory Diseases	St John of God Midland Public Hospital

Type of Medical Research	Research Purpose	NHMRC Broad Research Category	NHMRC Field Research	Site
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110203 Respiratory Diseases	St John of God Midland Public Hospital
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110310 Intensive Care	Sir Charles Gairdner Hospital
Comparative assessment of health care practices	Treatment	Clinical Medicine and Science	119999 Medical and Health Sciences not elsewhere classified	Fiona Stanley Hospital
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110310 Intensive Care	Fiona Stanley Hospital
Use of equipment or device	Prevention	Public Health	111702 Aged Health Care	In the community
Collection of samples from individuals (e.g. blood, tissues, fluids)	Treatment	Clinical Medicine and Science	110303 Clinical Microbiology	Fiona Stanley Hospital
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110310 Intensive Care	Sir Charles Gairdner Hospital
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110310 Intensive Care	Sir Charles Gairdner Hospital
Use of equipment or device	Treatment	Clinical Medicine and Science	110310 Intensive Care	Royal Perth Hospital
Use of equipment or device	Treatment	Clinical Medicine and Science	110310 Intensive Care	Royal Perth Hospital
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110310 Intensive Care	Sir Charles Gairdner Hospital
Collection of samples from individuals (e.g. blood, tissues, fluids)	Diagnosis	Clinical Medicine and Science	110303 Clinical Microbiology	Fiona Stanley Hospital
Collection of samples from individuals (e.g. blood, tissues, fluids)	Treatment	Clinical Medicine and Science	110303 Clinical Microbiology	Fiona Stanley Hospital
Collection of samples from individuals (e.g. blood, tissues, fluids)	Diagnosis	Clinical Medicine and Science	110305 Emergency Medicine	Royal Perth Hospital
Use of equipment or device	Treatment	Clinical Medicine and Science	110310 Intensive Care	Royal Perth Hospital
Procedure or practice (e.g. physiotherapy, mental health, surgical procedure)	Treatment	Clinical Medicine and Science	110317 Physiotherapy	Royal Perth Hospital
Procedure or practice (e.g. physiotherapy, mental health, surgical procedure)	Treatment	Clinical Medicine and Science	110317 Physiotherapy	Royal Perth Hospital
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110310 Intensive Care	Royal Perth Hospital
Collection of samples from individuals (e.g. blood, tissues, fluids)	Treatment	Clinical Medicine and Science	110303 Clinical Microbiology	Fiona Stanley Hospital
Use of equipment or device	Treatment	Clinical Medicine and Science	110310 Intensive Care	Royal Perth Hospital
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110310 Intensive Care	Sir Charles Gairdner Hospital
Collection of samples from individuals (e.g. blood, tissues, fluids)	Treatment	Clinical Medicine and Science	110303 Clinical Microbiology	Fiona Stanley Hospital

Type of Medical Research	Research Purpose	NHMRC Broad Research Category	NHMRC Field Research	Site
Use of equipment or device	Treatment	Clinical Medicine and Science	110310 Intensive Care	Royal Perth Hospital
Collection of samples from individuals (e.g. blood, tissues, fluids)	Treatment	Clinical Medicine and Science	110303 Clinical Microbiology	Fiona Stanley Hospital
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110310 Intensive Care	Royal Perth Hospital
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110310 Intensive Care	Sir Charles Gairdner Hospital
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110310 Intensive Care	Royal Perth Hospital
Collection of samples from individuals (e.g. blood, tissues, fluids)	Treatment	Clinical Medicine and Science	110303 Clinical Microbiology	Fiona Stanley Hospital
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110310 Intensive Care	Royal Perth Hospital
Collection of samples from individuals (e.g. blood, tissues, fluids)	Treatment	Clinical Medicine and Science	110303 Clinical Microbiology	Fiona Stanley Hospital
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110310 Intensive Care	Fiona Stanley Hospital
Collection of samples from individuals (e.g. blood, tissues, fluids)	Treatment	Clinical Medicine and Science	110305 Emergency Medicine	Royal Perth Hospital
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110310 Intensive Care	Royal Perth Hospital
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110310 Intensive Care	Royal Perth Hospital
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110310 Intensive Care	Royal Perth Hospital
Collection of samples from individuals (e.g. blood, tissues, fluids)	Diagnosis	Clinical Medicine and Science	110305 Emergency Medicine	Royal Perth Hospital
Collection of samples from individuals (e.g. blood, tissues, fluids)	Diagnosis	Clinical Medicine and Science	110305 Emergency Medicine	Royal Perth Hospital
Collection of samples from individuals (e.g. blood, tissues, fluids)	Treatment	Clinical Medicine and Science	110303 Clinical Microbiology	Fiona Stanley Hospital
Collection of samples from individuals (e.g. blood, tissues, fluids)	Treatment	Clinical Medicine and Science	110303 Clinical Microbiology	Fiona Stanley Hospital
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110310 Intensive Care	Sir Charles Gairdner Hospital
Use of equipment or device	Prevention	Public Health	111702 Aged Health Care	In the community
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110310 Intensive Care	Royal Perth Hospital

Type of Medical Research	Research Purpose	NHMRC Broad Research Category	NHMRC Field Research	Site
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110310 Intensive Care	Royal Perth Hospital
Collection of samples from individuals (e.g. blood, tissues, fluids)	Diagnosis	Clinical Medicine and Science	110305 Emergency Medicine	Royal Perth Hospital
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110310 Intensive Care	Sir Charles Gairdner Hospital
Use of equipment or device	Prevention	Public Health	111702 Aged Health Care	In the community
Use of equipment or device	Prevention	Health Services Research	110308 Geriatrics and Gerontology	Hollywood Private Hospital
Collection of samples from individuals (e.g. blood, tissues, fluids)	Diagnosis	Clinical Medicine and Science	110305 Emergency Medicine	Royal Perth Hospital
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110310 Intensive Care	Royal Perth Hospital
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110310 Intensive Care	Fiona Stanley Hospital
Comparative assessment of health care practices	Treatment	Clinical Medicine and Science	119999 Medical and Health Sciences not elsewhere classified	Fiona Stanley Hospital
Collection of samples from individuals (e.g. blood, tissues, fluids)	Treatment	Clinical Medicine and Science	110303 Clinical Microbiology	Fiona Stanley Hospital
Collection of samples from individuals (e.g. blood, tissues, fluids)	Treatment	Clinical Medicine and Science	110303 Clinical Microbiology	Fiona Stanley Hospital
Collection of samples from individuals (e.g. blood, tissues, fluids)	Treatment	Clinical Medicine and Science	110303 Clinical Microbiology	Fiona Stanley Hospital
Collection of samples from individuals (e.g. blood, tissues, fluids)	Treatment	Clinical Medicine and Science	110303 Clinical Microbiology	Fiona Stanley Hospital
Use of equipment or device	Prevention	Public Health	111702 Aged Health Care	In the community
Procedure or practice (e.g. physiotherapy, mental health, surgical procedure)	Treatment	Health Services Research	111701 Aboriginal and Torres Strait Islander Health	Champion Centre, 76 Champion Dr, Seville Grove WA 6112 (community centre)
Collection of samples from individuals (e.g. blood, tissues, fluids)	Treatment	Clinical Medicine and Science	110303 Clinical Microbiology	Fiona Stanley Hospital
Collection of samples from individuals (e.g. blood, tissues, fluids)	Diagnosis	Clinical Medicine and Science	110305 Emergency Medicine	Royal Perth Hospital
Collection of samples from individuals (e.g. blood, tissues, fluids)	Diagnosis	Clinical Medicine and Science	110305 Emergency Medicine	Royal Perth Hospital
Collection of samples from individuals (e.g. blood, tissues, fluids)	Treatment	Clinical Medicine and Science	110303 Clinical Microbiology	Fiona Stanley Hospital
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110310 Intensive Care	Royal Perth Hospital
Use of equipment or device	Prevention	Public Health	111702 Aged Health Care	In the community

Type of Medical Research	Research Purpose	NHMRC Broad Research Category	NHMRC Field Research	Site
Research Candidates enrolled under 110ZS – Urgent Medical Research (n=15)				
Use of equipment or device	Treatment	Clinical Medicine and Science	110310 Intensive Care	Royal Perth Hospital
Use of equipment or device	Treatment	Clinical Medicine and Science	110310 Intensive Care	Royal Perth Hospital
Use of equipment or device	Treatment	Clinical Medicine and Science	110201 Cariology (incl. Cardiovascular Diseases)	Fiona Stanley Hospital
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110310 Intensive Care	Royal Perth Hospital
Collection of samples from individuals (e.g. blood, tissues, fluids)	Diagnosis	Clinical Medicine and Science	110305 Emergency Medicine	Royal Perth Hospital
Comparative assessment of health care practices	Treatment	Clinical Medicine and Science	110201 Cariology (incl. Cardiovascular Diseases)	Fiona Stanley Hospital
Comparative assessment of health care practices	Treatment	Clinical Medicine and Science	119999 Medical and Health Sciences not elsewhere classified	Fiona Stanley Hospital
Collection of samples from individuals (e.g. blood, tissues, fluids)	Diagnosis	Clinical Medicine and Science	110305 Emergency Medicine	Royal Perth Hospital
Comparative assessment of health care practices	Treatment	Clinical Medicine and Science	119999 Medical and Health Sciences not elsewhere classified	Fiona Stanley Hospital
Collection of samples from individuals (e.g. blood, tissues, fluids)	Treatment	Clinical Medicine and Science	110303 Clinical Microbiology	Fiona Stanley Hospital
Administration of pharmaceuticals or placebos	Treatment	Clinical Medicine and Science	110310 Intensive Care	Royal Perth Hospital
Use of equipment or device	Treatment	Clinical Medicine and Science	110310 Intensive Care	Royal Perth Hospital
Use of equipment or device	Treatment	Clinical Medicine and Science	110310 Intensive Care	Royal Perth Hospital
Collection of samples from individuals (e.g. blood, tissues, fluids)	Treatment	Clinical Medicine and Science	110303 Clinical Microbiology	Fiona Stanley Hospital
Comparative assessment of health care practices	Treatment	Clinical Medicine and Science	119999 Medical and Health Sciences not elsewhere classified	Fiona Stanley Hospital