Research Candidates recruited under Part 9E – Medical Research of the Guardianship and Administration Act 1990

Summary Report to Parliament

Reporting Period: 7 April 2021 to 6 April 2022

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Introduction

Purpose

This report fulfils the requirement for the Minister for Health (Minister) to report to Parliament on medical research carried out under Part 9E – Medical Research of the Guardianship and Administration Act 1990 (Act), as per section 110ZZD of the Act.

Background

Part 9E of the Act has been in effect since 7 April 2020, following the passage of the Guardianship and Administration Amendment (Medical Research) Bill 2020 (Amendment Bill) on 6 April 2020.

The amendments to the Act provide pathways for the participation of adults who do not have the capacity to consent to their participation in medical research. These pathways are:

- Medical Research with consent of Research Decision Maker (section 110ZR); and
- Urgent Medical Research without consent (section 110ZS).

Reporting Obligations under the Act

Section 110ZZC of the Act requires that researchers provide a written notice to the Minister, in a form approved by the Minister, of all medical research conducted in relation to a research candidate under Part 9E of the Act. The Department of Health receives these notices from researchers on behalf of the Minister.

Section 110ZZD of the Act subsequently requires the Minister to report to Parliament on medical research carried out under Part 9E of the Act on an annual basis, as soon as practicable after each anniversary of the day on which the Bill came into operation.

Scope of this Report

This report provides Parliament with an update on the status of medical research carried out in relation to research candidates under Part 9E of the Act from 7 April 2021 to 6 April 2022. Specifically, this report addresses section 110ZD of the Act:

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

- (1) The Health Minister must, as soon as practicable after each anniversary of the day on which the *Guardianship and Administration Amendment (Medical Research) Act 2020* section 12 comes into operation, report to Parliament on the following in relation to the year to which the report relates
 - (a) the number of research candidates who have participated in medical research under this Part;
 - (b) whether the medical research is carried out pursuant to
 - (i) a research decision by the research decision-maker for the candidate under section 110ZR; or
 - (ii) an urgent medical research decision;
 - (c) the type of medical research the researcher is conducting in relation to the candidate;
 - (d) the purpose of the medical research;
 - (e) any other matter relating to the operation of this Part that the Health Minister considers appropriate.
- (2) The report under subsection (1)
 - (a) may include statistics or other general information derived from a written notice the Health Minister receives under section 110ZZC; but

(b) must not include personal information.

A separate Report has also been provided to the Minister which includes some additional details about the research candidates enrolled and research projects conducted under the Act. The additional details are removed in this Summary Report for Parliament to prevent potential reidentification of research candidates, noting that the report provided to Parliament must not include personal information under section 110ZD(2)(b).

This report draws only brief high-level conclusions based on the number of enrolments reported. It is not within the scope of this report to comprehensively review or comment on the operation and effectiveness of Part 9E. It is expected that these will be addressed by the Attorney General's statutory review which is currently underway.

Report Preparation

This report has been collated based on the notifications submitted to the Department from researchers in fulfilment of section 110ZZC of the Act. It includes, to the best of the Department's knowledge, information about all research carried out under Part 9E of the Act. However, it should not be assumed that this report outlines all research which has occurred under Part 9E of the Act as the Department is reliant on researchers completing the notification form within 15 calendar days of enrolling a research participant.

Collation of information and data analyses were conducted by the Research and Innovation Office at the Department. Discussion and interpretation of findings were informed by feedback provided to the Department from researchers, Health Service Providers and private/university human research ethics officers over the past 12 months.

Report on Medical Research carried out under Part 9E

Appendix A presents the information required under section 110ZZD for the Minister to report to Parliament on the medical research carried out under Part 9E of the Act.

The Department received notifications from researchers of 115 research candidates who were enrolled under Part 9E of the Act during the reporting period. Of these, 100 (87%) research candidates were enrolled under section 110ZR 'Medical Research with consent of Research Decision Maker', with the remaining 15 (13%) research candidates enrolled under section 110ZS 'Urgent Medical Research without consent'.

Research candidates were enrolled across 13 sites. Two-thirds (67%) of enrolments occurred within the WA health system at Royal Perth, Fiona Stanley or Sir Charles Gairdner Hospital. Other enrolment sites included public-private and private hospitals, a university, aged care centres and the general community.

The number of research candidates enrolled under Part 9E has substantially increased in the 2021/22 reporting period (n=115), compared to the 2020/21 reporting period (n=9), indicating that Part 9E is generally enabling the participation of incapacitated adults in medical research.

Appendix A: Research Candidates enrolled under Part 9E – Medical Research of the Guardianship and Administration Act 1990

Reporting period: 7 April 2021 – 6 April 2022. Information as required under section 110ZZD of the Act.

| Type of Medical Research | Research Purpose | NHMRC Broad Research Category | NHMRC Field Research | Site |
|---|---------------------|------------------------------------|---|--|
| | Research Cand | idates enrolled under 110ZR – Rese | earch 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 |
| 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 |
| 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 |

| ollection 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 |
| ollection 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 |
| Use of equipment or device | Treatment | Clinical Medicine and Science | 110310 Intensive Care | Royal Perth Hospital |
| ollection 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 |

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|--|------------|-------------------------------|---|-------------------------------|
| 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 |
| 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 |
| | Research Can | didates enrolled under 110ZS – Urg | ent 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 |

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