

Guide to WA legislation relating to adults who do not have the capacity to consent to their participation in health and medical research

Western Australia

This guide provides an outline of the requirements and legislative pathways under the *Guardianship and Administration Act 1990 (Act)* in the State of Western Australia, for the participation of adults who do not have the capacity to consent in health and medical research under Part 9E of the Act.

Disclaimer: The information provided in this guide is an overview of the relevant legal requirements and is of a general nature only. The guide does not provide legal advice in relation to any specific human research project or clinical trial. You should obtain legal or other professional advice appropriate to your circumstances before acting or relying on any matter referred to in this guide.

The information in this guide is adapted from the WA Department of Health (Department) *Guidance Document: Involving Incapacitated Adults in Health and Medical Research*. The most recent version of the Guidance Document should always be accessed from the Research Governance Service (RGS) website [Documents Templates page](#).

Relevant legislation

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

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

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

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

Scope of Medical Research

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

- means research conducted with or about individuals, or their data or tissue, in the field of medicine or health; and
- includes an activity undertaken for the purposes of that research.

Updated December 2020.
Please refer to the [RGS website](#) for the most current information.

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

Type of Research

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

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

Research Activity

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

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

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

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

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

Roles and Responsibilities

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

Research Candidate

A Research Candidate is an individual:

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

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

Research Decision-Maker

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

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

Independent Medical Practitioner

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

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- currently involved in the treatment of the Research Candidate under Part 9E of the Act¹;
- involved in or connected to the Medical Research²;
- a spouse, partner or family member of the person; or
- a member of the HREC that approved the research.

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

- the likelihood of the Research Candidate regaining the ability to make reasonable judgements within the timeframe for the research approved by a HREC³;
- whether the Research Candidate's participation in the research will be in accordance with the risk categories set out in the Act (refer below); and
- whether the Research Candidate's participation is in their best interests or not adverse to their interests⁴.

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

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

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

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

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

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

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

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

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

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

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

Lead Researcher

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

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

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

If a Research Candidate regains the ability to make reasonable judgments in respect to Medical Research while participating in the Medical Research, or a RDM refuses consent or decides that the Research Candidate will no longer participate in the Medical Research, the Lead Researcher is responsible for ensuring that the Medical Research is discontinued as soon as safely practicable and not recommenced unless a Research Decision is made by the Candidate, or the RDM consents to participation in the research.

Researcher

Researcher means -

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

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

Enrolment Pathways

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

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

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Please refer to the [RGS website](#) for the most current information.

Medical Research with consent of Research Decision-Maker

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

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

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

Urgent Medical Research without consent

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

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

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

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

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

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

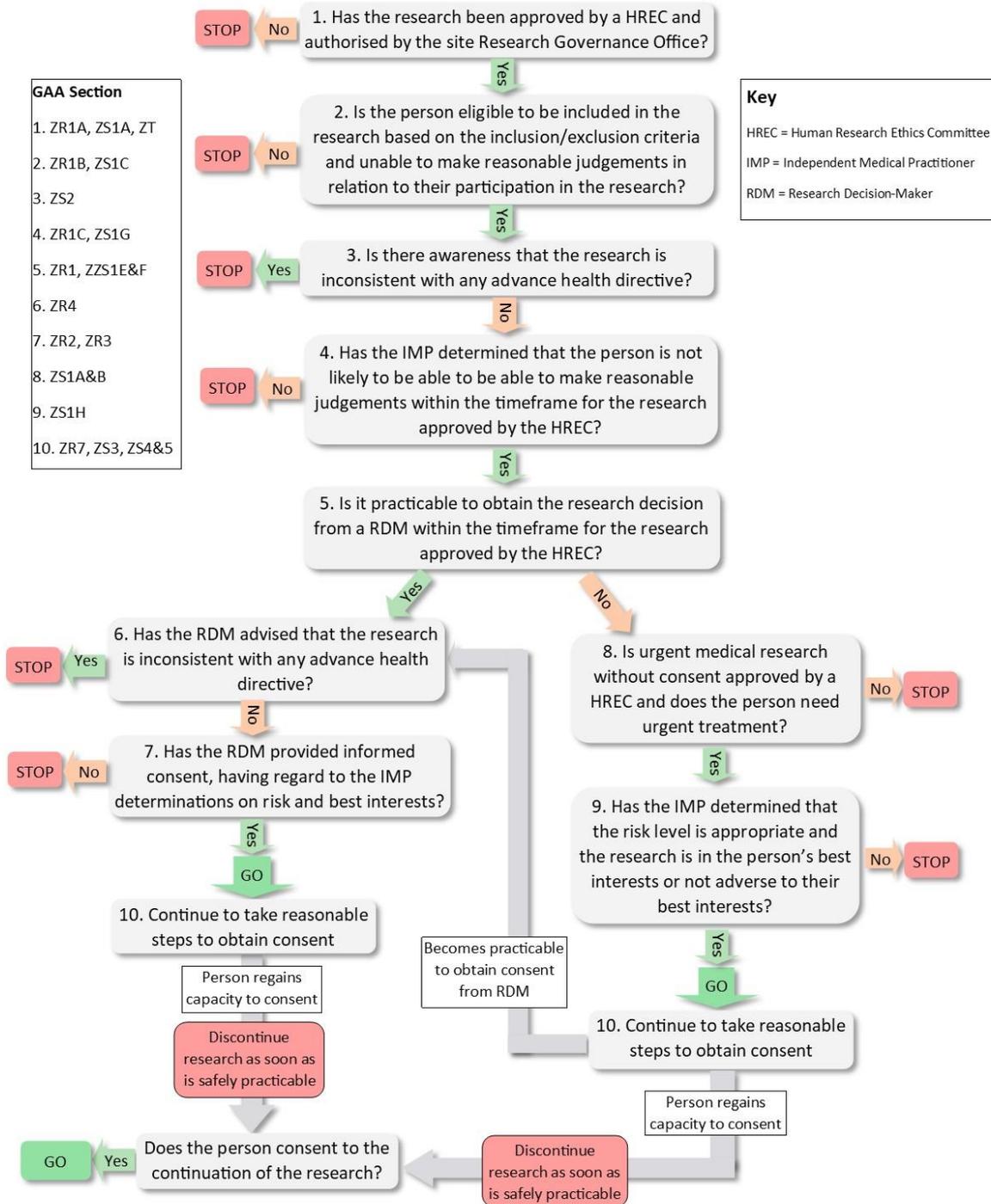
A Researcher must not make an Urgent Medical Research Decision if the Researcher is aware that the participation is inconsistent with any advance health directive in operation in respect of the Candidate, or a RDM Research Decision already exists.

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

Flowchart

Guardianship and Administration Act 1990: Enrolling Incapacitated Adults in Health and Medical Research

Guide for Researchers



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Please refer to the [RGS website](#) for the most current information.

Documentation Requirements

GAA Medical Research Decision Form

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

Two forms are available:

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

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

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

GAA Medical Research Decision Report

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

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

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

Checklist of matters for an HREC to consider

- Does the research involve adults who may have an impaired capacity to consent to their participation in the research?
- Does the application describe the 'timeframe' within which a Research Candidate must be enrolled in the research for the validity of the research to be maintained?
- Does the application describe the process for obtaining an Independent Medical Practitioner (IMP) determination regarding the Research Candidate's participation in the research?
- Does the application describe the process for obtaining consent from the Research Decision Maker (RDM), including how the IMP determination will be provided to the RDM?
- Does the application describe the steps that will be taken to determine when/if the Research Candidate regains capacity?
- When/if the Research Candidate regains capacity, does the application explain how the research will be discontinued as soon as safely practicable, and how the Research Candidate's consent to continue participation in the research will be sought?
- Does the application clearly indicate if approval is being sought to recruit Research Candidates via the 'Urgent Medical Research without consent' pathway?
- If approval to recruit via the 'Urgent Medical Research without consent' pathway is being sought:
 - Does the application justify the circumstances in which this enrolment pathway may be required?
 - Does the application describe the process for enrolling Research Candidates into 'Urgent Medical Research without consent', including how the IMP determination will be provided to the researcher?
 - Does the application describe the steps that will be taken to obtain a Research Decision from the RDM?
 - If the RDM does not consent to the Research Candidate's continuation in the research, does the application describe how the research will be discontinued as soon as safely practicable?
- Having considered the above, does the HREC need to seek further advice from the researcher?