# GAA Medical Research Decision Form – Urgent Medical Research

**Patient label/details**

This form must be used to document the decision when enrolling an incapable person in health and medical research with the consent of a research decision-maker; OR without consent if approved by a HREC.

Decisions must comply with the[*Guardianship and Administration Act 1990 (GAA)*](https://www.legislation.wa.gov.au/legislation/statutes.nsf/law_a336.html)***.***

Refer to the Department of Health Research Governance Service (RGS) for [guidance](https://rgs.health.wa.gov.au/Documents/GAA%20Medical%20Research%20Guidance%20Document.pdf) and [forms](https://rgs.health.wa.gov.au/Pages/Document-Templates.aspx).

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| **RESEARCH PROJECT DETAILS** |
| **Title** |  |
| **Project Reference No.***WA public health: use RGS No. Other: use HREC Reference No.*  |  |
| **Protocol No.** |  |
| **HREC**  |  |
| **Site** |  |
| **Site Lead Researcher\****\*Medical practitioner who has sole or joint overall responsibility for conducting the research* |  |
| **Researcher\****\*A lead researcher or an individual who conducts, or assists with the conduct of, medical research* |  |
| **Independent Medical Practitioner (IMP)** |  |

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| **RESEARCHER DECLARATION** |
| **1.** | The research candidate is eligible to be included in this research based on the inclusion/exclusion criteria and unable to make reasonable judgements in relation to their participation in the research.  | [ ]  |
| **2.**  | I am not aware of, and would not reasonably be expected to be aware of, any current advance health directive that is inconsistent with this research.  | [ ]  |

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| **INDEPENDENT MEDICAL PRACTITIONER (IMP) DECLARATION**  |
| **3.** | I am not currently involved in treatment of the research candidate which is related to this research. | [ ]  |
| **4.** | I am not involved in, nor connected to, the research, other than having a professional interest in the area of the research. Note: Investigators on this research project and persons who have vested interests in whether the research candidate is or is not enrolled in the research would not meet this criterion. | [ ]  |
| **5.** | I am not a spouse, de facto partner parent, grandparent, sibling, child or grandchild of the research candidate. | [ ]  |
| **6.** | I am not a member of the HREC that approved the research. | [ ]  |

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| **INDEPENDENT MEDICAL PRACTITIONER (IMP)** **DETERMINATION**   |
| **7.** | The research candidate is **not likely to regain the ability** to be able to make reasonable judgements within the timeframe for the research approved by the HREC. The IMP must take into account:1. the research candidate’s medical, mental and physical condition;
2. the severity of the research candidate’s condition and the prognosis for the candidate;
3. the current stage of treatment and care required for the research candidate;
4. any other circumstances relevant to the research candidate; and
5. the nature of, and the timeframe approved by the HREC for, the medical research in which the research candidate is to participate.
 | [ ]  |
| **Reasons: *(please address each point and explain the resulting determination)*** |
| **8.** | The research candidate’s participation in the research will be in accordance with one of following **risk** categories: 1. will only involve observing the candidate or carrying out another non-invasive examination, treatment or procedure; or
2. if (i) does not apply - will not involve any known substantial risks to the candidate; or
3. if (i) and (ii) do not apply and there is an existing treatment available to the candidate - will not involve any known substantial risks to the candidate greater than the risks associated with that treatment; or
4. if (i), (ii) and (iii) do not apply - will not involve substantial risks to the candidate greater than if the candidate did not participate in the research.

The IMP must take into account:1. whether the research candidate’s participation in the research will involve any known substantial risks to the candidate;
2. whether there is an existing treatment available to the research candidate;
3. if there is an existing treatment available to the research candidate –
	* whether there are substantial risks to the candidate involved in the existing treatment available to the candidate;
	* if there are substantial risks involved in the existing treatment – whether those risks are greater than the risks involved in participating in the research;
4. if there is no existing treatment available – whether the risks involved in participating in the research are greater than not participating in the research.
 | [ ]  |
| **Reasons: *(please address each point and explain the resulting determination including the risk category)*** |
| **9.** | Participation in this research is in the **best interests** of the research candidate or will not be adverse to the interests of the research candidate.The IMP must take into account:1. the wishes of the person (to the extent they can be ascertained) as the paramount consideration;
2. the likely effects of research participation, including:
	* the existence, likelihood and severity of any potential risks;
	* whether those risks are justified by any likely benefits of the research to the candidate or to the broader community;
3. any consequences for the research candidate if they are not involved in the research; and
4. any alternative treatments available to the research candidate.
 | [ ]  |
| **Reasons: *(please address each point and explain the resulting determination)*** |
| **10.** | I have an appropriate understanding of the research protocol (including the timeframe for the research approved by the HREC) and the circumstances relevant to the research candidate to make the above determinations. | [ ]  |
| **11.** | It was not practicable to provide the determinations in writing before the research commenced therefore the determinations were provided orally.Note: Oral determinations (in lieu of written determinations) should only apply if the research candidate is being enrolled into Urgent Medical Research without consent.  | [ ]  |
| **Date of Determination**  |  | **Time of Determination** |  |
| **IMP Full Name** |  |
| **IMP Signature** |  | **Date** |  |

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| **RESEARCHER ACTIONS** |
| **12.** | It has been determined by the IMP that the research candidate is not likely to be able to make reasonable judgements within the timeframe for the research approved by the HREC (point 7). | [ ]  |
| **13.** | ***Please select either (a) or (b):*****(a) Medical Research with consent of research decision-maker:** I confirm that the IMP determinations regarding risk (point 8) and best interests (point 9) have been provided to the RDM and they understand the determinations.The RDM has confirmed that the research is not inconsistent with any current advance health directive.The RDM has provided informed consent for enrolment of the research candidate in the research.***OR*** | [ ]  |
| **(b) Urgent Medical Research without consent:**I have enrolled the research candidate without consent and confirm that:1. this enrolment pathway has been approved by the HREC;
2. the candidate requires urgent treatment;
3. there is no existing research decision for the research candidate;
4. it is not practicable to obtain a research decision from an RDM within the timeframe for the research approved by the HREC; and
5. the IMP has determined that the research is in an appropriate risk category (point 8) and is in the candidate’s best interests or not adverse to their best interests (point 9).

Urgent treatment means treatment urgently needed by a patient -(a) to save the patient’s life; or(b) to prevent serious damage to the patient’s health; or(c) to prevent the patient from suffering or continuing to suffer significant pain or distress. | [ ]  |
| **14.** | I will ensure that written notice is provided to the Department of Health within 15 calendar days using the Department of Health report template (insert hyperlink), to meet my obligation to report to the Minister for Health of any enrolments under the GAA. | [ ]  |
| **Participant Study ID *(mandatory)*:** |  |
| **Comments *(optional):*** |  |
| **Researcher Full Name** |  |
| **Researcher Signature** |  | **Date** |  |

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| **SITE LEAD RESEARCHER RESPONSIBILITIES** |
| **15.** | **(a) Medical research with consent of research decision-maker:**If the RDM withdraws consent or the person regains capacity, I will ensure that the research is discontinued as soon as is safely practicable; and the research is not recommenced unless consent is provided to continue in the research. | [ ]  |
| **(b) Urgent Medical Research without consent:**I will ensure that reasonable steps are taken to obtain a research decision for continued participation from an RDM, if the person has not regained capacity. If the RDM does not provide consent or the person regains capacity, I will ensure that the research is discontinued as soon as is safely practicable; and the research is not recommenced unless consent is provided to continue in the research. | **☐** |
| **Site Lead Researcher Full Name** |  |
| **Site Lead Researcher****Signature** |  | **Date** |  |