Government of Western Australia
Department of Health

# WA Specific Module (WASM)

Version: 1.0

## 1. Project Details

This module must be completed in conjunction with the Human Research Ethics Application (HREA) for health and medical research projects conducted within WA or intending to access WA participants, tissue or data. If the WA specific questions have not been answered to the satisfaction of the reviewing Human Research Ethics Committee (HREC) or are not made available to the accepting WA institution for confirmation then the project will not be able to be conducted at a WA Institution.

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| **1.1 PRN:** | RGS0000002218 |
| **1.2 Project title:** | Example of the WASM with all questions shown |
| **1.3 Protocol number:** | na |
| **1.4 Protocol version number:** | 1.00 |
| **1.5 Protocol version date:** | 06/01/2021 |

## 2. Research Requiring Specific Ethical Consideration

**2.1 Indicate whether the research project involves:**

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| **2.1.1 Adults with impaired capacity or who are unable to consent:** | Yes |
| **2.1.2 The use of confidential information from the Department of Health data collections, data linkage and/or WA Health biobanks:** | Yes |
| **2.1.3 Aboriginal people:** | Yes |
| **2.1.4 Children and/or young people (i.e. < 18 years):** | Yes |
| **2.1.5 The use of human tissue from persons who were the subject of a post mortem:** | Yes |
| **2.1.6 A requirement to address Catholic Health Australia's Code of Ethical Standards:** | Yes |
| **2.1.7 Western Australian schools:** | Yes |

## 3. Adults without the capacity to consent to their participation in health and medical research

Where an adult is not capable of providing informed consent to participate in health and medical research, researchers and Human Research Ethics Committees (HRECs) should ensure that recruitment is in accordance with the ethical requirements set out in the *National Statement on Ethical Conduct in Human Research, 2007* (updated 2018) (National Statement).

The National Statement, Chapter 4.4, references the ethical requirements for research involving people highly dependent on medical care who may be unable to give consent. The National Statement, Chapter 4.5, references the ethical requirements for research involving people with a cognitive impairment, an intellectual disability or a mental illness.

Additionally, in every instance, relevant jurisdictional laws must be taken into account.

In WA, the
*Guardianship and Administration Act 1990*
(Act) was amended on 7 April 2020 to provide pathways for the participation of adults who do not have the capacity to consent to participate in health and medical research. The relevant section is Part 9E.

There are two potential enrolment pathways:

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

To ensure accurate and informed completion of the below sections, researchers are required to consult the WA Department of Health *Guidance Document: Involving Incapacitated Adults in Health and Medical Research*
regarding the requirements of the Act and its application.

Please note that for questions directly relating to the Act, the terminology used has been aligned with the legislation. E.g. "Research Candidate" is used as an equivalent of "potential participant".

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| **3.1 Indicate the condition, disease or general reasons why Research Candidates may be unable to make reasonable judgements in respect of their participation in the research.** | Insert text here |
| **3.2 (a) Describe the '*timeframe*' within which a Research Candidate must be enrolled in the research for the validity of the research to be maintained. Note: The 'timeframe' may not necessarily be defined in minutes/hours/days but may be an event occurring, or milestone being reached.**<br><br>**(b) Describe the process for obtaining an Independent Medical Practitioner (IMP) determination on the following:**<br>**(i) Likelihood of candidate being able to make reasonable judgements within the 'timeframe' approved by the HREC**<br>**(ii) The risk applicable to the candidate's participation in the research**<br>**(iii) Whether the research is in the best interests of the candidate or will not be adverse to the interests of the candidate.**<br><br>**Please label each section of your response as addressing points (a), (b)(i), (b)(ii) or (b)(iii), as applicable.** | Separate paragraphs to answer the multiple questions in this section, add text after identifying which part of the question you are addressing example below<br>**(a)** then text<br>**(b)(i)** then text<br>**(b)(ii)** then text<br>**(b)(iii)** then text |
| **3.3 Describe the process for obtaining consent from the Research Decision-Maker.**<br><br>**This must include how the IMP determination in 3.2 (b) (ii) and (iii) will be provided to the Research Decision-Maker.** | Insert text here |
| **3.4 (a) What steps will be taken to determine when/if the Research Candidate regains capacity?**<br><br>**(b) When/if the Research Candidate regains the capacity to consent:**<br>**(i) How will the research be discontinued as soon as is safely practicable?**<br>**(ii) How will the Research Candidate's consent to continue to participate in the research be sought?**<br><br>**Please label each section of your response as addressing points (a), (b)(i) or (b)(ii), as applicable.** | Separate paragraphs to answer the multiple questions in this section, add text after identifying which part of the question you are addressing example below<br>**(a)** then text<br>**(b)(i)** then text<br>**(b)(ii)** then text |
| **3.5 Is specific approval being sought to recruit Research Candidates via the 'Urgent Medical Research without consent' pathway?** | Yes |
| 3.6 **If 'yes' to Q3.5:**<br>**(a) Explain in what circumstances an 'Urgent Medical Research without consent' enrolment may be required.**<br><br>**(b) Describe the process for enrolling Research Candidates into 'Urgent Medical Research without consent', including how the IMP determination in 3.2 (b) (ii) and (iii) will be provided to the Researcher.**<br><br>**Please label each section of your response as addressing points (a) or (b), as applicable.**<br>**If 'no' to Q3.5, please answer 'N/A'.** | Separate paragraphs to answer the multiple questions in this section, add text after identifying which part of the question you are addressing example below<br>**(a)** then text<br>**(b)** then text |

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| 3.7 **If 'yes' to Q3.5:**<br>**(a) What reasonable steps will be taken to obtain a Research Decision from the Research Decision-Maker?**<br><br>**(b) If the Research Decision-Maker does not consent to the Research Candidate's continuation in the research, how will the research be discontinued as soon as is safely practicable?**<br><br>**Please label each section of your response as addressing points (a) or (b), as applicable.**<br>**If 'no' to Q3.5, please answer 'N/A'.** | Separate paragraphs to answer the multiple questions in this section, add text after identifying which part of the question you are addressing example below<br>(a) then text<br>(b) then text |
| **3.8 Have you read the WA Department of Health *Guidance Document: Involving Incapacitated Adults in Health and Medical Research* and completed the above questions in accordance with the Guidance Document?** | Yes |

## 4. Department of Health Data Collections, Data Linkage and/or WA Health Biobanks

The Department of Health is responsible for the statewide health data collections that contain summaries of personal health information collected from WA Health patients. The Department of Health Information About Health Data website provides information about the data collections. The Department of Health Data Linkage Branch maintains the WA Data Linkage System (WADLS), which comprises a system of linkages connecting data about the health events of Western Australians. The WADLS is used to link the statewide health data collections and some other organisations. The Data Linkage WA website and the Department of Health, WA Data Linkage Branch Access and Charging Policy provide details about the WADLS. Investigators wishing to access personal health information from the Department of Health data collections must consult with the relevant Data Custodian or with the Data Linkage Branch Project Officer about the data application process (including relevant forms and supporting documentation) before applying for the data or requesting Department of Health WA HREC approval.

The application will be formally reviewed by the Data Custodian in order to provide advice to the Data Steward on the release of the data. Further details about the data application, ethics and governance approval processes are available from the Data Linkage WA website or the Department of Health Information About Health Data website. The release of information from the Department of Health data collections for use in research must be approved by the Data Steward. The Data Steward will not approve the use or disclosure of personal information from the Department of Health data collections for research unless the research project has received Department of Health WA HREC approval (regardless of approval by another reviewing HREC) and Departmental site authorisation.

WA HEALTH BIOBANKS: Investigators requiring access to WA Health biobanks or the project involves the establishment or use of material from human tissue collections and their associated data should refer to the Department of Health Guidelines for human biobanks, genetic research databases and associated data. This forms part of an overarching governance and regulatory framework for WA biobanks and should be used in conjunction with existing guidelines, laws and regulations.

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| **4.1 Have the Data Custodian or Data Linkage Branch Project Officer been consulted regarding access to confidential information held by the Department of Health, to determine whether the data required is collected and accessible?** | Yes |
| **4.2 Does this project require approval from the Department of Health WA HREC?** | Yes |

## 5. Aboriginal People

The WA Aboriginal Health Ethics Committee (WAAHEC) is registered with the National Health and Medical Research Council's Australian Health Ethics Committee and sits within the Aboriginal Health Council of WA. WAAHEC exists to promote and support good ethically based health and medical (or the determinants of health) research, which will benefit Aboriginal people. In addition to the Lead HREC approval it is a requirement of WAAHEC to approve the conduct of health and medical research in WA where the research project involves relevant categories.

Refer to the Aboriginal Health Council of Western Australia

website for contact details and the ethics application form.

The use of the term "Aboriginal" within this document refers to Australians of both Aboriginal and Torres Strait Islander people.

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| **5.1 Choose the categories that apply to your research project** | Aboriginal people, as a group, will be examined in the results |
| **5.2 Has an application been submitted to WAAHEC?** | Yes |

## 6. Children and/or Young People (i.e. < 18 years)

If the research involves direct contact with WA participants under 18 years of age (*Age of Majority Act 1972* (WA)) the following points should be considered before submitting the proposal for approval. In WA Health paediatric research that involves direct interaction with children/infants is not considered low risk and therefore must undergo full HREC review. Some paediatric research in the form of chart reviews, retrospective studies, non-confrontational interviews with parents or other health professionals etc. may be considered as low risk (Note: Though if this involves a waiver of consent this will require a full HREC review). Check with the reviewing HREC to confirm requirements.

The composition of the reviewing HREC, or the scientific advisory panel to the reviewing HREC, must be appropriate for review of paediatric projects, by having access to the expertise necessary, to enable it to address the ethical issues arising from research involving children or young people. This may necessitate going outside the HREC membership. Depending on the risk, it may not be sufficient to include one paediatrician on the HREC or scientific advisory panel; rather, there should be a number of paediatricians included, representing the major sub-specialities.

For research that involves children there should be a discussion with all relevant family members. This must include the parent/guardian, and should include the child where appropriate, prior to consent being obtained. The discussion, including who participated, should be documented. The content of this discussion should be reflected in the information sheet provided to the parent/guardian and the child if the latter is deemed competent to consent. If the child is not deemed competent to consent, age appropriate information should be provided to them in accordance with their level of maturity. The type of information sheets required will depend on the type of project being proposed, and the patient group being recruited.

If the research may increase the body of knowledge in a clinical area, but will not be of direct benefit to the participant, the project should not be conducted if the parent is unwilling for their child/infant to participate (all ages); and/or the child has not indicated agreement (where appropriate). If a child or young person has the capacity to consent and is unwilling to participate in research, their refusal to participate should be respected. Where a child or young person lacks the capacity to consent, their refusal may be overridden by the parents' judgement as to what is in the child's best interest.

It is a requirement of WA Health HRECs that where recruitment of children or young people for research is through consent of a parent/guardian, then once the child has reached the age of 18 years, within reason, consent must be re-established for that individual to continue in the research.

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| **6.1 Will children be involved in this research?** | Yes |
| **6.2 Is it intended to obtain the consent of the child?** | Yes |
| **6.3 Investigators should document the consent discussion with both parents and child including details as to who is going to assess the capacity of the child and how this will be done. Please outline the process that will be followed:** | Insert text here. |
| **6.4 If applicable, will child participants be asked to consent or re-consent at age 18 years?** | Yes |
| **6.5 Explain how this will occur:** | Insert text here. |

## 7. Post Mortem Tissue

In Western Australia, if the research project involves the use of tissue samples taken during a coronial post-mortem, or access to coronial data or information that is held by the Office of the State Coroner (WA), the research project must comply with the *Coroners Act 1996* (WA) and ethics approval must be obtained from the
Coronial Ethics Committee
. For further information regarding this process contact the committee via:

Secretary, Coronial Ethics Committee, Coroner's Court of Western Australia
Level 10 Central Law Courts, 501 Hay Street
Perth WA 6000
PH: 08 9425 2900

If the project involves the use of tissue samples taken during a non-coronial post-mortem, investigators must comply with the

Non-Coronial Post-Mortem Examinations Code of Practice 2007
, (enacted under the *Human Tissue and Transplant Act* 1982 (WA)). The reviewing HREC must consider this code of practice when reviewing the application. Refer to the Department of Health
Non-Coronial Post Mortem
website for further information.

**7.1 Are samples to be taken from a non-coronial post mortem?** Yes

*Investigators must comply with the Non-Coronial Post-Mortem Examinations Code of Practice 2007, enacted under the Human Tissue and Transplant Act 1982 (WA).*

**7.2 Are samples to be taken from a coronial post mortem?** Yes

*Research must comply with the Coroners Act 1996 (WA) and be referred to the Coronial Ethics Committee (WA) for ethics approval. Any correspondence from the Coronial Ethics Committee relating to the project must be submitted with your application.*

**7.3 Do you require access to coronial data or information that is held by the Office of the State Coroner (WA)?** Yes

*Research must comply with the Coroners Act 1996 (WA) and be referred to the Coronial Ethics Committee (WA) for ethics approval. Any correspondence from the Coronial Ethics Committee relating to the project must be submitted with your application.*

## 8. Requirement to Address Catholic Health Australia's "Code of Ethical Standards"

If the research project involves a WA institution which functions in accordance with the Catholic Health Australia's Code of Ethical Standards for Catholic Health and Aged Care Services in Australia 2001 (the Catholic Code), then this must be addressed, particularly with respect to the type of research and Patient Information Sheet/Consent Form content. The Catholic Code is available at the Catholic Health Australia
website.

**8.1 Does the research project involve a WA institution which is required to address the requirements of the Catholic Health Australia's Code of Ethical Standards for Catholic Health and Aged Care Services in Australia?** Yes

*The investigator must contact the relevant WA institution(s) for specific advice, especially relating to the content of the Patient Information Sheet/Consent Form.*

*Submit any relevant correspondence from the institution relating to the project with your application.*

## 9. Western Australian Schools

If the research project involves a WA Department of Education site the investigators must comply with the Department of Education WA
Research Conducted on Department of Education Sites by External Parties
policy. This policy requires external investigators to obtain written approval from the Department of Education Central Office and the site manager before research can occur on the site, or for participants to be sought through the site. The policy and support material templates are available from the
Department of Education WA
website.

If the research project involves a WA Catholic School the investigators must comply with the Catholic Education Office of WA
Interim Research Application Guidelines
available from the
Catholic Education Office of WA
website. Prior to conducting research within Catholic Schools the investigator must submit an application to the Director, Catholic Education and obtain approval from the Catholic Education Office of WA Research Review Panel.

**9.1 Does the research project involve a WA Department of Education Site?** Yes

*The investigator should refer to the Department of Education WA*
*Research Conducted on Department of Education Sites by External Parties*
*policy.*

**9.2 Does your research project involve a WA Catholic School?** Yes

*The investigator should refer to the Catholic Education Office of WA*
*Interim Research Application Guidelines*
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