Government of Western Australia
Department of Health

WA Specific Module (WASM)

Version: 4.0

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.

1.1 PRN:	RGS0000000056
1.2 Project title:	Research Governance Service Test Project 2.
1.3 Protocol number:	V1.0 Date 01/02/2017
1.4 Protocol version number:	1.00
1.5 Protocol version date:	01/02/2017

2. Research Requiring Specific Ethical Consideration

2.1 Indicate whether the research project involves:

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 with an Impaired Capacity or Who Are Unable to Consent

Where a person is not capable of giving consent to participate in medical research, investigators and Human Research Ethics Committees (HRECs) should ensure their participation is guided by the ethical requirements set out in the National Statement on Ethical Conduct in Human Research, 2007 (National Statement). However, in every instance relevant jurisdictional laws must be taken into account.

In WA, the *Guardianship and Administration Act* 1990 (WA) (the Act) does not include a provision for consent by a substitute decision maker for a person to participate in medical research. Consent under the Act may only be provided by a substitute decision maker for a person to participate in treatment which is in the best interests of the patient.

Consent to treatment under the Act can be given by the patient if the patient has made an appropriate advance health directive, by an appointed enduring guardian, a guardian, or another responsible person as defined in section 110ZD and prioritised in section 110ZJ of the Act. See the Public Advocate's Statement on Decisions about Treatment.

Once the provisions of the Act have been satisfied such that the research is treatment which is in the best interests of the patient and the appropriate substitute decision maker under the Act has been identified, then the guidelines in the National Statement have application.

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 relevant sections relating to consent include 4.4.1, 4.4.9, 4.4.10, 4.4.13 and 4.4.14.

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. The relevant sections relating to consent include 4.5.1, 4.5.5, 4.5.6, 4.5.7, 4.5.8, 4.5.9, 4.5.10 and 4.5.11.

Consideration
If the research project intends to recruit persons in WA who may be deemed incapable (either mentally or physically) of providing consent the investigator will be required to provide the reviewing HREC with sufficient details to make an assessment of whether the provisions of the *Guardianship and Administration Act* 1990 (WA) and the ethical requirements set out in the National Statement have been met. This should be documented in the Western Australian Specific Module which accompanies the Human Research Ethics Application (HREA).

That is, where a person is not capable of providing consent to participate in medical research, a substitute decision maker may only provide consent for that person to participate in treatment which is in the best interests of the patient. In the case of a clinical trial or medical research that is not normally considered treatment, it may be difficult to establish that participation in the medical research is of direct therapeutic benefit to the individual person and therefore in their best interests.

Consent Process
If the medical research project meets the requirements of the *Guardianship and Administration Act* 1990 (WA) and the National Statement the substitute decision maker should be provided with sufficient information and opportunity to ask questions to reach an adequate understanding of the proposed research and the implications of the incapacitated patient participating in it. At the end of the process, if the substitute decision maker is willing to consent, then the substitute decision maker should be asked to sign an information and consent form. This form should require the substitute decision maker to record that there is no reason to believe that, were the participant to be informed of the proposal, he or she would be unwilling to consent. More than one information and consent form may need to be approved by the HREC to accommodate all potential participants (e.g. participants who have had a stroke and may comprehend the information provided but may physically not be able to sign a form. In this case, ways of obtaining consent from the participant may need to be explored to involve the participant in the consent process).

There should also be a process for reviewing, during the research, the participant's capacity to consent and to participate in the research. Consideration should be given to how consent will be obtained once the participant becomes able to give consent during the project. In research involving people with a mental illness, cognitive impairment or intellectual disability, the persons' medical practitioner should make a judgement on their capacity to give informed consent to participate in the research.

3.1 Indicate the condition, disease or general reasons why participants may be incapable or require assistance to provide consent to take part in the research: Text here.

3.2 How is the proposed research not against the interests of the potential participant? Text here.

3.3 How is the use of a proposed intervention and/or medication supported by the literature or current clinical best practice? Text here.

If Participant Incapable to Provide Consent

3.4 How will the project be discussed with the substitute decision maker and how is it intended to record whether they know of any objections the proposed participant may or may not have had? Text here.

3.5 Is any reading material being provided to the substitute decision maker? Yes

3.6 How will consent be obtained if the proposed participant becomes able to give consent during the project? Text here.

If Participant Requires Assistance to Provide Consent

3.7 How will the project be discussed with the proposed participant and the substitute decision maker where assistance with the consent process is required and how it is intended to record the process and document the participant's consent? Text here.

3.8 Is any reading material being provided to the proposed participant and the substitute decision maker in such instances? 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.

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?	No
If No, consult with the relevant Data Custodian or with the Data Linkage Branch Project Officer to discuss the requirements before applying for the data or requesting Department of Health WA HREC approval. Consultation with the appropriate data managers will be arranged following submission of an Expression of Interest (EOI) for Data, available on the Application for Data Form.	
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.

5.1 Choose the categories that apply to your research project	Aboriginality is a key determinant Data collection is explicitly directed at Aboriginal people Aboriginal people, as a group, will be examined in the results The information has an impact on one or more Aboriginal communities Aboriginal health funds are a source of funding
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.

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:	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:	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.