Government of Western Australia
Department of Health

WA Health Ethics Application Form

Version: 1.0

1. Introduction

1.1 Project

1.1.0 PRN:	RGS0000002217
1.1.1 Project title:	Example of the WAHEAF with all questions shown
1.1.2 Short title:	
1.1.3 Acronym:	
1.1.4.1 Protocol number:	na
1.1.4.2 Protocol version number:	1.00
1.1.4.3 Protocol version date:	[redacted]
1.1.5 Project summary:	This is the project summary a brief explanation of the project in lay language. This information comes from the Project Details section 2.Ethics Information

1.2 Sites

1.2.1 Number of sites - Australia:	1
1.2.2 Number of sites - Non-Australian sites:	0
1.2.3 Site names within Australia in RGS:	Sir Charles Gairdner Hospital
1.2.4 Other site names:	None

1.3 Scientific and Ethical Review

1.3.1 Reviewing HREC:	Sir Charles Gairdner Osborne Park Health Care Group Human Research Ethics Committee
1.3.2 Single-centre or multi-centre project:	Single-centre
1.3.3 Sites under approval - name of the site(s) which will rely on the ethical approval from the nominated HREC(s) for this application:	Sir Charles Gairdner Hospital
1.3.4 Risk type:	More than low risk
1.3.5 Is this project being submitted to (or has it been previously submitted to) another Australian HREC?	No

1.4 Academic/Scientific Review

1.4.1 Has the research project undergone a peer review process?	Yes
1.4.2 Provide details of the review and the outcome:	Insert text here

1.5 Consumer and Community Review

1.5.1 Has the project involved consumer or community input or review?	Yes
1.5.2 Describe this engagement:	Insert text here

1.6 Resources

1.6.1 Indicate how the project will be/or is intended to be funded or supported in-kind. Provide an estimate of the total for all sites covered by this ethics application form:	

Funder Organisation Type (For All Sites)	Funder Organisation Name	Estimate $ Amount of Any Funding (For All Sites)	Estimate $ Amount of Any In-kind-support (For All Sites)	Funding is Confirmed / Received or Being Sought
Government - state (WA)	Department of Health WA	$0.00	$0.00	Confirmed
Other	Self funded	$0.00	$0.00	Sought
Sub total		$0.00	$0.00	

Total funding/in-kind support for all sites: $0.00

1.6.2 How will a funding shortfall (if any) be met? Insert text here

1.6.3 Is this a project where capitation payments are to be made? No

2. Project Team

2.1 Investigators

Role	Name	Qualifications and Expertise Relevant to the Project	GCP Certified	Student	Name and Location of Student Supervisor	Site(s) for Which the Investigator Is Responsible
CPI PI	Dr Henry Amberley [redacted] Department Consultant [redacted]	This information is from Project Details section 4 Investigator Contact Information	Yes	No		PI: Sir Charles Gairdner Hospital CPI: All
AI	Dr April Clark [redacted] Consultant [redacted]	This information is from Project Details section 4 Investigator Contact Information	Yes	No		Sir Charles Gairdner Hospital

2.2 Disclosure of Interest

2.2.1 Have any of the investigators involved with the project have a conflict of interest to declare? No

2.3 Contact Person

2.3.1 Contact person for this project:

Name: Dr April Clark
Address: [redacted]
Organisation: [redacted]
Department: [redacted]
Position: [redacted]
Phone (business): [redacted]
Mobile: [redacted]
Email: [redacted]

3. Project Details

3.1 Background

3.1.1 Summary of findings from previous projects and references to literature and data relevant to the project:	Insert Text here
3.1.2 Product name(s):	This information comes from the Project Details section 2.Ethics Information

3.2 Aims and Significance

3.2.1 Aims, objectives:	Insert Text here
3.2.2 Hypothesis:	Insert Text here
3.2.3 Significance, justification and relevance to current research:	Insert Text here
3.2.4 Expected benefits to the participant and community. Potential contribution to knowledge, treatment, disease prevention, health promotion or social improvement:	Insert Text here
3.2.5 Actual and potential risks to participants and mitigation of risks:	Insert Text here

3.3 Methodology

3.3.1 Research type and design:	Insert Text here
3.3.2 Source and selection of participants/data:	Insert Text here
3.3.3 Treatment of participants:	Insert Text here
3.3.4 Assessment of efficacy:	Insert Text here
3.3.5 Assessment of safety:	Insert Text here
3.3.6 Data management, statistical analysis and record keeping:	Insert Text here

3.4 Project Duration

3.4.1 Expected start date:	[redacted]
3.4.2 Expected finish date:	[redacted]
3.4.4 Duration:	[redacted]

4. Participants

4.1 Source and Number

4.1.1 Provide the age range and source of participants, their tissue or data:	Insert Text here
4.1.2 What is the expected total number of participants in this project at all Australian sites?	20
4.1.3 What is the expected number of participants for each WA Health site involved with the project?	

Site	Number of Participants
Sir Charles Gairdner Hospital	20

4.2 What Categories of People Will Participate in Research?

4.2.1 People whose primary language is other than English (LOTE):	Probable coincidental recruitment
4.2.2 Women who are pregnant and the human fetus:	Probable coincidental recruitment
4.2.3 Children and/or young people (i.e. < 18 years):	Probable coincidental recruitment

4.2.4 People in existing dependent or unequal relationships:	Probable coincidental recruitment
4.2.5 People highly dependent on medical care who may be unable to give consent:	Probable coincidental recruitment
4.2.6 People with a cognitive impairment, an intellectual disability or a mental illness:	Probable coincidental recruitment
4.2.7 Aboriginal people:	Probable coincidental recruitment
4.2.8 People who may be involved in illegal activity:	Probable coincidental recruitment
4.2.9 People in other countries:	Probable coincidental recruitment

4.3 Recruitment

4.3.1 Process used to identify potential participants for the project at the site(s):	This information comes from the Project Details section 2.Ethics Information
4.3.2 How initial contact will be made with potential participants at the site(s):	This information comes from the Project Details section 2.Ethics Information
4.3.3 Will recruitment be from small rural communities?	No

4.4 People Whose Primary Language Is Other than English (LOTE)

4.4.1 List the main language, other than English, that the participants have as their primary language:	Insert Text here
4.4.2 Describe the steps taken to ensure that the information provided to these participants will enable them to understand the research project and freely give consent, e.g. interpreter, translated information sheet and consent, etc.	Insert Text here

4.5 Women Who Are Pregnant and the Human Fetus

4.5.1 Describe how the research conforms to the requirements as set out in Chapter 4.1 of the National Statement:	Insert Text here

4.6 Aboriginal People

4.6.1 Does the project involve Aboriginal people in the categories that require WAAHEC approval?	No

4.7 People Who May Be Involved in Illegal Activity

4.7.1 Describe how the research conforms to the requirements as set out in chapter 4.6 of the National Statement:	Insert Text here

4.8 People in Other Countries

4.8.1 Describe how the research conforms to the requirements as set out in chapter 4.8 of the National Statement:	Insert Text here

4.9 Consent

4.9.1 Will the research involve informed consent of participants?	Yes
4.9.2 Where informed consent is being obtained from potential participants (Research Candidates), describe the consenting process.	Insert Text here

4.9.4 Will any of the potential participants (Research Candidates) lack the capacity to provide consent to their participation in the research? **E.g. Children, and young people; people unconscious or highly dependent on medical care; or people with a cognitive impairment, an intellectual disability or mental illness?**	Yes
4.9.5 Indicate the condition, disease or general reasons why potential participants (Research Candidates) may be unable to make reasonable judgements in respect of their participation in the research.	Insert Text here
4.9.6 Does the research project involve limited disclosure, concealment or deception of participants?	Yes
4.9.7 Detail why this is required and how this will be conducted:	Insert text here
4.9.8 If a potential participant (Research Candidate) (or research decision-maker for a potential participant who lacks capacity to provide consent) chooses not to participate, are there specific consequences of which they should be made aware, prior to making this decision?	Yes
4.9.9 Provide details:	Insert Text here
4.9.10 If a potential participant (Research Candidate) (or research decision-maker for a potential participant who lacks capacity to provide consent) chooses to withdraw from the research, are there specific consequences of which they should be made aware, prior to giving consent?	Yes
4.9.11 Provide details:	Insert Text here
4.9.12 Will a participant or person on behalf of a participant who withdraws from the research be able to withdraw data about the participant?	Yes
4.9.13 Provide details:	Insert Text here
4.9.14 Is any financial remuneration/reimbursement or other benefit being offered to participants in the project?	Yes
4.9.15 State how much, or what, will be offered and for what purpose. Indicate whether participants will be informed of the remuneration/reimbursement and outline how this will be communicated to them:	Insert text here

4.10 Adults without the Capacity to Consent

4.10.1 Of the Research Candidates who lack capacity to give consent to their participation in the research, will any of them be adults, and therefore recruited under the *Guardianship and Administration Act 1990* ? **If 'Yes' - 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".**	Yes
4.10.2 (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. **(b) Describe the process for obtaining an Independent Medical Practitioner (IMP) determination on the following:** **(i) Likelihood of candidate being able to make reasonable judgements within the 'timeframe' approved by the HREC** **(ii) The risk applicable to the candidate's participation in the research** **(iii) Whether the research is in the best interests of the candidate or will not be adverse to the interests of the candidate.** **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 **(a)** then text **(b)(i)** then text **(b)(ii)** then text **(b)(iii)** then text
4.10.3 Describe the process for obtaining consent from the Research Decision-Maker, including how the IMP determination in 4.10.2 (b) (ii) and (iii) will be provided to the Research Decision-Maker.	Insert text here
4.10.4 What steps will be taken to determine when the Research Candidate regains capacity?	Insert text here
4.10.5 When the Research Candidate regains the capacity to consent: **(i) How will the research be discontinued as soon as is safely practicable?** **(ii) How will the Research Candidate's consent to continue to participate in the research be sought?** **Please label each section of your response as addressing points (i) or (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 **(i)** then text **(ii)** then text
4.10.6 Is specific approval being sought to recruit Research Candidates via the 'Urgent Medical Research without consent' pathway?	Yes

4.10.7 (a) Explain in what circumstances an 'Urgent Medical Research without consent' enrolment may be required. (b) Describe the process for enrolling Research Candidates into 'Urgent Medical Research without consent', including how the IMP determination in 4.10.2 (b) (ii) and (iii) will be provided to the Researcher. Please label each section of your response as addressing points (a) or (b), as applicable. If 'no' to Q4.10.6, 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 **(a)** then text **(b)** then text
4.10.8 (a) (a) What reasonable steps will be taken to obtain a Research Decision from the Research Decision-Maker? (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? Please label each section of your response as addressing points (a) or (b), as applicable. If 'no' to Q4.10.6, 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 **(a)** then text **(b)** then text
4.10.9 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

4.11 Children and Young people

4.11.1 Will children be involved in this research?	Yes
4.11.2 Is it intended to obtain the consent of the child?	Yes
4.11.3 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
4.11.4 If applicable, will child participants be asked to consent or re-consent at age 18 years?	Yes
4.11.5 Explain how this will occur:	Insert text here

4.12 Dependent Relationships

4.12.1 Is there any pre-existing or potential relationship between the investigators and the participants?	Yes
4.12.2 Specify the nature of any existing or potential relationship, between the participants and any members of the research team or organisation involved in the research. Describe the steps, if any, will be taken to ensure that the relationship does not impair participants' free and voluntary consent and participation in the project; or does not impair any existing or foreseeable future relationship between participants and the investigators or organisation:	Insert text here

5. Methodology

5.1 Project Methods

5.1.1 Indicate if the project involves any of the following methods or fields:	Interventions and therapies, including clinical and non-clinical trials, innovations, ionising radiation

5.2 Interventional

5.2.1 Conducted under clinical trial notification (CTN) or exemption (CTX) scheme:	Clinical trial notification
5.2.2 Does the project involve the exposure of participants to ionising radiation (including normal standard of care)?	Yes
5.2.3 Is the exposure of ionising radiation additional to the research participant's normal standard of care?	No

6 Data and Privacy

6.1 State Data

6.1.1 Does the research collect, use, or disclose individually identifiable or re-identifiable data of a personal nature (including personal information) held in State/Territory departments or agencies e.g. medical records, hospital data bases, State based registers (cancer, genetic etc.), State Departments or other non-Commonwealth Government records?	Yes
6.1.2 List all sources e.g. medical records, TOPAS, Hospital Morbidity Database:	Insert text here
6.1.3 Will the project involve the use of confidential information from the Department of Health data collections, data linkage and/or WA Health biobanks?	Yes
6.1.4 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
6.1.5 Does this project require approval from the Department of Health WA HREC?	Yes
6.1.6 Does the project require access to coronial data or information that is held by the Office of the State Coroner (WA)?	Yes

6.2 Commonwealth Data

6.2.1 Does the research involve access to data held by a Commonwealth Department or Agency?	Yes
6.2.2 Investigators will have to comply with the privacy principles established under the *Privacy Act 1988* (Cwlth). Identify the source of the data and whether the information is being collected, used or disclosed by the Commonwealth agency:	Insert text here

6.3 Non-government Data

6.3.1 Does the research involve access to data held by a non government organisation (e.g. general practitioner, private hospital, non-government medical research institute, private university)?	Yes

6.3.2 Investigators will have to comply with the privacy principles established under *Privacy Act 1988* (Cwlth). Identify the source of the data and whether the information is being collected, used or disclosed by the non-government organisation:	Insert text here

6.4 Privacy

6.4.1 Explain why the proposed activity cannot be achieved using data which is not identifiable:	Insert text here

6.5 Confidentiality

6.5.1 Explain what methods will be used to protect confidentiality/anonymity of participant data:	Insert text here

6.6 Data Storage and Security

6.6.1 Explain how and where data will be held both during and after the project, including any arrangements for data security:	Insert text here
6.6.2 Indicate how long the data will be kept:	Insert text here
6.6.3 How will data be disposed of?	Insert text here

6.7 Dissemination of Results

6.7.1 Explain when, how, where and to whom results will be disseminated e.g. a report, publication or thesis, including whether participants will be provided with information on the findings or outcomes of the project:	Insert text here

7. Declarations

The research team has certified that:

1. All information in this application and supporting documentation is correct and as complete as possible;
2. I have read and addressed in this application the requirements of the National Statement and any other relevant guidelines;
3. I have familiarised myself with, considered and addressed in this application any relevant legislation, regulations, research guidelines and organisational policies;
4. All relevant financial and non-financial interests of the project team have been disclosed; and
5. In the capacity of a supervisor, as applicable, I have reviewed this application and I will provide appropriate supervision to the student(s) in accordance with the arrangements specified in this application and those associated with the student's educational program.