

WA Health Research Authorisation and Monitoring Forms Guidelines

June 2017

Contents

CONTENTS.....	1
INTRODUCTION	1
1. RESEARCH AUTHORISATION	2
1.1. HUMAN RESEARCH ETHICS APPLICATION & WA SPECIFIC MODULE.....	5
1.2. WA HEALTH ETHICS APPLICATION FORM.....	5
1.3. SITE SPECIFIC ASSESSMENT FORM	6
1.4. ACCESS REQUEST FORM.....	7
1.5. RESEARCH CONFLICT OF INTEREST FORM.....	7
1.6. DECLARATION OF CONFIDENTIALITY & STUDENT RESEARCH AND CONFIDENTIALITY DECLARATION	8
1.7. CONFIDENTIALITY AGREEMENT	8
2. RESEARCH MONITORING	9
2.1. AMENDMENT FORM	9
2.2. ANNUAL PROGRESS REPORT	9
2.3. FINAL REPORT	10
2.4. SAFETY REPORT	11
2.5. RESEARCH COMPLAINT FORM	12

Introduction

The Research Governance Service (RGS) information technology system has been developed to support the WA Health research governance framework and allow WA to participate in national initiatives, including the National Mutual Acceptance (NMA) process and National Aggregated Statistics for Clinical Trials.

It provides a collaborative workspace for investigators, project members, sponsors, sites, Research Governance Officers (RGOs) and Human Research Ethics Committees (HRECs) to govern and report on human research through the life cycle of the project, from initial application to publication.

Approval/Authorisation

The RGS helps facilitate the scientific and ethical approval and site authorisation processes for human research projects conducted within WA Health or accessing WA Health participants, their tissue or data.

The RGS allows investigators (or delegates), project members and sponsors to complete and submit forms and supporting documents via the RGS to the relevant WA Health:

- HREC for scientific and ethical review and approval
- Research Governance (RG) Office for governance review and site authorisation.

Contact details for WA Health Ethics and RG Offices are available from the RGS [Contacts](#) tab.

Monitoring

Until the monitoring component (Stage 2) of the RGS is released in 2017/2018, the forms and documents related to research monitoring will continue to be submitted directly to the relevant Ethics Office and RG Office in hard copy, not through the RGS.

1. Research Authorisation

Human research projects cannot commence at a WA Health site until the Principal Investigator (PI) has received written notification of site authorisation from the Chief Executive/delegate to either conduct research at the site or access participants, their tissue or data.

Site authorisation will only be provided once the research project has undergone research governance review in accordance with the [WA Health Research Governance and Single Ethical Review Standard Operating Procedures 2013](#). This includes:

- scientific and ethical review and approval by a WA Health HREC constituted and operating in accordance with the National Health and Medical Research Council's (NHMRC) [National Statement on Ethical Conduct in Human Research 2007](#) (National Statement)
- governance review by a WA Health RGO, involving either a site specific assessment or access request review.

Before submitting a research project application all investigators should be conversant with the [National Statement](#), the NHMRC [Australian Code for the Responsible Conduct of Research 2007](#), the [WA Health Research Governance Policy and Procedures 2012](#) and the [WA Health Research Governance and Single Ethical Review Standard Operating Procedures 2013](#).

Who should complete the forms?

Ethics

The Coordinating Principal Investigator (CPI) is responsible for the completion and submission of the ethics application forms and their supporting documents to the reviewing HREC.

The CPI can delegate the completion and submission of these forms and documents to their CPI delegate or other project members (including a sponsor). Though, the CPI must authorise (sign) the ethics form prior to submission. Refer to the RGS [Help Wiki](#) tab for more information.

Governance

The PI (who is also the CPI in single-centre research) is responsible for the completion and submission of the governance application forms and their supporting documents to the relevant RG Office responsible for the site(s).

The PI can delegate the completion and submission of these forms and documents to their PI delegate or other project members (including a sponsor). Though, the PI must authorise (sign) the governance form prior to submission. Refer to the RGS [Help Wiki](#) tab for more information.

Which forms should be completed?

Application forms	When can the form be used?			
	WA Health Single Ethical Review	National Mutual Acceptance	Conducting research at a site	Accessing participants, tissue or data only
Ethics				
Human Research Ethics Application (HREA) & WA Specific Module (WASM)	Yes	Yes	Yes	Yes
WA Health Ethics Application Form (WAHEAF)	Yes	No	Yes	Yes
Governance				
Site Specific Assessment (SSA) Form	Yes	Yes	Yes	No
Access Request (AR) Form	Yes	Yes	No	Yes

Which supporting documents should be submitted?

Before submitting the application the CPI or PI should ensure all required supporting documentation is attached.

A research protocol **MUST** be submitted with the ethics application. Templates are available from the RGS [Document Templates](#) tab as a guide for investigators who do not already have a protocol for their research project.

Ethics

Table A: Ethics Documents – as applicable	
Data Application Form	Peer Review
Investigator Brochure	Product Information
Participant Information Sheet and Consent Form (Master) OR Participant Information Sheet (Master) Participant Consent Form (Master) AND/OR Participant Information Sheet and Consent Form (Site Master)	Protocol
	Radiological Council Approval
	Recruitment Documents (letters)
	Recruitment Documents (posters, advertisements)
Participant Documents (identification card, diaries)	Research Tools (interview outlines)
	Research Tools (questionnaires, surveys)

Governance

Table B: Governance Documents – as applicable	
Clinical Trial Research Agreements OR Funding Agreement OR Material Transfer Agreement OR Service Agreement	Participant Information and Consent Form (Site) OR Participant Information Sheet (Site) Participant Consent Form (Site)
Budget Supporting Document	Medical Physicist Report
Confidential Agreement	NHMRC Embryo Research Licensing Committee Licence
CTN or CTX Documentation	Office of the Gene Technology Regulator Approval
Indemnity Form	Reproductive Technology Council Approval
Institutional Biosafety Committee Notification	HREC approval letter
Insurance Certificate of Currency	HREC approval letter (Specialist)
Insurance Policy	Amendment approval letters for latest approved documents, site related investigators or CPI change

NB: The RGO must be able to review the latest approved ethics documents (as per Table A) except for the Recruitment and Research Tools (unless separate site branding is required).

If the ethics application has been submitted through the RGS all WA Health RG Offices will have access to the submitted ethics forms, documents and approval letters so these do not need to be submitted again. However if this has not occurred, the latest approved ethics documents listed above will have to be submitted via the RGS to the RG Office along with the governance documents.

Who do I submit my application to?

Ethics

Under the **WA Health Single Ethical Review** the reviewing HREC should be chosen in accordance with the following order of choice:

1. The Lead HREC has expertise in reviewing the relevant research category; these are documented in the [WA Health Research Governance and Single Ethical Review Standard Operating Procedures](#).
2. The Lead HREC is associated with the WA Health site where the CPI will be conducting the research; or where a PI is located (if the CPI has no association with WA Health sites).
3. If the CPI or PIs have no association with site, the selection of the Lead HREC (with the relevant expertise) is at the discretion of the CPI.

Some WA Health HRECs have alternative review pathways for low or negligible risk research projects. Contact details for Ethics Offices and links to their local webpages are available from the RGS [Contacts](#) tab.

For NMA process refer to the NMA guidelines on the RGS [Multi-centre Research](#) tab.

Governance

The governance application must be submitted to the relevant RG Office, responsible for site(s) where the research will be conducted, for consideration and review prior to final authorisation by the site Chief Executive or delegate. Contact details for RG Offices and their associated sites are available from the RGS [Contacts](#) tab.

What happens after I submit my application?

Ethics

Following submission of your ethics application, the Ethics Executive Officer (EEO) will assess whether it is valid (complete) and ready for ethical review.

If the application is valid, the CPI will receive a notification that the project is valid and the application will be tabled at the next alternative review, subcommittee or HREC meeting as applicable. If additional information is required (AIR), the CPI will receive a notification and asked to make the required changes and then resubmit a new version. If any forms or documents are deemed unnecessary for the application they will be marked as not valid and no further action is required.

Following review by the HREC, the EEO will notify the CPI in writing of the outcome of the HREC review within 7 calendar days following the HREC meeting.

Governance

Following submission of your governance application, the RGO will assess whether it is valid (complete) and ready for governance review.

If the application is valid, the PI will receive a notification that the project is valid and the application will then be reviewed by the RGO. If additional information is required (AIR), the PI will receive a notification and asked to make the required changes and then resubmit a new version. If any forms or documents are deemed unnecessary for the application they will be marked as not valid and no further action is required.

When review of the research governance application is completed, the RGO will make a recommendation to the Chief Executive/delegate as to whether the project should be authorised or requires Chief Executive/delegate consideration. Following consideration by the Chief Executive/delegate, the RGO will notify the PI in writing within 7 calendar days whether the project has been granted site authorisation.

1.1. Human Research Ethics Application & WA Specific Module

Human Research Ethics Application

The NHMRC's Human Research Ethics Application (HREA), which replaced the National Ethics Application Form (NEAF) in June 2017, is an ethics form designed to assist the reviewing HREC to assess the ethical and scientific suitability of a human research project.

The HREA can be used for both single-centre and multi-centre projects at both a State and national level but it is mandatory for the NMA single ethical review process. WA Health is currently not participating in the NMA process, but will be from late 2017.

Western Australian Specific Module

The WA Specific Module (WASM) must be completed in conjunction with the HREA for health and medical research projects conducted within WA or intending to access WA participants, their tissue or data. Within WA Health, the WASM must accompany all ethics applications using the HREA.

The WASM addresses additional ethical issues, specific to WA that is not addressed in the HREA and must be considered when conducting human research in WA including:

- adults with an impaired capacity or who are unable to consent
- the use of confidential information from the Department of Health data collections, data linkage and/or WA Health biobanks
- Aboriginal people
- children and/or young people (<18 years)
- the use of human tissue from persons who were the subject of a post mortem
- a requirement to address Catholic Health Australia's Code of Ethical Standards
- Western Australian schools.

1.2. WA Health Ethics Application Form

The WA Health Ethics Application Form (WAHEAF) is an ethics form designed to assist the WA Health HRECs to assess the ethical and scientific suitability of a human research project.

The WAHEAF is available for use by investigators, who are conducting human research projects within WA Health or accessing WA Health participants, their tissue or data; as an alternative to completing the HREA plus WA Specific Module.

Low or Negligible Risk Research

If the project fits the low or negligible risk (LNR) criteria, investigators should nominate the LNR category. The [National Statement](#) and the [WA Health Research Governance Policy and Procedures 2012](#) provide further information on what constitutes LNR. If the reviewing HREC has an alternative review process for LNR projects, they will decide whether the project meets the criteria. The HREC reserves the right to assign the project to a full HREC review.

For LNR projects, where explicit consent from participants is not being obtained, investigators should address all points of the [National Statement](#) Chapter 2.3.6 or 2.3.10 (as applicable), providing justification as to why consent will not be obtained from participants or the opt-out approach will be utilised.

Research that involves the use of information from Commonwealth agencies or private organisations must comply with the NHMRC [Guidelines under Section 95 of the Privacy Act 1988 \(2014\)](#) and the [Guidelines approved under Section 95A of the Privacy Act 1988 \(2014\)](#) respectively; where relevant the guideline requirements should be addressed in the WAHEAF.

Only a HREC may grant waiver of consent for research using personal information in medical research, or personal health information. Other review bodies may grant waiver of consent for other research.

1.3. Site Specific Assessment Form

The Site Specific Assessment (SSA) Form and associated Budget Form are governance forms to assist RGOs to assess the professional, legal and financial suitability and risk of *conducting a human research project at a site*. This process should run in parallel to the ethics approval process as ethical approval of a project is not a pre-requisite for submission of a SSA Form.

Final authorisation to conduct a project at a site requires:

- ethics approval (from a WA Health HREC or NMA HREC [when WA Health joins NMA])
- consideration and authorisation of resourcing by the site's Heads of Departments, Business Manager and Divisional Director (plus WA Country Health Service (WACHS) Regional Director, where relevant)
- governance review by a RGO
- authorisation by the Chief Executive/delegate.

For student projects the form should be completed by the student under supervision of a WA Health Research Supervisor.

In most cases, a separate SSA Form is required for each WA Health site involved in the project, except for when minor sites are involved as described below.

Minor Sites on one SSA Form

If a project is conducted across a 'group of minor sites'¹, within the jurisdiction of the same Region (as defined in RGS²); then details regarding these sites may occasionally be documented on the one SSA Form. However, if sites are grouped onto one SSA Form they must complete separate sections and budgets for each site involved. There will also be a requirement to have the one designated authority providing Regional Director authorisation (in the case of WACHS) and site authorisation for all sites on the form (e.g. Executive Director/delegate).

Before completing the SSA Form, investigators must check with the RG Office to ensure sites can be grouped onto the one form. Incorrect SSA forms, with sites that should not be grouped together on the one form, will be marked as invalid.

If an investigator is documenting multiple minor sites on one SSA Form, all details, including the Budget Form and approvals from all Heads of Departments, Divisional Directors must be documented separately for each site.


Budget Spreadsheet

Investigators should discuss the project and acquire authorisation and a quote for services on the Budget Form from WA Health/external supporting departments as early as possible.

For additional assistance in compiling clinical trial budgets (and other research projects) refer to the [Independent Hospital Pricing Authority \(IHPA\) Determination of Standard Costs Associated with Clinical Trials in Australia June 2015](#).

¹ For example, a group of hospitals/nursing outposts within one WACHS Region; or a group of adult mental health services within NMHS Mental Health.

² In the RGS, the Department of Health and Health Service Providers (HSPs) are nominated as separate regions, except for WACHS which is broken up into 7 separate regions e.g. Great Southern, Goldfields, Kimberley, Midwest, Pilbara, South West, Wheatbelt.



The determination does not bind jurisdictions and should be used as a starting point for discussing the unique features of each proposed trial and the associated costs. The determination is intended to be applied only to those clinical services that are over and above normal standard of care delivered to patients. Investigators should be aware that hourly rates of salaries quoted are fully absorbed i.e. they include on costs and overheads already built in.

1.4. Access Request Form

Purpose of the Access Request Form

The Access Request (AR) Form is a governance form to assist RGOs to assess whether to allow *access to its participants, their tissue or data* when a research project is not being conducted at the site.

When a project requires access across multiple sites within the jurisdiction of the same RG Office, then details regarding these sites may be documented on the one AR Form, though a declaration of authorisation will be required from each site involved. In WACHS the Regional Director must also provide a declaration.

This form is required when the research project involves:

- participant recruitment through personnel distributing posters, leaflets, handouts, and letter of invitation to potential participants (but does not involve direct recruitment of participants)
- distribution of surveys and questionnaires to personnel of the site by e-mail, in line with the site policies (but not collation and analysis of responses at that site)
- access to medical records, data or tissue held in the site collections or databases under their management, in line with ethical conditions imposed by the approving HREC (but not processing or analysis at that site).

Submit all documents to be distributed through the sites with your application, for example:

- posters, leaflets or handouts
- letters of invitation (on research site letterhead)
- surveys and questionnaires.

Access to data must be approved in accordance with the WA Health [Information Use and Disclosure Policy](#).

In addition to the AR Form, for projects requesting access to the Department of Health data collections the investigator must submit an [Application for Data Form](#). Contact details and information on the application process are on the [Information About Health Data](#) website and [Data Linkage WA](#) website.

1.5. Research Conflict of Interest Form

All investigators (including those that are non-WA Health employees/students) conducting a human research project at a WA Health site or requiring access to WA Health participants, their tissue or data must disclose any actual, perceived or potential conflicts of interest that may arise in relation to a proposed research project.

The WA Health Research Conflict of Interest Form must be completed by any investigator that has a conflict of interest to declare. The conflict of interest may be related to financial and material, or non-financial and partiality interests. All investigators must ensure they have read the [WA Health Managing Conflict of Interest Policy and Guidelines](#) prior to completion of this form.

The form must be submitted to the RG Office with the governance application (SSA or AR forms) and a copy must be kept on the project file. The AR Form only requires a copy from the CPI.

Whilst the project is being undertaken, if there are any changes relevant to this declaration, it is the responsibility of the CPI to notify the approving HREC, and the responsibility of the PI to notify the RGO.

DEFINITIONS

Conflict of Interest	Involves a situation arising from conflict between the performance of a public duty and private or personal interests. A conflict of interest can be: <ul style="list-style-type: none"> • actual - a conflict usually exists; • perceived - a conflict is only believed to exist; and • potential - a conflict is a future possibility.
Financial and Material Interest	Where a public officer (or someone associated with them) could gain or lose financially because of the way the public officer fulfils their official duties.
Partiality and Non-financial interest	Where a public officer's personal involvements, affiliations (e.g. institutional, collegiate, professional association), relationships, obligations, values or attitudes may influence the way they carry out their official duties.
Related entity	This could include: <ul style="list-style-type: none"> • a trust of which the member or a relative of the member is a trustee, a beneficiary or, if the trust has a corporate trustee, of which the member is a director or shareholder; and • a body corporate of which the member or a relative of the member is a director or shareholder.
Relative	This could include: <ul style="list-style-type: none"> • a spouse (which term includes de facto spouse) or partner; • a son, daughter or grandchild and their respective spouses; • a parent; and • a brother or sister and their respective spouses.

1.6. Declaration of Confidentiality & Student Research and Confidentiality Declaration

External research personnel who will be either conducting a research project within WA Health or accessing WA Health participants, their tissue or data for a research project will have to complete *one or both* of the following confidentiality declarations:

- The WA Health Declaration of Confidentiality must be completed in the RGS by all research personnel who are non-WA Health employees accessing a project. This includes research personnel with joint appointments, when the WA Health employee is conducting a project in their non-WA Health employee capacity.
- The Student Research and Confidentiality Declaration must be completed by all student research personnel (irrespective of whether they are WA Health employees). In the RGS the Student Research and Confidentiality Declaration should be attached as a supporting document to the governance application.

1.7. Confidentiality Agreement

WA Health has established a standard Confidentiality Agreement (CA) which is recommended for use in clinical trial research and data registries. Amendments to the CA can be negotiated with external parties by the RGO in consultation with the Department of Health Legal and Legislative Services.

The party's details on the CA should be completed by the PI and then signed by the external party, prior to forwarding to the RGO to obtain Chief Executive/delegate signage. Investigators do not have the legal delegation to bind or sign agreements on behalf of the site or organisation.

2. Research Monitoring

Monitoring forms are not available in the RGS and should be submitted directly to the Ethics or RG Office as appropriate. They can be accessed on the RGS [Ethics](#) and [Governance](#) webpages.

2.1. Amendment Form

This form should be used by the CPI and PI for amendments submitted to a WA Health HREC, a RG Office or both. All supporting documents should be submitted with the form.

Amendments in the form are broken into types. Guidance (using numbers①②③) is given to indicate whether this type of amendment would *usually* require review and approval by a HREC (ethics), RG Office (governance) or both:

1. **①Ethics Only Amendments** are amendments that have *only* ethical implications for the project with *no* governance implications for any of the sites involved in the project. This situation would be rare, as sites (through the RG Office) should be made aware of amendments to project documentation and relevant personnel.

The CPI should complete, sign and submit the amendment form to the Lead HREC (and any additional specialist HRECs) for ethics approval. Once approved, the CPI should send a copy of the ethics approval letter to the projects PIs.

2. **②Governance Only Amendments** are amendments that have *only* governance implications with *no* ethical implications, as they involve changes to site specific governance documentation. Therefore, they do not require review by the Lead HREC (and any additional specialist HRECs) prior to submission to the RG Office. Only a small minority of amendments fall into this category (e.g. changes to project documentation agreements, updated insurance policy, budget change not related to a protocol change).

The PI should complete, sign and submit the form to the RG Office, affiliated with the site, for site authorisation.

3. **③Both Ethics and Governance Amendments** are amendments that have ethical and governance implications; therefore they require ethics approval by the Lead HREC (and any additional specialist HRECs) prior to submission to the relevant RG Office affiliated with the site, for site authorisation.

The CPI should complete, sign and submit the amendment form to the Lead HREC (and any additional specialist HRECs) for ethics approval. Once approved, the CPI should send a copy of the approved ethics amendment form and ethics approval letter to the PIs whose sites are impacted by the amendment.

Once ethics approval is received, the relevant PIs should complete the amendment form (including details from the approved ethics amendment and any additional site specific documentation), sign and submit it to the RG Office. The ethics approval letter should be included as a supporting document.

2.2. Annual Progress Report

This report should be used by the Coordinating Principal Investigator (CPI)/CPI Delegate and Principal Investigators (PI)/PI Delegate for annual progress reports submitted to a WA Health Human Research Ethics Committee (HREC) and a Research Governance (RG) Office. The terms of approval for a research project require an annual (or more frequent) progress report to be submitted to both the HREC and RG Office as part of the project monitoring.

This report must not be used to submit amendments, safety reports and final reports to the HREC or RG Office, alternative forms are available for these submissions.

The report is divided into three sections:

- **Section A** should be completed by the CPI or their delegate for the whole of the project. The CPI/delegate must complete Section B for the sites that they are responsible for.
- **Section B** should be completed by the PI or their delegate for their site(s).
- **Section C** should be signed by the CPI and PI or their delegates prior to submitting the report.

Submission process to the HREC and RG Office:

1. Ethics Annual Progress Report

The CPI should complete Sections A&C and then send the report to all PIs to complete Sections B&C for their sites. Once the report is complete, the CPI can submit the report to the HREC for consideration and approval.

2. Governance Annual Progress Report

The CPI should complete Sections A&C and then send the report to all PIs to complete Sections B&C for their sites. Once the PI has completed their section (for their site), they can submit the report to their RG Office for consideration and approval.

2.3. Final Report

This report should be used by the Coordinating Principal Investigator (CPI) and Principal Investigators (PI) for final reports submitted to a WA Health Human Research Ethics Committee (HREC) and a Research Governance (RG) Office. The terms of approval for a research project require a final report to be submitted to both the reviewing HREC and RG Office for either the closure of a specific site (**Closing a Single Site**) or the completion of the project at all sites (**Closing the Project**).

The report is divided into four sections:

- **Section A** should be completed by either the CPI or PI (or their delegates) for their relevant report.
- **Section B** should be completed by the PI (or their delegate) when closing their site(s).
- **Section C** should be completed by the CPI (or their delegate) when closing the project.
- **Section D** should be signed by the CPI or PI (or their delegates) prior to submitting the report.

Submission process to the HREC and RG Office:

1. Final Report for Closing a Single Site

The PI or their delegate should complete Sections A,B,D of the report for the site that is closing (providing a summary of the project at the site) and submit it to their RG Office for their consideration and approval.

The PI should send a copy of the report to the CPI for forwarding to the reviewing HREC for their consideration and approval.

2. Final Report for Closing the Project

The CPI or their delegate should complete Sections A,C,D of the report at the completion of the research project (providing a summary of the whole project), and submit it to the reviewing HREC for consideration and approval.

The CPI should send a copy of the report to the PIs for forwarding to the RG Offices for their consideration and approval.

2.4. Safety Report

This report should be used by the Coordinating Principal Investigator (CPI)/CPI Delegate and Principal Investigators (PI)/PI Delegate and sponsors for safety reports submitted to a WA Health Human Research Ethics Committee (HREC), a Research Governance (RG) Office or both. All supporting documents should be submitted with the report. **In WA Health, the CPI must submit the report to the HREC on behalf of the sponsor.**

Safety issues in the report are broken into types. Guidance (using numbers①②③) is given to indicate whether this type of report would *usually* require consideration and possible further action by a HREC (ethics), RG Office (governance) or both:

1. **①Ethics Only Safety Reports** are reports that have safety implications across the whole project.

The sponsor or CPI should complete the report; the CPI should then sign and submit the report to the Lead HREC (and any additional specialist HRECs) for ethical consideration and acknowledgement.

2. **②Governance Only Safety Reports** are reports that have that have safety implications for the site.

The PI for the relevant site should complete, sign and submit the report to the RG Office, affiliated with the site, for governance consideration and acknowledgement.

3. **③Both Ethics and Governance Safety Reports** are reports that have safety implications that should be reported to both the Lead HREC (and any additional specialist HRECs) and relevant RG Office affiliated with the site, for consideration and acknowledgment.

- **If the safety issue originates from the site:** the PI should complete, sign and submit the report to the RG Office responsible for the site.
- **If the safety issue originates from the whole project:** the sponsor or CPI should complete the report. The CPI should sign and submit the report to the reviewing HREC(s). *If a SSI is involved, this report should be copied to the PI.* The PI should sign the copy of the report and submit the report to the RG Office.

Definitions:

Safety Critical Adverse Events	<i>Adverse events and/or laboratory abnormalities identified in the protocol as critical to safety evaluations that should be reported to the sponsor according to the reporting requirements specified in the protocol.</i>
Serious Adverse Event (SAE)/Serious Adverse Reaction (SAR)	<i>Any adverse event/adverse reaction that results in death, is life-threatening, requires hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect.</i>
Serious Breach	<i>A breach of the protocol or Good Clinical Practice (GCP) that is likely to affect to a significant degree:</i> <ul style="list-style-type: none"> • <i>the safety or rights of a participant; or</i> • <i>the reliability and robustness of the data generated in the project.</i>
Significant Safety Issue (SSI)	<i>A safety issue that could adversely affect the safety of participants or materially impact on the continued ethical acceptability of the trial. Often SSIs do not fall within the definition of a Suspected Unexpected Serious Adverse Reaction (SUSAR), thus are not reported as SUSARs but require other action such as the reporting of an urgent safety measure (USM), an amendment, a temporary halt or early termination of a trial.</i>
Suspected Breach	<i>A report that is judged by the reporter as a possible serious breach but has yet to be formally confirmed as a serious breach by the sponsor.</i>
Suspected Unexpected Serious Adverse Reaction (SUSAR)	<i>An adverse reaction that is both serious and unexpected.</i>

Unanticipated Serious Adverse Device Effect (USADE)	<i>A serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report.</i>
Urgent Safety Measure (USM)	<i>A measure required to be taken in order to eliminate an immediate hazard to a participant's health or safety.</i>

2.5. Research Complaint Form

This report should be used to make a complaint about either:

- a research project conducted within WA Health; or
- general research governance review processes within WA Health specific to a Human Research Ethics Committee (HREC) or Research Governance (RG) Office i.e. not related to a specific project.

1. Project:

Complaints regarding the project should be submitted to the:

- reviewing HREC if the complaint is related to the overall conduct of the research project or the research protocol; or
- relevant RG Office if the complaint is related to the conduct of the project specifically at the site.

2. HREC or RG Office:

Complaints regarding the research governance entity:

- HREC review processes should be directed to the relevant HREC Chair outlining the grounds of concern or complaint.
- RG Office review processes should be directed to the relevant RG Office outlining the grounds of concern or complaint.

This form can be completed by someone other than the complainant (e.g. the HREC or RG Office on behalf of a participant) if the complaint is provided verbally. All complaints must be documented in writing.