Government of **Western Australia**
Department of **Health**

WA Health Research Governance and Single Ethical Review

Standard Operating Procedures

Research Development Unit, Office of the Chief Medical Officer
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INTRODUCTION

1. Purpose

In accordance with the "WA Health Research Governance Policy and Procedures" 2012, these Standard Operating Procedures **(SOPs)** have been developed to support the requirements of the policy and promote a consistent approach within WA Health to research governance as well as the WA Health Single Ethical Review and National Approach/Mutual Acceptance processes. This process is outlined in **Figure 1**.

A large number of multi-centre human research projects are conducted within WA Health which require ethical and scientific approval by a Human Research Ethics Committee **(HREC)** prior to commencement. In line with the requirements of Chapter 5.3 of the National Health and Medical Research Council's **(NHMRC)** "National Statement on Ethical Conduct in Human Research" 2007 **(National Statement)** to minimise duplication of ethical review, WA Health supports the concept of single ethical review for all multi-centre (i.e. conducted under the authority of more than one HREC) human research carried out in Australia. This is to ensure the efficient use of resources, improve the quality and effectiveness of the ethical and scientific reviews and reduce delays in the commencement of research projects.

To this end, once approval has been given by the Director General, WA Health will implement the WA Health Single Ethical Review of Multi-centre Research **(Intro 2.1)** and the National Approach to Single Ethical Review of Multi-centre Research **(National Approach)** **(Intro 2.2)** processes. In addition, upon signing of a Memorandum of Understanding, WA Health will implement the National Mutual Acceptance of Ethical and Scientific Review for Multi-centre Clinical Trials Conducted in Public Health Organisations **(National Mutual Acceptance)** **(Intro 2.3)**. Notwithstanding the specific HREC review requirements stipulated by WA Health below, under these systems a research project which is conducted at a site under the jurisdiction of WA Health or involving participants, their tissue or data accessed through WA Health will be ethically and scientifically reviewed only once, irrespective of the number of Australian sites involved in the project.

Within WA Health, research involving Department of Health data collections, Aboriginal people and coronial material that require additional HREC approval, are exceptions to the once-only review for multi-centre research and applications must be referred to the relevant ethics committees **(Intro 4)**. Contact details for these HRECs are available on the Department of Health Research Development (ethics) website.

In accordance with the SOPs, WA Health sites must accept the ethical and scientific review undertaken by their local HREC or where relevant, another Lead HREC as sufficient ethical and scientific review for the purposes of the multi-centre projects conducted at sites under their control. In addition, Health Services and the Department of Health must implement the research governance procedures for the authorisation and ongoing monitoring of research projects conducted at their sites or accessing their participants, tissue or data.

2. Scope

In accordance with the "WA Health Research Governance Policy and Procedures" 2012, these standard operating procedures apply to human research:

- conducted within WA Health by WA Health employees (including visiting medical officers, visiting health professionals, contractors, consultants, agents and volunteers) and non-WA Health employees (including clinical and non-clinical university academics) who propose to undertake, manage, review and govern human research; and/or
- involving participants, their tissue or data accessed through WA Health.

2.1 WA Health Single Ethical Review of Multi-centre Research

The WA Health Single Ethical Review of Multi-centre Research must be utilised when it is not applicable to use the National Approach/Mutual Acceptance. That is, when it involves a multi-centre project which is:

- conducted at sites only within WA Health; or
- conducted at sites within Australia which are not participating in the National Approach/Mutual Acceptance.

WA Health has implemented a process, whereby, all multi-centre research projects being conducted at sites under the control of WA Health or involving participants, their tissue or data accessed through WA Health must be ethically and scientifically reviewed only once, by a Lead WA Health HREC (criteria for Lead WA Health HRECs are outlined in **Intro 3.1**). The exception is those projects that require additional specialist HREC review. The specialist HRECs within WA Health are outlined in **Intro 4,** the WA Health Ethics Application Form and the WA-Specific Module. WA Health sites must accept the ethical and scientific review undertaken by their associated HREC or where relevant, another Lead WA Health HREC as sufficient review for the purposes of the multi-centre projects conducted at sites under their control.

The WA Health Single Ethical Review of Multi-centre Research process applies to:

- all multi-centre research projects being conducted at sites under the jurisdiction of WA Health or involving participants, their tissue or data accessed through WA Health; and
- all categories of human research, irrespective of risk, including basic, clinical, health services and public health research.

If the WA Health Single Ethical Review process is extended to organisations external to WA Health (e.g. WA universities) through a reciprocal approval process, then the arrangement must be documented in a written agreement.

2.2 National Approach

The NHMRC has implemented a process, whereby, all multi-centre research projects being conducted at sites (participating in the National Approach) within Australia must be ethically and scientifically reviewed only once by a NHMRC Certified Lead HREC (criteria for Certified Lead HRECs are outlined in **Intro 3.2**). The exception is those projects that require additional specialist review. The specialist HRECs within WA are outlined in the WA-Specific Module which must be completed for the National Approach.

Institutions participating in the National Approach can be from public or private organisations, including universities. Institutions can participate in the National Approach as either Lead HRECs or 'accepting institutions' (refer to **Intro 3.2**).

The National Approach to Single Ethical Review of Multi-centre Research process applies to:

- all multi-centre research projects being conducted at sites within Australia (participating in the National Approach); and
- all categories of human research, irrespective of risk, including clinical trials, interventional clinical research, population/public health, paediatric, Aboriginal and justice health.

Documents related to the National Approach are available from the NHMRC Human Research Ethics Portal **(HREP)** and include:

- National, State & Territory Legislative Framework for ethical review of multi-centre research;
- Framework for Monitoring;
- Research Governance Handbook: Guidance for the national approach to single ethical review;
- Flowchart;
- Roles and Responsibilities in Single Ethical Review of Multi-Centre Research; and
- Best Practice Guidance of Information Sharing Activities.

2.3 National Mutual Acceptance

The State/Territory governments of Australia have signed a Memorandum of Understanding **(MoU)** to implement a version of the National Approach which is restricted to public health organisations and the single ethical review of clinical trials, known as the National Mutual Acceptance. Under this process, all multi-centre clinical trials being conducted at sites (participating in the National Mutual Acceptance) within Australia must be ethically and scientifically reviewed only once by a NHMRC Certified Lead HREC (participating in the National Mutual Acceptance - criteria for Certified Lead HRECs are outlined in **Intro 3.3**).The exception is those clinical trials that require additional specialist review. The specialist HRECs within WA Health are outlined in **Intro 4** and the WA-Specific Module which must be completed for the National Mutual Acceptance.

The National Mutual Acceptance of Ethical and Scientific Review of Multi-centre Clinical Trials process applies to all multi-centre clinical trials[1] being conducted at public health organisation sites (participating in the National Mutual Acceptance) within Australia.

Documents related to the National Mutual Acceptance are available from the Research Development (Multi-centre research) website and include:

- National, State & Territory Statutory and Administrative Frameworks for ethical review of multi-centre research;
- Monitoring and Reporting Tables;
- Mutual Acceptance Information Brochure;
- Factsheet;
- Standard Principles for Operations; and
- Standard Participant Information and Consent Forms.

3. Lead WA Health Human Research Ethics Committees

3.1 WA Health Single Ethical Review of Multi-centre Research

The following WA Health HRECs are registered with the NHMRC's Australian Health Ethics Committee **(AHEC)**, and are designated as Lead WA Health HRECs who have the ability to conduct the ethical and scientific review (within their area of expertise) of multi-centre human research projects on behalf of WA Health:

- North Metropolitan Area Mental Health Services Human Research Ethics Committee [EC00273];
- Princess Margaret Hospital for Children Ethics Committee [EC00268];
- Royal Perth Hospital Human Research Ethics Committee [EC00270];
- Sir Charles Gairdner Group Human Research Ethics Committee [EC00271];
- South Metropolitan Health Service Human Research Ethics Committee [EC00265];
- WA Country Health Service Board Research Ethics Committee [EC00261]; and
- Women and Newborn Health Service Ethics Committee [EC00350].

A WA Health HREC does not require certification under the National Certification Scheme to be a Lead WA Health HREC but must have expertise in the relevant category[2] of research as outlined in Table 1.

Within WA Health, the Department of Health WA HREC, which is registered with the NHMRC's AHEC, operates as a specialist HREC; and will not operate as a Lead WA Health HREC under the WA Health Single Ethical Review process. Research projects involving the use or disclosure of personal

[1] Some phases of clinical trials are restricted from single ethical review in other Australian jurisdictions; refer to the relevant State/Territory Government guidelines.

[2] Research categories are based on the National Certification Scheme research categories available on Human Research Ethics Portal.

information from the Department of Health data collections and/or data linkage require review by the Department of Health WA HREC regardless of whether they have been reviewed by a Lead WA Health HREC.

The Lead WA Health HREC (which has expertise in the relevant category of research as outlined in Table 1) must be selected according to the following criteria in descending order. That is, the HREC:

- is associated with the site at which the Coordinating Principal Investigator **(CPI)**[3] will be conducting the research; and
- if this is not applicable, the selection of the Lead HREC is at the discretion of the CPI.

Contact details for the Lead WA Health HRECs and associated sites are available on the Research Development (ethics) website.

Table 1: WA Heath HREC's Categories of Expertise

WA Health HREC	Expertise in research category
North Metropolitan Area Health Service, Mental Health Human Research Ethics Committee	Clinical interventional research other than clinical trials, Clinical trials – Phase III, Clinical trials – Phase IV, Mental health, Population health and/or public health, Qualitative health research.
Princess Margaret Hospital for Children Ethics Committee	Clinical interventional research other than clinical trials, Clinical trials – Phase I, Clinical trials – Phase II, Clinical trials – Phase III, Clinical trials – Phase IV, Mental health, Other clinical research, Paediatric research, Population health and/or public health, Qualitative health research.
Royal Perth Hospital Human Research Ethics Committee	Clinical interventional research other than clinical trials, Clinical trials – Phase I, Clinical trials – Phase II, Clinical trials – Phase III, Clinical trials – Phase IV, Mental health, Population health and/or public health, Qualitative health research.
Sir Charles Gairdner Group Human Research Ethics Committee	Clinical interventional research other than clinical trials, Clinical trials – Phase I, Clinical trials – Phase II, Clinical trials – Phase III, Clinical trials – Phase IV, Population health and/or public health, Qualitative health research.
South Metropolitan Health Service Human Research Ethics Committee	Clinical interventional research other than clinical trials, Clinical trials – Phase I, Clinical trials – Phase II, Clinical trials – Phase III, Clinical trials – Phase IV, Mental health, Population health and/or public health, Qualitative health research.
WA Country Health Service Board Research	Clinical interventional research other than

[3] If the CPI is not associated with a site in WA Health, the site must be chosen where a WA Health Principal Investigator is conducting the research.

Ethics Committee	clinical trials, Population health and/or public health, Qualitative health research, Rural and/or remote health research.
Women and Newborn Health Service Ethics Committee	Clinical interventional research other than clinical trials, Clinical trials – Phase I, Clinical trials – Phase II, Clinical trials – Phase III, Clinical trials – Phase IV, Population health and/or public health, Qualitative health research Women's health (midwifery, neonatal, perinatal).

3.2 National Approach

The Australian HRECs which have been certified by the NHMRC as Certified Lead HRECs, have the ability to conduct the ethical and scientific review (within their area of expertise) of multi-centre human research projects on behalf of 'accepting institutions' within Australia including WA Health. Certified Lead HRECs, their area of expertise and their contact details are listed on the HREP. Organisations outside WA Health will have to be contacted directly to establish whether they are 'accepting institutions'.

WA Health institutions' ethical review processes that are certified by the NHMRC under the National Approach will participate in this process as either a Certified Lead HREC or an 'accepting institution' once approval has been granted by the Director General of Health. Institutions with a Certified Lead HREC must accept the ethical and scientific review undertaken by their own HREC, or where relevant, another Certified Lead HREC, as sufficient review for the purposes of the multi-centre projects conducted at sites under their control.

WA Health institutions that are not certified will become 'accepting institutions' (but cannot act as Certified Lead HRECs) under the National Approach, once approval has been granted for this process by the Director General of Health. An 'accepting institution' must accept the ethical and scientific review undertaken by a Certified Lead HREC as sufficient review for the purposes of the multi-centre projects conducted at sites under their control.

For research conducted within WA Health the Certified Lead HREC (which has expertise in the relevant category of research) must be selected according to the following criteria in descending order. That is, the HREC:

- is associated with the site at which the CPI[4] will be conducting the research; and
- if this is not applicable, the selection of the Lead HREC is at the discretion of the CPI.

Certified Lead HRECs must ensure they are aware of legislation related to specific jurisdictions as outlined in the NHMRC "National, State & Territory Legislative Framework for ethical review of multi-centre research" 2012. WA Health certified and 'accepting institutions' must ensure that they are aware of the liabilities attributed to Certified Lead HRECs and 'accepting institutions' as outlined on the NHMRC HREP and ensure they have adequate research governance measures in place.

3.3 National Mutual Acceptance

The State/Territory government (public health) HRECs which have been certified by the NHMRC as Certified Lead HRECs (for clinical trials) have the ability to conduct the ethical and scientific review (within their area of expertise) of multi-centre clinical trials on behalf of 'accepting institutions' within the Australian public health organisations including WA Health. Certified Lead HRECs, their area of expertise and their contact details are listed on the NHMRC HREP. Public health organisations participating in the MoU as either Certified Lead HRECs or 'accepting institutions' are listed on the

[4] If the CPI is from outside WA Health then the Certified Lead HREC must be selected in accordance with the applicable jurisdictional requirements.

jurisdictional websites; for WA Health refer to the Research Development (Multi-centre research) website.

The same processes apply for Certified Lead HRECs, 'accepting institutions' and selecting a Lead HREC as the National Approach (refer to **Intro 3.2**). Certified Lead HRECs must ensure they are aware of legislation related to specific jurisdictions as outlined in the "National, State & Territory Statutory and Administrative Frameworks for ethical review of multi-centre research" 2013 available on each jurisdiction's website.

4. Specialist Human Research Ethics Committees

Within WA Health, (as outlined in "WA Health Research Governance Policy and Procedures" 2012 and WA-Specific Module) certain research projects will require additional review by specialist HRECs regardless of whether or not they have been, or are to be, reviewed by a Lead HREC[5]. These include:

- the Western Australian Aboriginal Health Ethics Committee for health and medical research projects where Aboriginality is a key determinant or are explicitly directed at Aboriginal people;
- the Coronial Ethics Committee WA for research projects that require access to coronial samples, data or information; and
- the Department of Health WA HREC for all research projects that require the use and disclosure of personal information from the Department of Health data collections or data linkage.

Within WA, research projects which will require additional review by specialist HRECs regardless of whether or not they have been, or are to be, reviewed by a Lead HREC are outlined in the WA-Specific Module.

In other States/Territories, the multi-centre research projects which require additional specialist review (i.e. are excluded from the single ethical review process) are listed on the jurisdictional websites and documented in the National Mutual Acceptance Fact Sheet.

5. Ethics Review

All multi-centre projects must have an Australian CPI who will coordinate the Lead HREC review of the project and/or any amendments; progress reporting requirements as specified by the approving Lead HREC; report any serious adverse events; and communicate with all the site Principal Investigators **(PIs)**, funders or sponsors.

According to the National Statement (Chapter 5.3), where a WA Health site decides to rely on the ethical review by a HREC it has not established, the institution (through the site PI), must undertake to identify any local circumstances relevant to the ethical review of the research, disclose these circumstances to the Lead HREC (through the CPI), and provide for their management. The local circumstances relevant to the ethical review of the research must be outlined in the ethics application form and be included in the application by the CPI, on behalf of the PI, to the Lead HREC. The CPI must provide a copy of the ethics application form to the PI and maintain ongoing dialogue regarding the research as needed. The CPI must communicate the outcome of the ethical review to the PI to include in the governance application. This process is outlined in the NHMRC "Flowchart of Single Ethical Review Process for Multi-centre Research".

The National Ethics Application Form **(NEAF)** plus WA-Specific Module must be used for ethics applications utilising the National Approach/Mutual Acceptance. For applications utilising the WA Health Single Ethical Review process the WA Health Ethics Application Form may be used as an alternative to using the NEAF and WA-Specific Module.

[5] Lead HREC refers to both a Certified Lead HREC and a Lead WA Health HREC.

6. Governance Review

In accordance with the "WA Health Research Governance Policy and Procedures" 2012 human research projects cannot commence within WA Health until the PI has received written notification of authorisation by either the:

- Health Service Chief Executive/delegate to conduct research at a site or access participants, tissue or data; and/or
- Data Steward to access the Department of Health data collections.

In addition to the scientific and ethical review by a Lead HREC, all human research conducted in WA Health must undergo a governance review before authorisation can be granted. For access to the Department of Health data collections the PI must submit a data application to the Data Custodian for a data governance review before recommendation to the Data Steward. At Health Services, the PI must submit a governance application to the Research Governance Officer **(RGO)** who will assess the suitability of a research project to be conducted at/or access a site before recommendation to the Chief Executive/delegate, this must involve either:

- a Site Specific Assessment **(SSA)** for research projects conducted at the site; or
- an Access Request Review for research that is not conducted at the site but requires access to the site's participants, their tissue or data.

If the research is authorised to be conducted at/or access a site the PI must inform the CPI when the research commences. The CPI can then inform the Lead HREC Ethics Office. The Health Service (through the PI and RGO), Department of Health WA HREC (if applicable) and the Lead HREC must implement monitoring of the research.

7. WA Health Research Governance Service

The WA Health Research Governance Service **(RGS)** and Research Governance Portal **(RGP)** (once available) will be used to support the WA Health Single Ethical Review and National Approach/Mutual Acceptance processes. This information technology **(IT)** system will assist investigators, ethics and governance personnel to manage applications through the ethics and governance review process; and monitoring of the research projects once they have commenced. The RGS will have the ability to insert digital signatures for authorisation of applications. Users of the system should refer to the RGS on-line guidelines for more detailed instructions of how to use the system.

NB: The estimated availability of the RGS and RGP is 2014. Until the IT system is developed, any submission/review processes documented in these SOPs will be manual (i.e. normal email or hard copy processes will apply). The application forms must be sent to the Lead HRECs or RGOs in accordance with their SOPs.

8. Fees

HREC and Research Governance administrative fees will be levied for all commercially sponsored research. Fees for HREC review and Research Governance Officer review within WA Health are available from the Ethics Executive Officers **(EEOs)** and RGOs respectively; contact details are available from the Research Development website. These fees are reviewed annually. Standard WA Health Fees will be charged in accordance with 18(2a) of the *Hospitals and Health Services Act 1927* (WA), that is, the Minister for Health must give approval for the provision of services to a person or body, including payment for those services.

9. Implementation

The Department of Health and Health Services are required to operate in accordance with the "WA Health Research Governance Policy and Procedures" 2012 and the WA Health Research Governance and Single Ethical Review SOPs. The SOPs do not override any requirements of the policy. The Department of Health and Health Services may develop additional local operating procedures to address local detail and procedural requirements. It is expected that where the Department of Health or Health Services amend the SOPs to reflect local matters, that the amendments will extend the requirements of the WA Health Research Governance and Single Ethical Review SOPs.

10. Acronyms/Definitions Used Within This Document

Aboriginal	The use of the term "Aboriginal" within this document refers to both Aboriginal and Torres Strait Islander people.
Access Request Review	A mechanism used by WA Health to ensure that the proposed research project complies with governance requirements, and gives consideration whether to support the provision of access to participants, their tissue or data through the Health Service.
Australian Business Number (ABN)	A unique identifying number that businesses use when dealing with other businesses.
Australian Health Ethics Committee (AHEC)	The committee that advises the National Health and Medical Research Council on ethical issues related to health.
Australian Prudential Regulation Authority (APRA)	The prudential regulator of banks, insurance companies and superannuation funds, credit unions, building societies and friendly societies.
Business Manager	The individual who is responsible to the Health Service's Department, Division, site or Region for financial information, advice on financial management information systems, financial advice on implications and risks of current and projected services and future financial management strategy within their area of responsibility.
Certified Lead HREC	A HREC certified by the NHMRC (from WA or other jurisdictions) to conduct the single ethical and scientific review of multi-centre human research on behalf of WA Health, utilising the National Approach and National Mutual Acceptance processes.
Clinical Data Registry Agreement (CDRA)	A written agreement between two or more parties, which sets out the responsibilities of each party. WA Health uses a standard CDRA. The CDRA contains common, standard provisions based on the Medicines Australia Clinical Trial Research Agreements and should, in most cases, reduce the need for institutions to obtain extensive legal advice in negotiating a CDRA.
Clinical Investigation Research Agreement (CIRA)	A written agreement between two or more parties, which sets out the responsibilities of each party. WA Health uses a standard CIRA. Based on the Medical Technology Association of Australia version, the CIRA contains common, standard provisions and should, in most cases, reduce the need for institutions to obtain extensive legal advice in negotiating a CIRA.
Clinical Trial	A form of human research designed to find out the effects of an intervention, including a treatment or diagnostic procedure. A clinical trial can involve testing a drug, a surgical procedure, other therapeutic procedures and devices, a preventive procedure, or a diagnostic device or procedure.
Clinical Trial Exemption (CTX) Form	A form used to make an application to the Therapeutic Goods Administration under the Clinical Trial Exemption scheme, which is required for clinical investigational use of: • any medicine, biological or device not entered in the Australian Register of Therapeutic Goods, including any new formulation of an existing product or any new route of administration; or • a marketed medicine, biological or device beyond the conditions of its marketing approval, including new indications extending the use of the product to a new patient group and the extension of doses or duration of treatments outside the approved range. Under the CTX scheme the Therapeutic Goods Administration conducts an evaluation of the clinical trial and provides written advice to the Lead Human Research Ethics Committee.

Clinical Trial Notification (CTN) Form	A form used to notify the Therapeutic Goods Administration of the intent to conduct a clinical trial under the Clinical Trial Notification scheme, which is required for clinical investigational use of: • any medicine, biological or device not entered in the Australian Register of Therapeutic Goods, including any new formulation of an existing product or any new route of administration; or • a marketed medicine, biological or device beyond the conditions of its marketing approval, including new indications extending the use of the product to a new patient group and the extension of doses or duration of treatments outside the approved range. Under the CTN scheme the Human Research Ethics Committee reviews all material relating to the proposed trial.
Clinical Trial Research Agreement (CTRA)	A written agreement between two or more parties, which sets out the responsibilities of each party. WA Health uses a set of standard CTRAs. Based on the Medicines Australia versions, the CTRA contains common, standard provisions and should, in most cases, reduce the need for institutions to obtain extensive legal advice in negotiating a CTRA.
Collaborative or Cooperative Research Group (CRG)	A collaborative research group.
Commercial Clinical Trial	A clinical trial where the sponsor or Contract Research Organisation **(CRO)** is a company or organisation that takes responsibility for the initiation, management, indemnity and financing of a clinical trial and endorses the CTN or CTX form. The project protocol has been developed by the commercial entity, and it retains ownership of the product, project material and intellectual property. Consequently, the risks and liabilities associated with the trial are borne primarily by the sponsor/CRO and they must provide indemnity and insurance.
Confidentiality Agreement (CA)	A written agreement between two or more parties, which sets out the responsibilities pertaining to the privacy of each party. Parties involved are usually pharmaceutical/device companies who wish to control confidential information relating to clinical trials and investigators/institutions who undertake to keep the provided information confidential. WA Health uses a standard CA to be used by institutions.
Contract Research Organisation (CRO)	A person or organisation (commercial, academic or other) contracted by a sponsor to perform one or more of a sponsor's trial-related duties or functions.
Coordinating Principal Investigator (CPI)	The individual who takes overall responsibility for the research project and submits the project for ethical and scientific review for multi-centre projects. They are responsible for ongoing communication with the Human Research Ethics Committee and passing on any outcomes from this to the Principal Investigators. For single-centre research, the CPI and Principal Investigator's roles are synonymous.
Data Custodian	The person responsible for the ongoing development, data collection, maintenance and review of the collection. They are responsible for the quality of the data, its security, timeliness and adherence to standards.
Data Safety Monitoring Board (DSMB)	An independent data monitoring committee that may be established by the sponsor/investigator to assess at intervals the progress of a clinical trial, the safety data, and the critical efficiency endpoints, and to recommend to the sponsor whether to continue, modify or stop the trial.
Data Steward	The person responsible for setting the strategic direction of the specific data collection to ensure it's developed, maintained and utilised in accordance with WA Health strategic goals. They authorise the access, use and disclosure of data from the data collection for purposes that comply with WA Health's statutory obligations.
Department of Health	A department within WA Health responsible for developing health policy across WA Health.

Ethics	As defined in the National Statement (Section 1).
Ethics Executive Officer (EEO)	The individual appointed within the Health Service who is responsible for providing administrative support to the HREC and their subcommittees regarding the scientific and ethical review and ongoing monitoring of research projects.
Grants	Arrangements of financial assistance. Funds provided for a single discrete specified purpose and period and not constituting the entire financial base of an organisation.
Health Corporate Network (HCN)	A service within WA Health which provides human resources, supply, finance and reporting and business systems services to WA Health.
Health Service	A health service within WA's public health system, governed by a council made up of community members and clinicians selected by the Minister for Health. There are five Health Services responsible for the management and delivery of services within WA Health, these include: • South Metropolitan Health Service; • North Metropolitan Health Service; • Southern Country Health Service; • Northern and Remote Country Health Service; and • Child and Adolescent Health Service.
Human Research Ethics Portal (HREP)	A web based Human Research Ethics Portal which hosts information on the National Approach to Single Ethical Review.
Human Research Ethics Committee (HREC)	A Human Research Ethics Committee constituted under the guidance of the National Statement to conduct the ethical and scientific review of a human research project and registered with the NHMRC's AHEC.
Intellectual Property (IP)	IP means the legal rights which result from intellectual activity in the industrial, scientific, literary, artistic, musical and dramatic fields and includes all rights, including, without limitation: (a) patents, copyright (including moral rights), rights in circuit layouts, plant breeders' rights, registered designs, trade marks, and the right to have trade secrets kept confidential; (b) any application or right to apply for registration of any of those rights; and (c) any rights which may be introduced or come into existence through international and national laws.
Information technology (IT)	The application of computers and telecommunications equipment to store, retrieve, transmit and manipulate data.
Lead HREC	Refers to both a Certified Lead HREC and a Lead WA Health HREC.
Lead WA Health HREC	A WA Health HREC that is able to conduct the single ethical and scientific review of multi-centre human research on behalf of WA Health, when it is not applicable to use the National Approach/Mutual Acceptance. The Lead WA Health HREC is registered with the NHMRC's AHEC and identified in the WA Health Research Governance Single Ethical Review Standard Operating Procedures (Table 1).
Legal & Legislative Services (LLS)	A Directorate within the Department of Health, responsible for providing legal services to WA Health.
Medicines Australia (MA)	The national association that represents companies in the pharmaceutical industry.
Medical Technology Association of Australia (MTAA)	The national association representing companies in the medical technology industry.
Memorandum of Understanding (MoU)	A document describing a bilateral or multilateral agreement between two or more parties.
Multi-Centre Research	Research that is conducted at more than one site within the authority of more than one HREC.

National Approach to Single Ethical Review of Multi-Centre Research (National Approach)	The National Approach to Single Ethical Review of Multi-centre Research is a process to enable the single ethical review of multi-centre research, within or across Australian jurisdictions, utilising the NHMRC's certified ethical review processes. This process was formerly known as the Harmonisation of Multi-centre Ethical Review (HoMER) initiative.
National Ethics Application Form (NEAF)	The NEAF is the NHMRC's national, web-based application form for investigators of all disciplines to complete research ethics proposals for submission to HRECs.
National Health & Medical Research Council (NHMRC)	The national organisation responsible for health and medical research funding and development of advice.
National Mutual Acceptance of Ethical and Scientific Review of Multi-centre Clinical Trials (National Mutual Acceptance)	The National Mutual Acceptance of Ethical and Scientific Review of Multi-centre Clinical Trials is a process to enable the single ethical review of multi-centre clinical trials, within or across Australian public health organisations.
National Statement	NHMRC's "National Statement on Ethical Conduct in Human Research" 2007
Non-Commercial Clinical Trial	A clinical trial which is investigator-initiated and can be unsponsored, sponsored, involve grants or be part of a CRG. The CPI, PI, CRG or the site is the primary author and custodian of the trial protocol and is responsible for the initiation, management, financing and IP of the trial. Although these projects are not sponsored by a commercial entity; industry or a non-commercial organisation may provide some funding or product support for the trial. In the case of non-commercial trials, the project material and IP typically rests with primary author and custodian of the trial protocol. Typically the indemnity and insurance is mutual or specifically tailored to the risks and liabilities associated with the project
Non-HREC level alternative	A person or body (e.g. subcommittee or delegate) that conducts an ethical review of a research project which is an alternative to that of a full HREC.
North Metropolitan Health Service (NMHS)	A Health Service within WA Health.
Patient Information Sheet and Consent Form (PICF)	A document providing information and the ability to provide consent for participants involved with a research project.
Principal Investigator (PI)	The individual responsible for the overall conduct, management, monitoring and reporting of research conducted at a site and who submits the research project for site authorisation. For single-centre research, CPI and PI roles are synonymous.
Project Reference Number (PRN)	The unique project number allocated to a research project processed through the WA Health Research Governance Service IT system.
Project Completion	When no further contact with participants/data source is foreseen including the data analysis and reporting period.
Quality Improvement (QI) Audit	A project designed to define optimum therapeutic methods, benchmarks and goals and is the means of ensuring via retrospective or prospective audit, that this aim is being achieved.
Recipient Created Tax Invoice (RCTI)	An invoice issued by the recipient of the supply 'on behalf' of the supplier.
Research	Original investigation undertaken to gain knowledge, understanding and insight as described in the NHMRC "Australian Code for the Responsible Conduct for Research" 2007.
Research Department	The department within WA Health which is associated with the PI and is undertaking the major component of the research project.
Research Governance	The framework through which WA Health implements the principles, requirements and standards of research. It addresses protection of research participants, the safety and quality of research, privacy and

	confidentiality, financial probity, legal and regulatory matters, risk management and monitoring arrangements and promotes good research culture and practice. The governance of research will ensure that its delivery meets its objectives and conforms to relevant institutional, jurisdictional and national ethical, scientific, regulatory and professional standards and applicable laws.
Research Governance Officer (RGO)	The individual appointed within the Health Service who is responsible for the review and management of research governance site specific applications involving site authorisation and oversight of authorised research projects.
Research Governance Portal (RGP)	A secure web-based portal that is part of the WA Health Research Governance Service information technology system that enables investigators to electronically complete their applications for ethical, scientific and governance review, required for research authorisation and ongoing monitoring requirements. *Estimated availability 2014.*
Research Governance Service (RGS) Information Technology System	A research governance IT system that supports the workflow and reporting required for research governance processes. It allows investigators to complete and submit their applications for the authorisation and monitoring of research through the online RGP. All details on the ethics and governance submission can be electronically downloaded into the RGS IT system for processing and review by the EEO, HREC, RGO and the site. *Estimated availability 2014.*
RiskCover	A division of the Insurance Commission of Western Australia, a statutory body created to manage and administer the self-insurance fund of the Western Australian Government Public Authorities and to promote risk management throughout State Government agencies.
Serious Adverse Device Event (SADE)	Any untoward medical occurrence in human device trials that results in death, is life threatening, requires hospitalisation, results in disability or requires intervention to prevent permanent impairment/damage.
Serious Adverse Event (SAE)	Any untoward medical occurrence in human drug trials that at any dose results in death, is life threatening, requires hospitalisation, results in disability, abnormality or requires intervention to prevent permanent impairment/damage.
Suspected Unexpected Serious Adverse Reaction (SUSAR)	Serious adverse reactions in participants given a drug that may or may not be dose related, but are unexpected, as they are not consistent with current information.
Site	A facility, location or service (e.g. hospital, institution, community based clinic) where the research is being conducted within a Health Service.
Site Authorisation	The authorisation granted by the Chief Executive or delegate of the Health Service for the commencement of a research project at the site.
Site Specific Assessment (SSA)	A mechanism used by WA Health to ensure that the proposed research project complies with governance requirements, and to consider whether the research must be conducted and supported at the proposed site.
Sixty (60) calendar day time frame	The maximum period of calendar days, measured separately, for ethics and governance review of new/amendment applications and includes: • the ethics timeframe measured from the Lead HREC application closing date (for a valid application) to the date of final written notification to the CPI of the ethical opinion on the research project; and • the governance timeframe measured from the research governance application submission date (for a valid application) to the date of final written notification to the PI of the authorisation to conduct the research project. This excludes the time during which a Lead HREC/RGO is awaiting a response from the CPI/PI to a request by that Lead HREC/RGO for additional information.

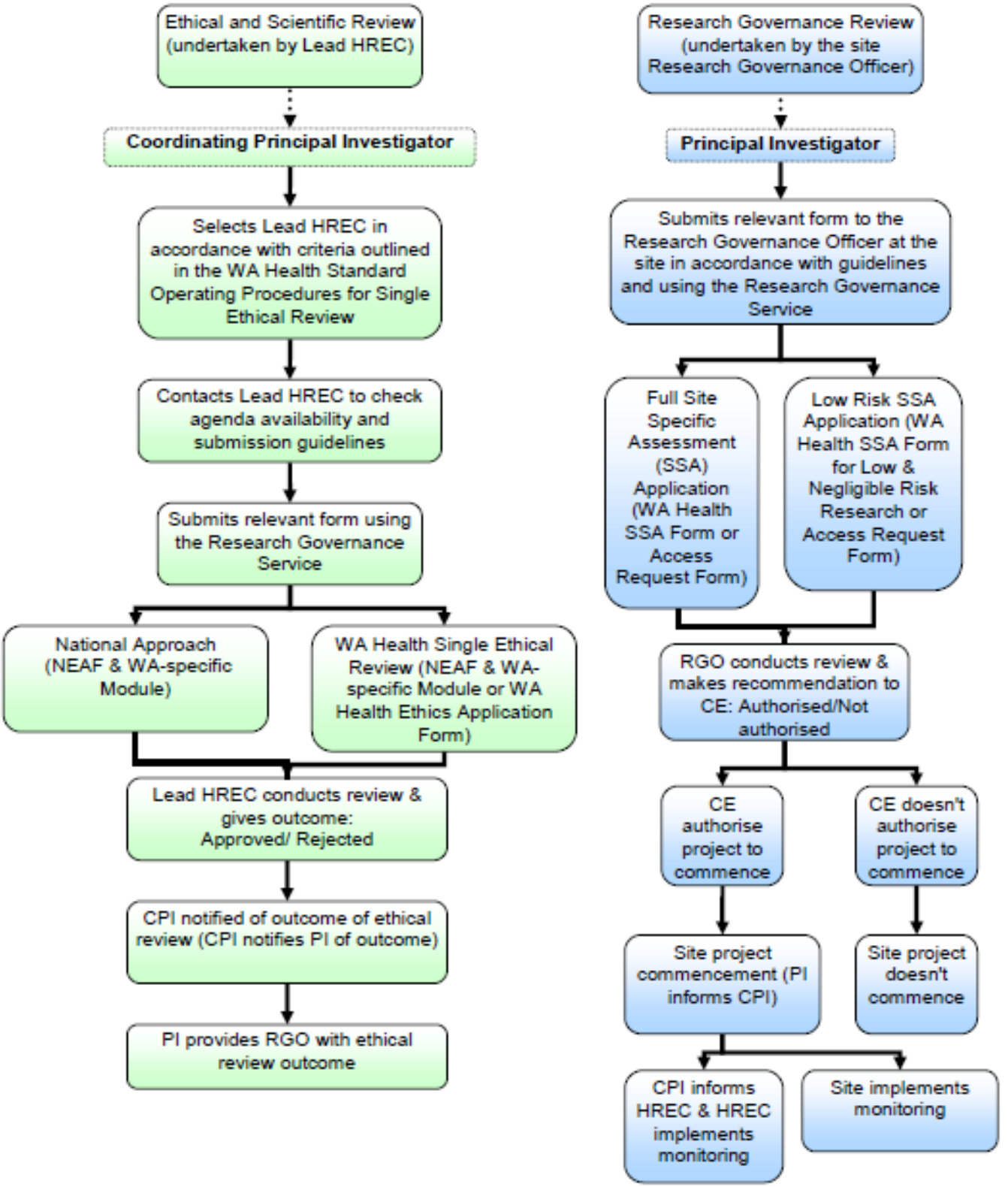
South Metropolitan Health Service (SMHS)	A Health Service within WA Health.
Sponsor	An entity that provides funding for a research project. A sponsor may be a pharmaceutical/technology company, CRO, collaborative research group or institution (if an investigator-initiated project).
Standard Operating Procedures (SOPs)	The documented procedures and processes supporting the WA Health Research Governance Policy and Procedures as published by WA Health, the Department of Health or a Health Service.
Supporting Departments	Health Service departments that are not specifically conducting the research project within their department but will be providing services to support the research project (e.g. pharmacy, pathology and imaging).
The Code	NHMRC, Australian Research Council and Universities Australia "Australian Code for the Responsible Conduct of Research" 2007.
Therapeutic Goods Administration (TGA)	The organisation in Australia that is responsible for the regulation of therapeutic goods (medications and devices).
Unanticipated Serious Adverse Device Events (USADE)	Serious adverse device events in participants involved with a device trial, that are unexpected, as they are not consistent with current information.
User Identification Number (ID)	The unique identifier for each user accessing the WA Health Research Governance Service IT system.
WA Country Health Service (WACHS)	The use of the term WA Country Health Service within this document includes both the Southern Country Health Service and the Northern and Remote Country Health Service.
WA Health	A phrase used to represent the Western Australian public health system including all health systems and hospitals. It includes the five Health Services (South Metropolitan Health Service, North Metropolitan Health Service, Southern Country Health Service, Northern and Remote Country Health Service and Child and Adolescent Health Service) and the Department of Health.
WA Health Single Ethical Review	An initiative intended to expedite the approval of multi-centre research projects by ensuring that the research project conducted under the authority of more than one WA Health HREC must undergo single ethical review by a Lead WA Health HREC.

11. Review

The Standard Operating Procedures will be reviewed every five years unless there are changes to WA Health corporate or research governance directives.

Endorsed by:	Professor Bryant Stokes, A/Director General, Department of Health
Review Date:	30 July 2018. This document remains effective until a subsequent version is endorsed by the Director General.
Accessing Standard Operating Procedures	via the Whole of Health Operational Directives and Information Circulars link at: http://www.health.wa.gov.au/circularsnew/ or the Research Development link at: http://www.health.wa.gov.au/researchdevelopment/home/research_framework.cfm
Primary Contact:	Research Development Unit

12. Figure 1: Overview of Research Governance and Single Ethical Review Process



SOP 01: Role of the Coordinating Principal Investigator, Principal Investigator, Ethics Executive Officer and the Research Governance Officer

Purpose: To describe the roles and responsibilities of the Coordinating Principal Investigator, the Principal Investigator, Ethics Executive Officer and the Research Governance Officer in the single ethical review process in addition to those outlined in the Department of Health "WA Health Research Governance Policy and Procedures" 2012.

Coordinating Principal Investigator

1.1 For a multi-centre research project, the CPI takes overall responsibility for conducting and monitoring a research project. The CPI is responsible for the submission of an application (with input from the PIs) to the Lead HREC for ethical and scientific approval of the research project; ensuring any specific review requirements are met **(SOP 05)**. If the CPI is conducting the research within WA Health, or requiring access to a WA Health site any conflicts of interest must be declared in the **WA Health Research Conflict of Interest Form** **(SOP 12.9),** available from the RGS and Research Development (governance) website.

1.2 The research team must select an Australian CPI for a multi-centre research project in communication with the research sponsor (if applicable). The CPI must be determined prior to submission of an application to the Lead HREC.

1.3 If the CPI is conducting research at a WA Health site and they are not a WA Health employee they must be working under an agreement between their employing organisation and WA Health. In addition, a **WA Health Declaration of Confidentiality** (as applicable) must be completed, available from the RGS and Research Development (governance) website.

1.4 If the multi-centre research project requires support from a Health Service in the form of access to participants, tissue or data but does not involve the conduct of research at that Health Service, the CPI is responsible for submitting an **Access Request Form** to the relevant RGO **(SOP 11)** available from the RGS and Research Development (governance) website.

1.5 Once the project is authorised to commence, the CPI is responsible for ensuring:

- the distribution of Lead HREC approval documents to the site PIs;
- the adherence to reporting and monitoring standards **(SOP 27)**, including the prompt response to protocol deviations/violations and adverse events **(SOP 29)**, and complaints **(SOP 30)**;
- the submission and communication of all results and notifications to the Lead HREC including annual progress/final reports **(SOP 28)**, amendments **(SOP 24)** and notification of early project termination **(SOP 32)**;
- ongoing communication with the Lead HREC and liaising between the Lead HREC and the PI/sponsors. The CPI may delegate in part, some of their communication responsibilities;
- if applicable, the clinical trial is registered on a publicly accessible clinical trial registry, prior to the commencement of the clinical trial;
- clinical intervention projects are conducted in accordance with credentialing privileges and experience; and
- the research project is conducted in accordance with the conditions of ethics approval, current professional (ethical and legal) standards, national guidelines, legislation and the "WA Health Research Governance Policy and Procedures" 2012.

1.6 Where a new CPI is to be appointed, the Lead HREC must be notified in writing by the departing CPI through the Ethics Administrative Amendment **(SOP 24)** process.

Principal Investigator

1.7 For a multi-centre project the PI (who may also be the CPI) is responsible for the overall conduct, management, monitoring and reporting of the research project at the site and for the governance application required for the authorisation of research at the site **(SOP 22)**. Any conflicts of interest must be declared in the **WA Health Research Conflict of Interest Form,** available from the RGS and Research Development (governance) website.

1.8 If the PI is conducting research at a WA Health site and they are not a WA Health employee they must be working under an agreement between their employing organisation and WA Health. In addition, a **WA Health Declaration of Confidentiality** (as applicable) must be completed, available from the RGS and Research Development (governance) website.

1.9 The PI is responsible for ongoing communication with the CPI, RGO and sponsor/Contract Research Organisation **(CRO)**. The PI may delegate in part, some of their communication responsibilities. Any communication between the PI and the Lead HREC must be through the CPI, except for extenuating circumstance where a delay in reporting urgent serious adverse events could lead to a safety issue.

1.10 Where a WA Health site is reliant on the ethical review by a HREC it has not established, the PI must undertake to identify any local circumstances relevant to the ethical review of the research, disclose these circumstances to the Lead HREC (through the CPI) and provide for their management.

1.11 The PI is responsible for preparing and providing information for participants at a local level that relates specifically to the site e.g. the Participant Information Sheet and Consent Forms **(PICFs)**.

1.12 Once the project is authorised to commence, the PI is responsible for ensuring:

- the CPI is notified when the research project has commenced at the site;
- the adherence to reporting and monitoring standards **(SOP 27)**, including the prompt response to protocol deviations/violations and adverse events **(SOP 29)** and complaints **(SOP 30)**;
- the submission and communication of all results and notifications to the RGO including Lead HREC outcomes/changes, annual progress/final reports **(SOP 28)**, amendments **(SOP 25)** and notification of early project termination **(SOP 32)**;
- relevant site specific information is relayed to the sponsor and Lead HREC (through the CPI);
- clinical intervention projects are conducted in accordance with credentialing privileges and experience; and
- the research project is conducted in accordance with the conditions of ethics approval, current professional (ethical and legal) standards, national guidelines, legislation and the "WA Health Research Governance Policy and Procedures" 2012.

1.13 Where a new PI is to be appointed, the relevant RGO must be notified in writing by the departing PI through the Governance Administrative Amendment **(SOP 25)** process.

Ethics Executive Officer

1.14 For a multi-centre project the EEO is responsible for the administrative support for the subcommittees/Lead HREC. They are responsible for providing communication between the subcommittees/Lead HREC and the CPI (delegate) regarding the application for ethical and scientific review and, once approved, the ongoing monitoring and reporting related to the research project. In exceptional circumstances the EEO may communicate directly with the PIs and RGOs (e.g. safety issue). The WA Health EEO must use the RGS to provide WA Health RGOs with a copy of correspondence regarding ethical outcomes. Contact details for WA Health EEOs are on the Research Development (ethics) website.

1.15 Responsibilities of the EEO will include:

Pre-authorisation

- advising and liaising with investigators, sponsors and other stakeholders regarding the appropriate ethics documentation, fees and the preparation of applications for ethics approval;
- validation of the ethics application **(SOP 06)** prior to being reviewed by the subcommittee/Lead HREC;
- documenting any subcommittee/Lead HREC decisions following ethical review and maintaining a current record on the RGS; and
- facilitating the invoicing of appropriate fees for ethical review.

Post-authorisation

- managing and reviewing amendments to authorised research projects;
- maintain an oversight of authorised research projects through facilitating Lead HREC review of annual and final progress reports and safety reports submitted by the CPI;
- preparing reports to the NHMRC;
- managing complaints, misconduct and conflicts of interest related to the Lead HREC or project;
- communicating with a wide range of stakeholders in the research community by providing information, education and high level advice on the ethical component of research governance;
- maintaining records, including databases and filing systems; and
- monitoring relevant regulatory and policy developments to ensure changes are incorporated into local policies and procedures.

1.16 The EEO is required to ensure that investigators are aware of and compliant with relevant laws, policies and codes of conduct namely:

- Therapeutic Goods Administration's **(TGA)** "Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95)" 2000;
- NHMRC, Australian Research Council and Australian Vice-Chancellors Committee "National Statement on Ethical Conduct in Human Research" 2007 – Updated 2009;
- NHMRC, Australian Research Council and Universities Australia "Australian Code for the Responsible Conduct of Research" 2007 **(the Code)**; and
- Department of Health "WA Health Research Governance Policy and Procedures" 2012.

Research Governance Officer

1.17 The RGO is responsible for management of applications for site authorisation and monitoring of authorised research projects within their jurisdiction. The RGO is responsible for the review of site specific governance applications (including professional, regulatory, ethical, contractual and financial documentation) and making a recommendation to the Chief Executive/delegate to authorise/not authorise the conduct of a research project at a site(s). Once the project is approved, the RGO is responsible for the ongoing monitoring and reporting at the site(s).

1.18 Responsibilities of the RGO will include:

Pre-authorisation

- advising and liaising with investigators, sponsors and other stakeholders regarding the appropriate governance documentation, fees and the preparation of applications for site authorisation;
- assessing applications and managing the process of site authorisation; and
- facilitating the invoicing of appropriate fees for site authorisation.

Post-authorisation

- managing and reviewing amendments to authorised research projects;
- maintaining an oversight of authorised research projects through review of annual and final progress reports submitted by the PI;
- conducting or coordinating audits of research projects, where required;
- preparing reports to regulatory bodies, as required;
- communicating with a wide range of stakeholders in the research community by providing information, education and high level advice on research governance;
- maintaining records, including databases and filing systems; and
- monitoring relevant regulatory and policy developments to ensure changes are incorporated into local policies and procedures.

1.19 The RGO is required to ensure that investigators are aware of and compliant with relevant laws, policies and codes of conduct namely:

- Therapeutic Goods Administration's "Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95)" 2000;
- NHMRC, Australian Research Council and Australian Vice-Chancellors Committee "National Statement on Ethical Conduct in Human Research" 2007 – Updated 2009;
- NHMRC, Australian Research Council and Universities Australia "Australian Code for the Responsible Conduct of Research" 2007; and
- Department of Health "WA Health Research Governance Policy and Procedures" 2012.

1.20 The Health Services and Department of Health are responsible for adequately resourcing their own staff in this position, determining responsibility for this role and establishing reporting lines. Contact details for WA Health RGOs are on the Research Development (governance) website.

1.21 The RGO is responsible for the ongoing communication with the PI, the Chief Executive/delegate and the sponsor/CRO. In exceptional circumstance the RGO may communicate with the EEO (e.g. safety issue). The WA Health RGOs must use the RGS to provide the WA Health EEO with a copy of correspondence regarding governance outcomes.

SOP 02: Selection of the Lead HREC and Ethics Application Form(s)

Purpose: To outline the criteria for selecting a Lead HREC and the appropriate ethics application form(s).

2.1 Only a Lead HREC may conduct the single ethical review of a multi-centre research project conducted within WA Health utilising the WA Health Single Ethical Review, National Approach or National Mutual Acceptance processes.

2.2 Health Services must ensure information regarding their Lead HREC is publicly available on its website regarding the following:

- HREC contact details; and
- HREC meeting dates and application closing dates (for HREC and scientific subcommittees meetings).

2.3 The CPI can view the Lead HREC specific information through the RGP, including:

- HREC membership details (e.g. name, position, biography);
- HREC and EEO contact details;
- HREC certification status; and
- HREC meeting dates and application closing dates.

2.4 A Lead HREC may decline to review a research project if it is does not have sufficient expertise in the relevant category of research in accordance with the requirements of the National Statement and **SOP 2.8** and **SOP 2.12**. If a Lead HREC does decline to review a project they must advise the CPI and if possible recommend another Lead HREC.

2.5 The Lead HREC may cap the number of multi-centre research applications they are able to accept at any particular meeting. The CPI may choose to submit the application to the next available meeting or submit to another Lead HREC as long as it meets the criteria for selecting a Lead WA Health HREC in **Intro 3.1** or for selecting a Certified Lead HREC in **Intro 3.2** and **Intro 3.3**.

2.6 An ethics review fee will be charged for the review of commercial research projects by the Lead HREC within WA Health **(SOP 23)**.

WA Health Single Ethical Review

2.7 The WA Health Single Ethical Review process must be utilised in accordance with its scope as outlined in the **Intro 2.1**.

2.8 The Lead WA Health HREC must be selected by the CPI in accordance with the criteria outlined in the **Intro 3.1**. A Lead WA Health HREC may only undertake reviews of multi-centre research projects where they have expertise in the research category as outlined in **Table 1**. Contact details for Lead WA Health HRECs are available on the Research Development (ethics) website.

2.9 The CPI should contact the Lead HREC Executive Officer to discuss the research project and submission process.

2.10 The application for ethical and scientific review must be submitted (with all applicable signatures) to one Lead WA Health HREC only using one of the following forms, available from the RGS and the Research Development (ethics) website:

National Ethics Application Form plus the Western Australian-Specific Module

The NEAF can be used for ethical and scientific review irrespective of risk for both single-centre and multi-centre research projects involving humans. The WA-Specific Module must accompany ethics applications using the NEAF. This module addresses additional ethical issues, specific to WA that are not addressed in the NEAF and must be considered when

conducting both single-centre and multi-centre research in WA. The NEAF and WA-Specific Module can be accesses through the RGS, alternatively the NEAF can be completed and imported from either the NHMRC site (www.neaf.gov.au) or the other jurisdictions IT systems (www.ethicsform.org/au).

WA Health Ethics Application Form

The WA Health Ethics Application Form is available for use by investigators conducting human research projects within WA Health or accessing WA Health participants, their tissue or data. This is an alternative to completing the NEAF plus WA-Specific Module. It can be used for ethical and scientific review, irrespective of risk, for both single-centre and multi-centre research projects (except when using the National Approach/Mutual Acceptance).

National Approach/Mutual Acceptance

2.11 The National Approach and National Mutual Acceptance processes must be utilised in accordance with their scope as outlined in **Intro 2.2** and **Intro 2.3** respectively.

2.12 The Certified Lead HREC must be selected by the CPI in accordance with the criteria outlined in the **Intro 3.2** and **Intro 3.3.** A Certified Lead HREC may only undertake reviews of multi-centre research projects in accordance with their NHMRC certified research category as listed on the HREP. Contact details for WA Certified Lead HRECs are available on the Research Development (multi-centre research) website. All Australian Certified Lead HRECs are listed on the NHMRC HREP.

2.13 The CPI should contact the Certified Lead HREC EEO to discuss the research project and submission process. CPIs should be aware of the requirements of other jurisdictions i.e. the requirement to complete specific jurisdictional ethics modules in addition to the NEAF. Details of these requirements should be obtained from the PIs within those jurisdictions or from the relevant jurisdictional website.

2.14 The application for ethical and scientific review must be submitted to one Certified Lead HREC only using one of the following forms, available from the RGS and the Research Development (ethics) website:

National Ethics Application Form plus the Western Australian-Specific Module

The NEAF must be used when utilising the National Approach/Mutual Acceptance and must be accompanied by the WA-Specific Module when conducting research within WA. The NEAF and WA-Specific Module can be accessed through the RGS, or alternatively the NEAF can be completed and imported from either the NHMRC site (www.neaf.gov.au) or the other jurisdictions' IT systems (www.ethicsform.org/au).

2.15 Under the National Approach/Mutual Acceptance processes, the CPI must sign the declaration section of the NEAF. PIs are not required to sign the declaration as they will make a declaration in the SSA Form.

SOP 03: Participant Information Sheets and Consent Forms

Purpose: To describe the process for the review and approval of Participant Information Sheets and Consent Forms submitted to the Lead HREC and sites.

3.1 The NHMRC has developed standard national templates for PICFs, to serve as a guide for investigators in the formulation of PICFs for both single-centre and multi-centre research projects. Under the WA Health Single Ethical Review process investigators are encouraged (but it is not mandatory) to utilise these standardised documents which are available from the RGS and Research Development (ethics) website. Under the National Approach/Mutual Acceptance it is recommended that investigators use the NHMRC PICFs.

3.2 Both the Master and Site Master (based on the Master with specific site requirements) PICFs must be submitted using the RGS with the ethics application, to be reviewed by the Lead HREC **(SOP 05)**.

Master PICF

3.3 Where the PICF is identical (except for local contact information) for each site, the CPI (or delegate) is only required to submit a Master PICF to the Lead HREC (not one for each site).

3.4 If special consent requirements apply (e.g. consent forms for parents/guardians of children) there may be more than one Master PICF that must be submitted to the Lead HREC.

3.5 The Master PICF(s) must contain the CPI details and the required wording applicable to all project sites. The Master PICF must include the:

- letterhead of the CPI's site;
- name of the site where recruitment is to occur (CPI site);
- name and contact details of the CPI;
- name and contact details of the person dealing with complaints at the CPI's site;
- name and contact details of the Lead HREC; and
- current version date in the footer on each page.

3.6 Following Lead HREC approval, the Master PICF(s) must be used for all project sites the Lead HREC has approved. The approved document may only be modified to reflect individual sites' details. Permissible changes are:

- letterhead of the site;
- name of the site where recruitment is to occur;
- name and contact details of the site PI;
- name and contact details of the person dealing with complaints at the PI's site; and
- site name, version number and date in the footer on each page.

Site Master PICF

3.7 Where there is specific standard wording required by one or more organisations, (e.g. for religious reasons or site policy) the CPI (or delegate) must also submit a Site Master PICF (in addition to the Master PICF) for review by the Lead HREC. The Site Master PICF must be based on the Master PICF with the site-specific wording inserted and the site name and version date in the footer of each page. These changes must either be tracked or a summary of changes must be provided.

3.8 The Site Master PICF with the site-specific wording must include the:

- letterhead of the site that has the specific policy requirements;
- name of the site where recruitment is to occur (PI site);
- name and contact details of the site PI;
- name and contact details of the person dealing with complaints at that site;
- name and contact details of the Lead HREC;

- Master PICF version date (on which the Site Master PICF is based) and the Site Master PICF version date in the footer of each page; and
- front page explanatory statement, e.g. “Based on the [project title] [HREC Reference Number] Master PICF [Version date]”.

PICF Not Approved

3.9 Following review by the Lead HREC, if there are changes required to the Master PICF (and Site Master PICF), then the PICF(s) must be updated with the latest version, number and date and resubmitted to the Lead HREC using the RGS.

PICF Approved

3.10 The CPI must send the Lead HREC-approved version of the Master PICF and Site Master PICF (as relevant), along with all other approved documents to all PIs at participating sites, and to sponsor/CRO (as applicable).

3.11 The Lead HREC approval letter must document the Master (and Site Master) PICFs with the version and date.

3.12 The PI must submit the Master (or Site Master) PICF with local details inserted with the SSA (using the RGS) to the relevant RGO as part of the governance application **(SOP 19)**.

SOP 04: Clinical Trial Notification and Exemption Scheme Requirements

Purpose: To describe the additional requirements for clinical trials conducted under the TGA's Clinical Trial Notification **(CTN)** or Clinical Trial Exemption **(CTX)** schemes.

4.1 For clinical trials conducted under the TGA's CTN or CTX schemes (as outlined in "WA Health Research Governance Policy and Procedures" 2012) a "Notification of Intent to Supply Unapproved Therapeutic Goods under the CTN Scheme" or a "Notification of the Conduct of a Clinical Trial under the CTX Scheme" must be completed respectively. The forms and further information is available from the TGA website.

4.2 For the purposes of the CTN Form the sponsor of the clinical trial must be an Australian entity i.e. it must have a registered Australian Business Number **(ABN)**.

4.3 Under the CTX scheme Part 1 of the Form is completed by the sponsor and submitted to the TGA with data for evaluation. Part 2 of the Form is used for notification of the commencement of each new trial conducted under the CTX scheme.

4.4 The CTN Form or Part 2 of the CTX Form (as relevant) must either:

- contain details of each participating site in Section 1.5 and a separate signed Section 2 for each site; or alternatively
- be competed for each site participating in the trial.

4.5 The sponsor must complete Section 1 of the CTN/CTX Form(s) and provide the original(s) (either one form containing multiple sites or a different form for each site) to the CPI. The CPI must sign the original CTN/CTX Form(s) and send it to the Lead HREC at the same time as the ethics application is submitted **(SOP 05)**. Conducting a clinical trial under the CTN scheme requires the approval of a HREC.

4.6 Details on the CTN/CTX Form(s) must be checked by the EEO in accordance with **SOP 4.10**.

4.7 The PIs at each site are not required to sign Section 2 prior to submission of the form(s) to the Lead HREC.

4.8 Following Lead HREC approval of an ethics application, a Lead HREC Member must sign Section 3 of the original CTN/CTX Form(s). The EEO must return the original signed form(s) with the approval letter, to the CPI, who will send the original (or a copy if part of a multi-site form) to the appropriate PIs for signing and submission to the RGO for signing by the site.

4.9 The PI must send the signed CTN/CTX Form to the RGO at the same time as the governance application **(SOP 19)**.

4.10 The CTN/CTX will be reviewed by RGO as part of the governance application ensuring that:

- the sponsor name on the CTN corresponds with the sponsor name on all the other vital documents – in cases where the sponsor is an overseas entity the CRO may be named as the sponsor on the CTN/CTX;
- the title of the project and protocol numbers are correct;
- the medicine details correspond with those in the protocol and all medicines and placebo have been included and dosages printed correctly;
- any unregistered devices being utilised in the project are included in Device Details;
- if approving for other sites, each individual site must ensure that the PI signs Section 2;
- if the site is acting as the sponsor for a local CPI/PI, then the site (e.g. Chief Executive/delegate) will also need to sign as the sponsor;
- HREC name and address and other pertinent details; and
- approving authority name and address are correct.

4.11 As part of the authorisation process the RGO must facilitate the signing of Section 4 by the approving authority (Chief Executive/delegate) at the site. Once the form is signed, the RGO must return the signed form to the PI who will send it to the sponsor (if original) or to the CPI (if part of a multi-site form for collation prior to sending to the sponsor). Upon receipt by the sponsor, they will sign the form and send the fully executed form to the TGA. The RGO must keep a copy of the CTN/CTX with the project file.

4.12 If a new site is added to an approved research project, either a new CTN/CTX Form or an additional Trials Site Details page (Section 1) must be submitted by the CPI to the Lead HREC for signing. This must then be signed by the site's PI and approving authority before being returned to the sponsor for signing and forwarding to the TGA.

4.13 For investigator-initiated projects, the CPI must obtain the form, ensure it is completed and lodge it with the TGA once it has been reviewed by the RGO and has been signed by the Lead HREC Chair and Chief Executive/delegate. CPIs who are unsure if they require a CTN or require information on completing the form and the costs for lodging a CTN must contact the TGA.

4.14 The CTN Scheme is a notification scheme and, as such, no TGA approval is given. A clinical trial is deemed to have been notified as soon as the CTN Form has been completed and the relevant fee is sent to the TGA. Thus, legally, a sponsor or investigator does not have to wait for the TGA's acknowledgment letter before commencing the trial. However, it may be advisable for sponsors to wait for the TGA's acknowledgment letter as the sponsor's insurance does not take effect until the TGA acknowledgement letter is issued.

4.15 A new CTN must be lodged with the TGA where there:

- is a significant change in the protocol that results in a change in the Lead HREC approval or conditions of the approval; or
- are any additional new unapproved therapeutic products being added to the trial. The Lead HREC approval must indicate that each site, at which the trial is being conducted, has approved the additional investigational therapy.

If there is any doubt as to whether a new notification is required then advice should be sought from the TGA.

SOP 05: Completion and Submission of an Application for Ethical and Scientific Review

Purpose: To outline the submission process to a Lead HREC for ethical and scientific review of a research project utilising either the WA Health Single Ethical Review or National Approach/Mutual Acceptance processes.

5.1 The CPI is responsible for submitting the ethics application to the Lead HREC using the RGS and submitting hard copies if required **(SOP 5.14)**. The CPI must review the Lead HREC contact details, meeting and application dates and ensure that the application is submitted before the close of business (or as otherwise specified) on the subcommittee/Lead HREC application closing date.

5.2 All submissions or communications between WA Health HRECs, WA Health RGOs investigators and their research group must be conducted through the RGS in order to electronically manage the research governance process and allow the research group to view the status of their application.

5.3 To access the RGS the CPI must log onto the RGP and register to create a user identification number (**ID**). An application for a user ID is only required once. The CPI must complete an online application and select the appropriate RGO to approve the application. This request is forwarded to the relevant RGO for validation and to nominate the level of access to specific research projects. The RGO must send notification to the CPI either granting access (with login credentials) or denying access as appropriate.

5.4 WA Health research support employees (e.g. Heads of Department, Business Managers and Chief Executive Officers) involved with authorising research applications must request a user ID for access to the RGP, following the same process as **SOP 5.3**. An application for a user ID is only required once.

5.5 The CPI must create a research project which generates a Project Reference Number **(PRN)**; this number will be carried through both the ethics and governance forms. Once the CPI gains access to the RGP, the CPI can nominate and grant a user ID to a delegate to take over the administrative responsibilities of the CPI (from **SOP 5.5** onwards). The CPI must grant a user ID to the delegate following the same process that is outlined in **SOP 5.6**.

5.6 The CPI is responsible for validating/approving the requests for user IDs for the remainder of the research group, both internal/external to WA Health. Once the PRN is assigned, the CPI must create a research group, include the contact details of the research group members and nominate their level of access to the specific project documents. Due to confidentiality, external sponsors must not be given access to the SSA Forms. The CPI is required to send an invitation to the research group, which can be accepted or declined. Once the request is accepted, a user ID will be allocated to the group member. CPIs must follow up any group member that rejects the invitation, to either remove them from the group or resend the invitation.

5.7 The CPI (delegate) must complete or import the relevant ethics application forms **(SOP 2.10 or 2.14)**. An ethics form must be created prior to creating the relevant governance forms that will be affiliated with it **(SOP 12 & 13)**. The CPI can either create a new ethics application form (which will generate a HREC Reference Number) or import a completed ethics application (from www.neaf.gov.au or www.ethicsform.org/au). If the NEAF and WA-Specific Module have already been reviewed and approved by another Lead HREC, the NEAF can be imported into the RGS to populate the governance forms, (the HREC Reference Number will be populated from this NEAF) and the WA-Specific Module can be submitted as an attachment.

5.8 Ethics application forms can be partially completed and saved for later completion. The CPI/research group members can request input from research group members to complete a task (i.e. complete the application form and provide authorisation via digital signatures). PIs

from the different sites must sign the declaration (except for the National Approach/Mutual Acceptance refer to **SOP 2.15**). Notification will be sent to the CPI when tasks are completed.

5.9 The CPI must ensure the submission to the Lead HREC relates to the proposed ethical conduct of the research at all sites involved with either the WA Health Single Ethical Review or National Approach/Mutual Acceptance processes. Local circumstances of each site relevant to the ethical review of the research must be outlined by the CPI (on advice from the PI) in the ethics application form.

5.10 In consultation with the PIs, the CPI must ensure that the ethics application documents contain the following:

- the known Australian sites at which the research is to be conducted;
- the names of the PIs, Associate Investigators at the sites;
- the signatures of the PIs (except for the National Approach/Mutual Acceptance **(SOP 2.15)**;
- a declaration regarding any conflicts of interest; and
- the number of participants that will be recruited at the site (or the number of data records that will be accessed).

5.11 Once the forms are completed, the CPI must lock the form, select the relevant Lead HREC and then submit the form, ensuring that applicable support documents are attached, including:

- protocol (these may have to be scanned and attached or sent separately to the Lead HREC as hard copies). A **WA Health Protocol Template for Clinical Trials** and **WA Health Protocol Template for Non-Clinical Trials** are available on the RGS and the Research Development (ethics) website;
- PICF;
- questionnaire, survey, interview outline;
- recruitment documents (letters, posters, advertisements);
- other participant documents (identification card, diaries);
- other HREC approvals;
- Investigator's Brochure/Device Manual (these may have to be scanned and attached or sent separately to the Lead HREC as hard copies); and
- other documents as applicable e.g. Department of Health WA HREC Application for Data Form, Variable lists, Data Governance Feasibility Letter.

Any documents that are attached to the ethics forms will automatically be linked to the governance forms. Additional documents can be attached at a later date if not completed at the time of submission.

5.12 The original hard copy of the CTN/CTX Form must be sent separately to the Lead HREC. If the protocol or Investigator Brochure are unable to be attached to the RGS they may also be sent in hard copy to the Lead HREC.

5.13 All documents submitted to the Lead HREC will be tracked using the PRN; therefore the PRN and HREC Reference Number must be quoted in all communications. The CPI and research group can use the RGS to track the status of the ethics application through the review process.

5.14 If it is a requirement of the Lead HREC, the CPI must submit the required number of ethics application hard copies as stipulated in the Lead HREC's SOPs.

5.15 If required, the CPI must ensure that research projects requiring additional review by specialist HRECs are submitted to the relevant HRECs. For projects conducted within WA Health these include:

- the Western Australian Aboriginal Health Ethics Committee for health and medical research projects where Aboriginality is a key determinant or explicitly directed at Aboriginal people;
- the Coronial Ethics Committee WA for research projects that require access to coronial samples, data or information; and

- the Department of Health WA HREC for all research projects that require the use or disclosure of personal information from the Department of Health data collections.

Further information is available in the "WA Health Research Governance Policy and Procedures" 2012 and WA-Specific Module.

5.16 If an additional review of the research project is required by the Department of Health WA HREC then the CPI must submit the ethics application forms and any attachments (Application for Data Form, refer to **SOP 11.9**) using the RGS as per the Lead HREC submission outlined in **SOP 5.11**. Applications to Western Australian Aboriginal Health Ethics Committee and the Coronial Ethics Committee cannot be submitted via the RGS and must be in accordance with their guidelines; contact details are available on the Research Development (ethics) website.

SOP 06: Acceptance and Validation of a Research Proposal by a Lead HREC

Purpose: To describe the process for acceptance and validation of an ethics application prior to the review by the Lead HREC.

6.1 Following a submission by the CPI, the EEO for the Lead HREC will receive a notification to review the ethics application form(s) and supporting documentation. An acknowledgement email of receipt will be sent to the CPI.

6.2 The EEO will be able to search for an ethics application by the PRN, date of submission, project title and type, protocol number, HREC Reference Number, Lead HREC name and subcommittee name (as applicable); and application outcome.

6.3 The Lead HREC must conduct the ethical and scientific review (including validation by the EEO) within 60 calendar days (allowing for a stop clock capability). The EEO must start the timing from the HREC application closing date (or from date of submission if there is no application closing date) and stop the clock if additional validation information is required. The clock will be stopped from the time the request is issued to the CPI to the time the additional information is received.

6.4 On receipt of a HREC application, the EEO must check the application for validity within 7 calendar days (a reminder will be sent at 3 and 7 days). The EEO must note/record the version, date of submission and HREC application closing date (to start the clock) in the RGS. The application must be checked to ensure it is complete and accurate (including signatures). The project must be recorded as either research, quality improvement requiring HREC exemption letter, or authorised prescriber (the single ethical review process does not apply to the authorised prescriber process). Validation may include receipt of hard copies if this is the requirement.

6.5 Following the validation review of the application, the EEO must record in the RGS the date of decision and the outcome, either as:

- application valid;
- application valid, modification required (record the modification required); or
- application invalid (record the reason for the invalid status).

6.6 The EEO must then send an acknowledgment notification to the CPI within 7 calendar days of receiving the application. RGS standard outcome templates include:

- receipt of valid application;
- receipt of valid application, modification required (including additional information required); or
- receipt of invalid application (including reason).

6.7 If the application is valid the acknowledgement must indicate the date the application will be reviewed by either the subcommittee/Lead HREC or expedited review process. Once an application has been validated revisions cannot be made prior to the subcommittee/Lead HREC meeting. If revisions are required the CPI must withdraw and resubmit the application **(SOP 10)**. This applies to the validation process only; the EEO might request revisions after the Lead HREC has conducted their review.

6.8 If the EEO requests additional information, the date, requesting party, information required and from whom; and the date the CPI resubmits the application must be noted/recorded (a resubmission notification will be generated). If the application still requires modification the CPI/EEO will be alerted every month for 4 months. If additional information is not provided in this time, the project will be withdrawn **(SOP 10)**.

6.9 If the application is invalid, the WA Health RGO must be copied into the notification and the project will be withdrawn **(SOP 10)**. The CPI should discuss the reasons with the EEO and if the issues can be resolved a new application can be submitted **(SOP 10)**.

SOP 07: Managing Subcommittee/Lead HREC Meetings

Purpose: To describe the process for administering subcommittee/Lead HREC meetings by the Ethics Executive Officer.

Subcommittee/Lead HREC Member Details

7.1 The EEO must enter into the RGS the committee members details including:

- title, name, hospital affiliation, contact details (e.g. e-mail, phone, mobile, fax);
- male/female;
- committee position, deputy/alternate;
- active/inactive members;
- appointment terms/dates, resignation dates;
- membership category e.g. lay, expert in research areas, expert in professional care, religious representative, lawyer, observer, other;
- qualifications, biographies, curriculum vitae;
- educational activities (i.e. HREC training); and
- other relevant information.

Subcommittee/Lead HREC Meeting Details

7.2 The EEO must determine and publish the schedule for their Lead HREC and subcommittee meetings and application dates for the following calendar year by November on their website and in the RGS. The time between HREC meetings must not be longer than 2 months. Meeting rooms must be booked.

7.3 The EEO must create meeting details which can be viewed by the CPI through the RGP. Details must include but not be restricted to:

- meeting reference number (generated by RGS);
- meeting type e.g. scheduled, ad hoc, subcommittee;
- meeting title;
- meeting date, time, location; and
- subcommittee/Lead HREC application closing date.

Subcommittee/Lead HREC Meeting Agenda

7.4 Once received, the EEO must assign the latest versions of an ethics application, amendment **(SOP 24)**, complaint **(SOP 30)**, report **(SOP 28 & 29)** to an ethics meeting agenda and record the date and who it has been assigned to including:

- the HREC (scheduled or adhoc meeting);
- the Scientific Subcommittee (or alternative);
- a non-HREC level alternative (e.g. Quality Improvement Subcommittee);
- the HREC Chair;
- Delegate of the Chair; or
- an expert advice/expert reviewer.

7.5 The EEO must produce subcommittee/Lead HREC meeting agendas which include:

- meeting title including type;
- meeting date, time and venue;
- meeting attendees including investigators and proxies;
- meeting apologies;
- declarations of conflict of interest;
- confirmation of minutes of the previous meeting;
- business arising from the previous meeting;
- applications (indicating whether it is a national or State research application);

- reciprocal/expedited approvals;
- authorised prescriber;
- quality improvement projects;
- items approved by Chair out of session;
- amendments;
- adverse events, protocol violations/deviations;
- project withdrawal or termination;
- complaints;
- progress/final reports (including project terminations/withdrawals);
- notice of upcoming education activities that may be of interest to the committee members;
- matters arising;
- other business for discussion;
- other business for information; and
- next meeting date, time, location.

7.6 Once the agenda is complete the EEO must notify the subcommittee/Lead HREC that projects are ready to be reviewed. The agenda, plus all attached documents, including the previous meeting minutes must be made available to committee members in either electronic or hard copy (the distribution of hard copies will be in accordance with the Lead HREC's SOPs). The subcommittee and Lead HREC are encouraged to review the documents directly through the RGS. This will provide them with the ability to share comments, ask questions of other members and make electronic notes on the documents that can be discussed at the meeting.

Subcommittee/Lead HREC Meeting Minutes

7.7 Following the subcommittee/Lead HREC meeting the EEO must create meeting minutes based on the agenda items, which includes links to the National Statement. Minutes must include decisions on each research project including:

- the main scientific and ethical issues discussed by the subcommittee/Lead HREC and the outcome of the review based on the headings - Research Merit and Integrity, Justice, Beneficence and Respect;
- whether scientific/technical review was obtained, from whom and the outcome of the review;
- whether more information is required and the process by which that information will be reviewed; and
- whether the single ethical review process was involved.

SOP 08: Scientific and Ethical Review by a Subcommittee/Lead HREC

Purpose: To describe the scientific and ethical review process by a Lead HREC, including any subcommittee.

Scientific and Ethical Review

8.1 The operations of a Lead HREC and its manner of conducting its ethical and scientific review (including the use of a scientific subcommittee) are a matter for it, provided that it operates in accordance with the National Statement. Lead HRECs within WA Health must be directly accountable to the WA Health organisations that they are constituted under and must operate in accordance with their Terms of Reference and their SOPs.

8.2 The local HREC (where it is not the Lead HREC for a project) has no role in conducting the ethical review of a multi-centre research project. The local HREC is not responsible for reviewing amendment requests, notification of adverse events and monitoring for a project reviewed by the Lead HREC. The local WA Health HRECs will continue to conduct ethical and scientific review for single-centre research.

8.3 Managing conflicts of interest for members of the Lead HREC and its subcommittees must be carried out in accordance with the National Statement and the Lead HRECs SOPs.

8.4 Managing conflicts of interest for investigators must be carried out in accordance with the National Statement and the Lead HRECs SOPs.

8.5 A multi-centre research project which involves low or negligible risk may undergo expedited HREC review at the discretion of the Lead HREC and in accordance with the National Statement and the "WA Health Research Governance Policy and Procedures" 2012. The Lead HRECs review pathways must be outlined in their SOPs.

8.6 When reviewing the multi-centre research project the Lead HREC must take into consideration relevant State/Territory legislation as outlined for the National Approach in the "National, State & Territory Legislative Framework for ethical review of multi-centre research" 2012 and National Mutual Acceptance in the "National, State & Territory Statutory and Administrative Frameworks for Ethical Review of Multi-centre Clinical Trials" 2013. Ethical issues particular to WA are outlined in the WA-Specific Module.

8.7 The Lead HREC is responsible for signing the CTN/CTX Form **(SOP 04)**.

8.8 For ethically approved projects, the Lead HREC must consider the proposed duration of the project, when determining the duration of its approval:

- WA Health Single Ethical Review - in accordance with the "WA Health Research Governance Policy and Procedures" 2012, the ethical approval applies for three (3) years with the option for five (5) years if justified, except where action is taken to suspend or terminate the decision. The Lead HREC has the capacity to set a shorter approval period dependent on the risk and complexity of the project. An extension of approval must be through an amendment process (submitted by the CPI) and will be limited to another three (3) years, except where action is taken to suspend or terminate the decision. Subsequent requests for extension should undergo a resubmission and be considered at the discretion of the Lead HREC.
- National Approach/Mutual Acceptance – the ethical approval should be for five (5) years or rolling approval on receipt of an annual/progress report. An exception to a five (5) year period may occur in cases where a shorter time is requested for the research. Extension of the ethical approval period must be through an amendment process and initially for a further five (5) year period unless rolling approval is in place. Thereafter, if an additional ethical approval period is required, the process to be followed will depend on the decision of the Lead HREC.

8.9 The Lead HREC must only consider the ethical and scientific issues when reviewing a multi-centre research project. Matters of research governance and final authorisation related to the conduct of research at Australian sites will be conducted by the RGOs responsible for those sites.

8.10 A Lead HREC within WA Health will be indemnified by WA Health for its decisions in reviewing multi-centre research projects. For commercially sponsored clinical trials and research projects the sponsor must provide indemnity for the Lead HREC **(SOP 17).**

8.11 The Lead HREC must conduct the ethical and scientific review within 60 calendar days (applicable to valid applications only). The timeframe is measured from the HREC application closing date (associated with the meeting that the application is reviewed at) until written notification of the final ethical opinion is sent to the CPI. The 60 day measurement will apply to the subcommittee/Lead HREC review only and does not include site authorisation.

8.12 The 60 day measurement allows for a stop clock capability (i.e. the timing stops when additional input is required by the Lead HREC from a sponsor or investigator). The clock is stopped on the day the request is sent to the CPI. The clock is recommenced when all the required information is received (either electronically or in hard copy as stipulated in the Lead HRECs SOPs) at the office of the EEO.

8.13 The 60 day measurement is a measure of the Lead HREC's performance and the outcome does not have any implications for the review or approval of a research project or the charging of Lead HREC review fees (i.e. the review process and fees will be applied as normal).

SOP 09: Notification of the Scientific and Ethical Review Outcome

Purpose: To describe the process for notification of the scientific and ethical review outcome by a Lead HREC (including any subcommittee) by the Ethics Executive Officer.

9.1 Once the subcommittee/Lead HREC has made its decision on an ethics application the EEO must note/record the decision, date of decision (i.e. the date correspondence is sent to the CPI) and who made the decision e.g. HREC, subcommittee, delegate. These outcomes must be recorded in the meeting minutes and on the RGS. Outcomes include:

- subcommittee/HREC approved;
- HREC approved, conditions apply;
- subcommittee/HREC, more information required; or
- subcommittee/HREC not approved.

Notification of Subcommittee Outcome

9.2 Following the subcommittee meeting the EEO must provide a letter of notification within 7 calendar days to the CPI with the outcome of the subcommittee review, RGS standard outcome letters include:

- subcommittee approved;
- subcommittee, more information required; or
- subcommittee not approved.

9.3 If the project is approved or requires more information the EEO must add the item to the HREC agenda.

9.4 If additional information is required by the subcommittee in order to make a decision, the CPI must provide a response within 4 months or the application will be withdrawn **(SOP 10)**. The response from the CPI will be reviewed by the subcommittee Chair and if approved the CPI will be notified by the EEO and the submission will remain on the HREC agenda.

9.5 When additional information is required, the EEO must stop the clock until the information is received and keep a record of information requested including:

- who requested the additional information and from whom;
- what information was required;
- the date the request was sent; and
- the date the additional information was provided.

9.6 If the project is not approved, the EEO must notify the CPI (and WA Health RGO through the RGS) and withdraw the application **(SOP 10)**.

Notification of HREC Outcome

9.7 Following the Lead HREC meeting, the EEO must provide a letter of notification within 7 calendar days to the CPI (and WA Health RGO through the RGS) with the outcome of the HREC review (and HREC meeting attendees if required – often required by sponsored clinical trials). It is a responsibility of the CPI to send a copy of the letter to PIs and the sponsor/CRO. RGS standard outcome letters include:

- HREC approved;
- HREC approved, conditions apply;
- HREC, more information required; or
- HREC not approved.

Application Approved

9.8 The Lead HREC approval letter must contain the:

- research project, HREC and CPI details;

- HREC meeting date and the date of the decision (this is the date of notification and signifies the end of the 60 day measurement for ethical review);
- list of sites applicable to the approval;
- list of documentation reviewed and approved (including version numbers/dates);
- duration of approval and any conditions of approval (including NHMRC requirements and the CPI's responsibilities (e.g. notification to the HREC of the start date); and
- statement that the research cannot commence until site authorisation is received.

9.9 Ethics approval by the Lead HREC does not imply authorisation to conduct research at a site. This is granted by the relevant WA Health Chief Executive/delegate responsible for the site following governance review. It is the responsibility of the CPI to notify the PIs of the HREC decision. The PI must notify the relevant RGO and provide a copy of the approval as part of the SSA.

9.10 Where applicable, the TGA's CTN/CTX Form(s) (signed by the Lead HREC) must accompany the final HREC approval letter to the CPI. The CPI must forward the form(s) to each site PI for signing and forwarding to the RGO as part of the governance application. The RGO will then facilitate signing by the authorising authority and return it to the PI **(SOP 04)**.

Conditions Apply or More information Required

9.11 The Lead HREC must establish procedures for reviewing CPI responses to HREC/subcommittee requests for more information and may include:

- delegated review (either by a delegate, Chair or subcommittee) with reporting to the next HREC meeting of the outcome; and/or
- review at the next HREC meeting (in exceptional circumstances or when the delegate refers the matter back to a further HREC meeting).

9.12 Where the Lead HREC has approved the application but requires modification, the CPI must submit their response (with attachments as required) to the EEO for delegated review. Once approved by the delegate the EEO will notify the CPI (and WA Health RGO through the RGS) of the approval.

9.13 If further information or a modification is requested by the Lead HREC in order to make a decision, the EEO must stop the clock until the information is received. The CPI must provide a response within 4 months or the application will be withdrawn (requests for further information must be linked to the National Statement wherever possible). The process must be managed in accordance with **SOP 9.5**. Once the additional information is received from the CPI the application will be resubmitted to the next HREC meeting.

Application Not Approved

9.14 If the application is not approved, the letter to the CPI must link reasons to the National Statement or legislation wherever possible, and provide advice regarding available options for further review. The application will be withdrawn **(SOP 10)** and the CPI (through the PI) must notify the RGO (WA Health RGOs will be notified by the EEO through the RGS) to cease the governance review of the project.

SOP 10: Withdrawal and Resubmission of an Application

Purpose: To describe the processes for:
(a) Withdrawal of a project prior to approval by the Lead HREC (either prior to or after review) by either the:

- CPI who wishes to make significant changes to the project application or withdraw a project altogether; or
- Lead HREC as part of the validation or review process when the application is not approved or the CPI fails to provide additional information within the requested timeframe.

(b) Resubmission of an application by the CPI to the original Lead HREC.

Withdrawal

10.1 The CPI may withdraw an application which has been submitted to a subcommittee/Lead HREC at any time prior to approval. The CPI must provide the Lead HREC with notification that they intend to withdraw a submitted ethics application, including the reason for the withdrawal. An acknowledgement email of receipt will be sent to the CPI (via the RGS). Following notification, the EEO must review and document the withdrawal details in the RGS including the stage of the process when the application was withdrawn.

10.2 The EEO has the ability to withdraw an application during the validation or review process when the application is not approved or the CPI fails to provide additional information within the requested timeframe.

10.3 The EEO must send a letter to the CPI (and WA Health RGO through the RGS) acknowledging withdrawal of the project or notifying the withdrawal of the project (if the withdrawal was instigated by the subcommittee/Lead HREC). The letter must include but not be limited to:

- date of withdrawal;
- requested by whom; and
- reason for the withdrawal (and other relevant information).

Amend Application for Resubmission (prior to approval)

10.4 If the CPI wishes to resubmit an application they must submit the amended application to the same Lead HREC that received the original application (retaining the original PRN and HREC Reference Number) unless there are extenuating circumstances (e.g. the Lead HREC is unable to review the project as per **SOP 2.5**).

10.5 The CPI must access the latest version of the application through the RGP, amend the application (with changes clearly marked if possible; if not, provide a summary of changes) sign it electronically, 'lock' the form and resubmit it to the Lead HREC as per **SOP 05**. The CPI will be able to track the resubmitted application through the review process.

10.6 Should the application be resubmitted to another Lead HREC, the CPI must include all previous documentation associated with the initial Lead HREC review.

Record re-submission receive date

10.7 The EEO will receive a notification that an application has been changed with a new version and its status will be updated. The EEO must note/record the date the resubmission is received and reset the stop clock to zero, as this is treated as a new application (though it retains the original HREC Reference Number and PRN). The 60 day measurement will commence from the HREC application closing date for the meeting at which the new submission will be reviewed.

10.8 The EEO must validate the application **(SOP 06)** and the Lead HREC will evaluate the resubmitted applications **(SOP 08)**.The Lead HREC receiving the resubmission has the right to request that the CPI resubmits the project to the original Lead HREC.

SOP 11: Selection of the Appropiate Research Governance Process and Governance Application Form(s)

Purpose: To outline the criteria for selecting the appropriate the research governance process and governance application form(s) prior to authorisation of research within WA Health.

11.1 In a multi-centre research project, the PI is responsible for obtaining authorisation from Health Service sites or the Department of Health (as applicable) prior to conducting research at the site or accessing participants, tissue or data. The CPI is responsible for obtaining authorisation for an Access Request **(SOP 11.7).**

11.2 The authorisation process must involve a governance review **(Intro 6)** by either the Health Service RGO or the Department of Health Data Steward. The governance review is a separate process to the scientific and ethical review conducted by the Lead HREC and does not involve ethical review by the local HREC (unless the local HREC is the Lead HREC or a Specialist HREC **(Intro 4)**).

11.3 Both ethical and governance review processes can occur separately and concurrently. However, the governance review process (and recommendation for authorisation) cannot be completed until the Lead HREC scientific and ethical approval has been received.

11.4 The CPI and sponsor/CRO (if applicable) should provide the relevant documentation required for the research governance review to all PIs at participating sites as soon as they are nominated, to reduce delays in authorisation. Where new or modified documentation has been submitted to the Lead HREC for review, this must also be submitted to the PI to include in/amend the governance application to the RGO.

Health Services

11.5 Each PI (or CPI for Access Request) at a site involved in a multi-centre research project must complete (with all applicable signatures) **(SOP 12)** and submit **(SOP 19)** a separate application for research governance review to the RGO responsible for the site using one of the SSA/Access Request Forms, available from the RGS. The PI/CPI should contact the RGO responsible for the site to discuss the research project and submission process. Contact details are on the Research Development (governance) website.

Site Specific Assessment

11.6 The SSA is a governance review mechanism for professional, legal and financial accountability and transparency, and is consistent with The Code and the *Financial Management Act 2006* (WA), refer to Section 2.4 "WA Health Research Governance Policy and Procedures" 2012. A SSA is required when the research conducted at the site involves:

- enrolling participants into research;
- carrying out protocol specific research procedures with or on participants; and
- managing and analysing data, tissue and responses from surveys and questionnaires collected for or from research.

The SSA Forms are available from the RGS and Research Development (governance) website and include the:

WA Health Site Specific Assessment Form

This form must be used for single-centre and multi-centre human research projects, conducted within WA Health, that require a full HREC review. A SSA Form is required for each site (e.g. institution) involved in the research within the Health Service. Except for the following, where one SSA Form may incorporate a 'group of sites' within a Region or Health Service. Examples of groups of sites include:

- WA Country Health Service **(WACHS)** Regions;
- North Metropolitan Health Service **(NMHS)** Mental Health;
- NMHS Public Health;

- South Metropolitan Health Service **(SMHS)** Mental Health; and
- SMHS Public Health.

The form must include details of the sites and a declaration of support from the relevant site Directors (plus Regional Directors for WACHS) that are involved in that Health Service.

WA Health Site Specific Assessment Form for Low and Negligible Risk Research

This form must be used for single-centre and multi-centre human research projects, conducted within WA Health, that require an ethics review for low or negligible risk research. In the case of a low or negligible risk project involving multiple sites (or 'groups of sites' within a Region or Health Service) within the jurisdiction of a Health Service RGO only one SSA Form is required for that project, but it must include a declaration of support on the SSA Form from all the site Directors (plus Regional Directors for WACHS) that are involved in that Health Service.

Access Request Review

11.7 The access request is a governance review process for a human research project that requires support from a Health Service in the form of access to participants, tissue or data but does not involve the conduct of research at any facilities, locations or services under the control of that Health Service, refer to the "WA Health Research Governance Policy and Procedures" 2012. An Access Request Review is required when the research project involves:

- participant recruitment through posters, leaflets, handouts, letters of invitation (but not recruitment through direct contact with potential participants or enrolment);
- distribution of surveys and questionnaires through personnel of the Health Service (but not collation and analysis of responses at the Health Service); and
- access to data or tissue held at the Health Service (but not processing or analysis at that Health Service).

The **WA Health Access Request Form** is available from the RGS and Research Development (governance) website:

This form must be submitted to the responsible RGO by the CPI. Only one Access Request Form for each RGO contained within a Health Service will be required for each research project, even if the project requires access from a number of sites covered by that RGO. An ethics approval from a WA Health or National Approach/Mutual Acceptance Lead HREC must accompany this form. The RGO has the discretion to request that the application be submitted for SSA if the project involves conduct of research at the site.

Department of Health Data Collections/Data Linkage

11.8 The CPI/PI of the multi-centre research project that requires the use and disclosure of personal health information from a Department of Health data collection and/or data linkage must liaise with the appropriate Data Custodian and Data Linkage Branch Officer about the data requirements of their project and the data application process before applying for data or requesting Department of Health WA HREC approval. This will involve an Expression of Interest process. Contact details and information on the application process are on the Information About Health Data website and Data Linkage WA website.

11.9 For requests of personal health information from a single Department of Health data collection, the CPI/PI must submit an application for data governance review to the relevant Data Custodian using the **Application for Data Form** which is not available on the RGS and must be obtained from the Department of Health WA HREC website. Once the Data Custodian has completed the governance review, the Application for Data Form must be submitted, through the RGS, as an attachment to the Department of Health WA HREC ethics application.

11.10 For requests for linked data the CPI/PI must submit a draft application for governance review to the Data Linkage Branch Project Officer, who will coordinate a governance review by the relevant Data Custodian(s) and Data Linkage Branch Managers. The draft application must include the **Application for Data Form** as well as other modules relevant to the project, including Data Services forms and Variable Lists. These forms and submission instructions can

be obtained from the Data Linkage WA website and must be submitted as attachments via email to DataServices@health.wa.gov.au. Once the governance review is completed, the application (including all modules) must be submitted, through the RGS, as an attachment to the Department of Health WA HREC ethics application.

SOP 12: Completion of Site Specific Assessment Form(s)

Purpose: To describe the requirements for completing either of the WA Health SSA Forms.

12.1 All submissions or communications between WA Health HRECs, WA Health RGOs investigators and their research group must be conducted through the RGS in order to electronically manage the research governance process and allow the research group to view the status of their application. The RGP will provide RGO contact details as well as guidelines for making a submission.

12.2 WA Health research support employees (e.g. Heads of Department, Business Managers and Chief Executive/delegate) involved with authorising research applications must request a user ID for access to the RGP, following the same process as **SOP 5.3**.

12.3 Once the PI has accepted an invitation from the CPI to join a research group they will be sent a user ID, login details to the RGP and given access to the research project documentation identified by the PRN. Once the PI gains access to the RGP, the PI can nominate a research group member (delegate) to take over the administrative responsibilities of the PI.

12.4 The PI (delegate) must generate the relevant governance form **(SOP 11)** affiliated with the PRN and ethics application form (already generated by the CPI **(SOP 05)**). Each governance form will generate a Governance Reference Number. Some information from the ethics application form will be populated into the relevant SSA/Access Request Form including the HREC Reference Number.

12.5 The PI responsible for conducting the research at the site (this may be also the CPI) is responsible for submitting a separate SSA Form for each site (or group of sites as outlined in **SOP 11.6**) to the relevant RGO using the RGS. For multi-centre projects where there is only a CPI, they are responsible for completing a separate SSA Form for each site (or group of sites as outlined in **SOP 11.6**). PIs will have the ability to generate one or multiple forms for different sites and have the ability to make copies of the original governance form and then amend data for specific sites.

12.6 Governance application forms can be partially completed and saved for later completion with the ability to refresh information if the ethics application documents are updated. The PI/research group members can request input from research group members and Supporting Departments to complete a task (i.e. complete the application form and provide authorisation via digital signatures). Notification will be sent to the PI when tasks are completed.

12.7 The SSA form consists of several sections:

- Project Details;
- Broad Research Area, NHMRC Group and Field of Research;
- Research Personnel;
- Training;
- Participants;
- Other Approvals (where applicable);
- Regulatory Documents – CTN, indemnity, insurance, research agreements;
- Intellectual property;
- Safety Issues;
- Resource and Budget Information;
- Funds Management Details; and
- Declarations – PI, Heads of Supporting Departments, Head of Research Department, Business Manager, Divisional Director.

12.8 The SSA form ensures that the PI, Head of Department, Business Manager and Divisional Director under whose auspices the research is taking place have all signed the declaration to show they understand the financial, human resource, logistical and other resource implications

a particular research project will have upon their Departments. The Declaration should be signed using a digital signature through the RGS **(SOP 12.6)**. The Divisional Director must not sign until all other signatures have been obtained.

Conflict of Interest

12.9 In accordance with Section 2.17 "WA Health Research Governance Policy and Procedures" 2012 it is a requirement of WA Health that all investigators must indicate any perceived conflicts of interest. Any conflicts of interest must be outlined by the investigators in the standard WA Health Research Conflict of Interest Form (available from the RGS and Research Development (governance) website) and submitted with the SSA to the RGO for review prior to authorisation of the project.

12.10 If the RGO identifies that there is an issue, the investigator will be required to either provide further information or take a course of action. The research will not be authorised until the conflict is addressed to the satisfaction of the Chief Executive/delegate.

Resource and Budget Information

12.11 The PI must manage their research budget, funds and accounts in accordance with Sections 2.6 & 2.7 "WA Health Research Governance Policy and Procedures" 2012.

12.12 The PI must document in the SSA Form any funding or in-kind support that is being provided for the research project. Infrastructure costs (institutional overheads) should be negotiated between the institution and the provider of funding.

12.13 The PI and the Supporting Department authorised personnel (Pharmacy, Pathology, Imaging etc.) must document in the SSA Form the costs related to the research project (i.e. activities that are secondary to the primary purpose of providing patient care), ensuring all WA Health fees are included in the budget (refer to the SSA Form budget guidelines):

12.14.1 Research Department

In collaboration with their Business Manager, the PI will document on the SSA Form the estimated Research Departmental costs (e.g. investigator and support personnel, setup, administrative, infrastructure, travel, archiving), and Lead HREC and RGO review fees as per the following guidelines:

- **Investigator and support personnel** (e.g. Clinical Research Coordinator, Research Nurse) costs should be based upon salary costs (includes direct salary costs + on-costs) for time spent on the research project. With assistance from the Business Manager, on-costs should be applied in accordance with the Department of Health "Health Accounting Manual". These costs should be calculated per participant and then multiplied by the number of participants to give the total cost for the project;
- **Administrative support** costs should include personnel costs and stationary items directly related to the administrative aspects of the research e.g. large mail out, questionnaires; and
- **Infrastructure costs** (institutional overhead) are additional corporate/clinical costs to the site which the institution provides to support the conduct of the research project (e.g. additional administrative support [e.g. Business Managers], facilities and utilities). This institutional salary overhead is calculated as a % of salary costs (includes direct salary costs + on-costs) and should be applied in accordance with institutional rates. The institutional overhead should only be applied to the Research Department salaries (not to Supporting Departments who will calculate their own costs) and should not be applied to set costs e.g. archiving, screen failures, set-up costs. The institutional overhead should be calculated per participant and then multiplied by the number of participants to give the total cost for the project.

12.14.2 Supporting Departments

All Supporting Departments that are asked to provide a service for the research project must review the protocol requirements and agree to participate by signing the SSA declaration.

The PI should begin negotiations with site Research and Supporting Departments as soon as possible to ensure financial and resourcing implications are identified and documented on the SSA Form. If a research project utilises the services of a Supporting Department, even if it is considered normal patient care (standard of care), the PI must still contact the Head of Department to discuss the research requirements (e.g. costs, procedures, reporting) and obtain authorisation on the SSA Form. All research projects that involve the use of a pharmaceutical must obtain sign off from Pharmacy, even those projects where Pharmacy will not be directly involved.

Once the PI has completed the costs for the Research Department, the PI must send a request through the RGS to the relevant Supporting Departments (with a copy of the protocol), to document costs and provide approval to use their facilities to conduct the research project. The PI must give the Supporting Departments sufficient time to review the protocol, determine the impact on their department, document costs and sign the SSA Form. This should be at least two weeks prior to the intended RGO submission date. More time will be required where multiple departments are involved and where the project involves radiation exposure, possible dosimetry assessment and Radiological Council approval. Once the Supporting Departments have completed the SSA Form they must send a notification to the PI.

If there is uncertainty as to whether a Supporting Department needs to sign off for a particular research project, the PI should discuss the project with the Head of Department or the RGO.

12.14 Once the budget is completed, the PI will notify the Business Manager to review the SSA Form and provide authorisation. For clinical trials, where the budgets are complex, if required by the RGO, the PI must attach to the SSA Form the relevant site specific departmental budgets/authorisation forms (e.g. Service Agreement, Financial Agreement Form).

12.15 If the research is sponsored, the PI must negotiate the funding/sponsorship and payment schedule with the sponsors based on WA Health fee structures and the costs documented in the SSA Form. Due to confidentiality; external sponsors must not be given access to the SSA Forms. The agreed budget must then be documented in the SSA and funding documented in the research agreement. If required, the RGO will provide support with additional negotiations after the application has been received.

12.16 Payments for services provided by the Supporting Departments are invoiced directly to the Research Department unless the Supporting Department has a separate agreement with the sponsor. When Supporting Departments are invoicing the Research Department a cover letter identifying the particular project should be sent with the general ledger.

12.17 On submission, the SSA form must be completed (with all required signatures) with all supporting documents **(SOP 19)** for the RGO to validate the application and commence review of the project. If this form is not completed satisfactorily, review and approval may be delayed.

Ionising Radiation

12.18 Should a research project involve ionising radiation, the PI must manage their research in accordance with Sections 3.8.2 "WA Health Research Governance Policy and Procedures" 2012. The PI must ensure the project is reviewed by the Imaging Service Head of Department to establish whether the ionising radiation is additional to/or part of the research participant's normal clinical management (standard of care). If exposure is additional to normal standard of care, the Medical Physicist must review the project in accordance with the Australian Radiation Protection and Nuclear Safety Agency and Radiological Council of Western Australia guidelines and provide a dosimetry report. Research that involves participant radiation exposure greater than 5mSv will generally be required to be submitted to the Radiological Council for approval. The institution's Medical Physicist with the Radiation Safety Officer will decide if this is required and will advise the investigators and RGO accordingly, and will submit the application to the Radiological Council. If Radiological Council approval is required, the RGO will not recommend to the Chief Executive/delegate to authorise the research until the approval is received.

SOP 13: Completion of Access Request Form

Purpose: To describe the requirements for completing the WA Health Access Request Form.

13.1 The Access Request Form must be completed in accordance with **SOP 12 (1-4 and 6)**.

13.2 If there is uncertainty as to whether a site needs to provide confirmation for access, the CPI/PI should contact the RGO to discuss.

13.3 The CPI is responsible for fully completing the Access Request Form **(SOP 11.7)** to request access to participants, tissue or data at a site. The Access Request form consists of several sections:

- Project Details;
- Research Personnel;
- Sites Requested for Project - including details of requested access and confirmation of support; and
- Declaration by CPI.

13.4 For an Access Request the CPI must provide a copy of their research proposal, together with an outline of their request, to the relevant sites. If the request is acceptable to the site(s), the Heads of Departments (or equivalent) must provide written confirmation of approval indicating support for the facilities/locations/services requested.

13.5 Supporting documents to be submitted with the form include:

- a copy of the WA Health HREC (or Non-HREC level alternative) or NHMRC Certified Lead HREC letter of approval;
- a copy of WA Health Ethics Application Form or NEAF plus WA-Specific Module (as relevant);
- A copy of the WA Health Research Conflict of Interest Form for the CPI (if a conflict of interest exists);
- all documents to be distributed through the sites within the Health Service, e.g. posters, leaflets or handouts; letters of invitation (on research site letterhead); and surveys and questionnaires; and
- written confirmation of approval from personnel of the sites through which the CPI is seeking access to participants, tissue or data, for example:
  - Head of Department who agrees to personnel distributing posters and leaflets about the research project or letters of invitation to potential participants;
  - Head of Department who agrees to questionnaires or surveys to personnel by e-mail, in line with the Health Service policies; and
  - Relevant Senior Executive and/or Data Steward who agree to provide access to medical records, data or tissue held in collections or databases under their management, in line with ethical conditions imposed by the approving HREC.

13.6 On submission, the Access Request Form must be complete (with all required signatures) for the RGO to validate the application and commence review of the project. If this form is not completed satisfactorily, review and approval may be delayed.

SOP 14: Confidentiality Agreements

Purpose: To describe the process for executing a Confidentiality Agreement between WA Health and an external party.

14.1 Confidentiality Agreements **(CA)** are legally binding agreements that can give rise to legal liability and as such must only be applied in accordance with Sections 2.8 & 2.9 "WA Health Research Governance Policy and Procedures" 2012.

14.2 If a CA is required by an external party (i.e. sponsor/CRO) at the outset of clinical trial/data registry discussions, the PI should contact the RGO for advice. A template is available on the Research Development (governance) website and RGP and this should be sent to the sponsor/CRO by the PI during the initial correspondence regarding a trial. In the first instance the PI should check with the RGO to establish if a CA is already in place (refer to **SOP 14.5**).

14.3 The RGO is responsible for negotiating and processing the agreements prior to signing by the Chief Executive/delegate responsible for the site. If the sponsor/CRO agrees to the terms of the CA, both parties must insert their details before signing. It is preferable if the sponsor/CRO signs two (2) originals and returns them to the RGO who will facilitate signing by the Chief Executive/delegate; and return one of the original fully executed CAs to the sponsor/CRO.

14.4 If the sponsor/CRO requires changes to the terms of the CA, the RGO will negotiate any changes directly with the sponsor/CRO in consultation with Legal and Legislative Services **(LLS)**.

14.5 Upon execution of the CA, the RGO must notify the PI and keep a copy of the original CA on file. The RGO must maintain a record of the CAs executed with external parties and (if these are not trial specific) are available to cover all future trials within that Health Service for the period stated in the CA (usually 5 years).

SOP 15: Research Agreements

Purpose: To describe the process for executing a Clinical Data Registry Agreement **(CDRA)**, Clinical Trial Research Agreement **(CTRA)**, Clinical Investigation Research Agreement **(CIRA)**, and Non Standard Research Agreement between WA Health and an external party.

Selection of the Research Agreement

15.1 Research agreements are legally binding agreements between two or more parties that establish the respective responsibilities and obligations of the parties conducting a research project. They can give rise to legal liability and as such must only be applied in accordance with Sections 2.8, 2.10, 2.11 & 2.12 "WA Health Research Governance Policy and Procedures" 2012.

15.2 All research involving WA Health personnel, participants or resources conducted with an external sponsoring entity must be the subject of a written agreement (i.e. the research project involves an arrangement between WA Health and an external party for provision of a product, service or funding). The type of research activity undertaken will determine the type of contractual agreement required.

15.3 At the outset of the research project discussions, the PI should contact the RGO to establish whether an agreement is required and if so, which form of agreement is necessary. If in doubt, the RGO must consult LLS.

15.4 If an agreement is required, the PI must send the recommended agreement (refer to **SOP 15.5 & 15.6**) to the external party as soon as possible to provide time for review and negotiation.

15.5 If the research project involves a clinical trial, clinical investigation or data registry, the PI must send the external party (sponsor, CRO or Collaborative or Cooperative Research Group **(CRG)**) the applicable WA Health CTRA, CIRA or CDRA templates approved by LLS. These contain amendments specific to WA Health (available from the Research Development (governance) website). The types of CTRAs for commercial and non-commercial clinical trials and CIRAs are outlined in Section 2.11.1 "WA Health Research Governance Policy and Procedures" 2012. In clinical trials it is particularly important that these agreements are used as they address issues including insurance, indemnity and intellectual Property **(IP)**. Refer to Section 2.11.2 "WA Health Research Governance Policy and Procedures" 2012 regarding CTRA/CIRA clauses.

NB: In accordance with Section 2.11.2.8 "WA Health Research Governance Policy and Procedures" 2012 a number of sponsors/CROs and CRGs have negotiated specific CTRAs/CIRAs for use with WA Health and the RGO can advise whether such an agreement is available for use. Once a sponsor specific agreement has been negotiated it is preferred that this contract is used, where applicable, for all future clinical trials involving the same parties. Future changes may be negotiated between WA Health and the external party, where deemed appropriate.

15.6 If the research project is externally sponsored but does not involve a clinical trial, clinical investigation or data registry, the PI must send the external party the research agreement recommended by the RGO. For these projects a project specific agreement will be required. Depending on the requirement, the following agreements are available from the RGOs:

- Material Transfer Agreement;
- Study Funding Agreement;
- Agreement for Clinical Equipment on Loan or Trial; and
- Service Agreement.

15.7 In accordance with Section 2.11.2.8 "WA Health Research Governance Policy and Procedures" 2012 external parties must ensure amendments to the CTRA, CIRA or CDRA are set out in a Special Conditions Schedule to the agreement and not in the actual body of the

agreement. Sponsors, CROs and CRGs are strongly encouraged to accept the WA Health approved versions without change. Where changes are requested by those parties, they should not seek to substantially amend the CTRA/CIRA/CDRA or introduce provisions that contradict or undermine the intent of the CTRA/CIRA/CDRA. See **SOP 15.10** for further details.

15.8 Following review by the external party, the PI must submit the draft research agreement (e-version with no signatures) with the SSA Form **(SOP 19)** for review by the RGO.

Supporting Department Service Agreements

15.9 Clinical trials involving drugs and radiological investigations will attract pharmacy and imaging fees respectively. Pharmacy/Imaging Departments can either charge their fees as part of the CTRA/CIRA and invoice through the Research Department or deal directly with the sponsor using a separate Pharmacy/Imaging Financial Agreement. In the latter case no pharmacy/imaging fees are documented in the Payment Schedule but will be documented in an appendix to the CTRA/CIRA and invoiced to the sponsor independently. The Pharmacy/Imaging Financial Agreement must be submitted with the SSA and CTRA/CIRA for review by the RGO as it will form an appendix to the CTRA/CIRA and be signed by the Chief Executive/delegate.

Review by the RGO

15.10 Once the draft agreement is received by the RGO, a review must be undertaken in accordance with one of the following processes:

15.10.1 For CTRA, CIRA and CDRA, the RGO must review the agreement to ensure consistency with WA Health approved agreements and negotiate the agreement with the external party in accordance with the following processes:

- where an external entity uses the WA Health standard CTRA/CIRA/CDRA for a clinical trial without alteration, the Health Service should accept this agreement without further legal review;
- where an external entity uses the WA Health Standard CTRA/CIRA/CDRA with the addition only of amendments under Special Conditions Schedule that have been reviewed and pre-approved by WA Health for that particular entity, the Health Service should accept this agreement without further legal review;
- RGOs should contact LLS to check if that external entity has a standard set of pre-approved amendments under the Special Conditions Schedule;
- Health Services retain the ability for RGOs to negotiate specific additional operational terms and conditions for a particular CTRA/CIRA/CDRA with the sponsoring external entity;
- Health Services must obtain legal advice from LLS where an external entity insists on using their own contract or uses the WA Health Standard CTRA/CIRA but makes significant alterations or additions to it, other than the addition of pre-approved amendments in the Special Conditions Schedule;
- where legal review of the non-standard CTRA/CIRA/CDRA is required, the external entity should be informed that this may cause significant delays to the approval process;
- new or revised amendments in the Special Conditions Schedule intended for general use for all research projects, should be submitted to LLS to enable legal review and pre-approval; and
- project specific amendments in the Special Conditions Schedule are approved only for that project and do not affect current approved Special Conditions clauses for that external entity.

15.10.2 For Non Standard Research Agreements the RGO must review and negotiate the agreement in consultation with LLS.

15.11 RGOs must negotiate any changes to the research agreements directly with the external party using electronically tracked documents until a mutually agreeable contract is finalised. This

process may cause delays to the governance approval, so it is essential that it is commenced as early as possible.

15.12 The RGO must examine the agreement to determine that the correct details are included and that these details correspond with information contained in the application and are consistent with other documents. Depending on the agreement this includes:

- the site's and external party's legal name (including the ABN) as parties to the agreement;
- title of the clinical trial/project;
- for clinical trials, the same parties details corresponds with the details on the Form of Indemnity, CTN and other vital documents; and
- for CTRA/CIRA/CDRA the schedules (as applicable) are correct, including:
  - Schedule 1: Key Information;
  - Schedule 2: Payments - must contain the following information:
    - Payment amounts, regularity and time interval
    - Invoicing method – tax invoice or recipient created invoice
    - Payment method – cheque, credit card, EFT
    - Payee details (Debtor)
    - Recipient details (Health Corporate Network **(HCN)** or PI/delegate details)
    - Payment of Supporting Departments
    - If a Special Purpose Account is to be used – distribution of unspent funds;
  - Schedule 3: Form of Indemnity for Clinical Trials;
  - Schedule 4: Insurance Arrangements;
  - Schedule 5: Guidelines for Compensation for Injury Resulting from Participation in a Company-Sponsored Trial/Investigation;
  - Schedule 6: Project Protocol Identification; and
  - Schedule 7: Special Conditions.

15.13 Once an agreement has been reviewed and approved by the RGO, the external party must send the complete signed originals (one for each party and the PI) to the PI for signing (if required). In a clinical trial/investigation the PI does not have the legal authority to be a party to the agreement but they must sign the agreement to acknowledge their obligations as set out in the terms and conditions. It is important that the PI reads the agreement and is aware of their own and their research team's obligations.

15.14 Once signed by the PI, the RGO will arrange for signing of the agreements (with the other approved documents) by the Chief Executive/delegate, once all the research governance requirements have been met. Once signed by the Chief Executive/delegate the original agreements will be sent by the RGO to the PI and external party(ies) (as relevant) and retain an original on the project file.

15.15 Once the above process is complete and the agreement has been approved, any subsequent changes will be required to be submitted as an amendment **(SOP 25)**.

SOP 16: Intellectual Property, Authorship and Publications

Purpose: To outline the requirements for authorship, publications and the protection of intellectual property in research conducted within WA Health.

Intellectual Property

16.1 Research in WA Health must comply with Section 2.13 "WA Health Research Governance Policy and Procedures" 2012. For further information on IP policy refer to Department of Health Intellectual Property Management website. Any queries regarding IP matters must be referred to the RGO in the first instance and then the Department of Health IP Coordinator.

16.2 If there are reasonable grounds to anticipate that significant IP could be developed in the research project, there should be an agreement between the parties involved with the research project stating:

- arrangements for the use of existing IP and the parties' rights in relation to ownership; and
- arrangements for the use of all new IP developed through the research project.

An agreement may consist of an overarching agreement between WA Health and an organisation or a research project specific agreement. If there is no agreement in place the PI should contact the RGO to discuss the issue of incorporating IP terms into an agreement; and/or contact the Department of Health IP Coordinator to determine if the terms are suitable for WA Health.

IP in WA Health Employee Investigator-Initiated Projects

16.3 When a WA Health employee is involved in an investigator-initiated research project that has been approved by the site, the site supports this project by providing indemnity and insurance. If there are reasonable grounds to anticipate that significant IP could be developed in the research project, the investigator will be requested to acknowledge the ownership of this IP by the State of Western Australia, represented by WA Health. The appropriate form can be sourced from the RGO.

16.4 WA Health supports innovation and has the ability to provide innovative Government employees with rewards for developing or creating commercially valuable IP assets in the course of their work. This is discussed in the document WA Government "Encouraging Innovation by Government Employees" 2003.

IP in Collaborative Research Projects

16.5 The ownership and use of both Background (pre-existing) IP and newly developed (Project) IP in collaborative research should be specified in a written agreement between the participating parties. Research agreements must state the arrangements for use of existing IP and the parties' rights in relation to ownership and use of all new IP developed through the research project. These agreements must be approved by the RGO, in consultation with LLS and the Department of Health IP Coordinator (as required).

16.6 Patent protection or commercialisation of WA Health IP should not be undertaken without prior authorisation and guidance from the RGO, in consultation with the Department of Health IP Coordinator.

Authorship and Publications

16.7 Authorship and Publications with WA Health must comply with Section 2.14 & 2.15 "WA Health Research Governance Policy and Procedures" 2012.

16.8 A clear agreement between all parties, describing the method of disseminating results and protection of IP rights, should be reached and documented at the planning stage of any research. This should be incorporated into the research protocol and any relevant agreement.

16.9 It is a responsibility of WA Health employees involved in the publication of professional or scientific papers on behalf of WA Health, to inform their Manager or the relevant delegated authority. WA Health must be acknowledged in all publications by WA Health employees.

16.10 Unless IP assignment is required by the journal publisher, any publication, whether in print or electronic form, arising from WA Health activities should carry the copyright disclaimer available on the Department of Health IP Management website.

SOP 17: Indemnity for Research Projects

Purpose: To describe the process for administering the indemnity provisions for clinical trial and non-clinical trial research projects.

Non-Clinical Trials

17.1 In research projects that are not clinical trials, the indemnity provisions must comply with Section 2.12.2 "WA Health Research Governance Policy and Procedures" 2012. The indemnity clauses should be mutual or specifically tailored to the risks and liabilities associated with the project; which should be documented in agreements as required.

17.2 Under the National Approach/Mutual Acceptance WA Health has the appropriate insurance to respond to any liabilities that might be incurred in relation to its research activities, but this does not preclude WA Health from requiring indemnity from a third party. In regards to a non-clinical trial project which has been reviewed by an external private HREC the indemnity provisions in Section 2.12.2 "WA Health Research Governance Policy and Procedures" 2012 must be adhered to.

Clinical Trials

17.3 In research projects that are clinical trials, the indemnity provisions must comply with Section 2.11.2.4 "WA Health Research Governance Policy and Procedures" 2012.

17.4 Projects conducted under the non-commercial CRG CTRA **(SOP 15.5)** do not require the CRG to indemnify the site and HREC with an indemnity. If a CRG offers to provide an indemnity it is preferred that it be in the form of the Medicines Australia **(MA)** version.

17.5 In all commercial trials conducted under the commercial CTRA/CIRA **(SOP 15.5)**, the sponsor or CRO must indemnify the site and members of the Lead HREC against claims arising from the research in accordance with the relevant MA and Medical Technology Association of Australia **(MTAA)** Form of Indemnity for Clinical Trials. Those forms are:

- Standard Form of Indemnity (for use where the Indemnified Party is providing premises for the conduct of the project and HREC review, or is providing premises only); and
- Form of Indemnity - HREC review only (for use where the Indemnified Party is providing HREC review ONLY of the project).

17.6 The Standard Form of Indemnity does not cover liabilities that may arise from negligence on the part of the Institution or its employees.

17.7 Non WA Health parties may seek to be indemnified by a commercial sponsor. Where a third party, such as a research institute, wishes to be indemnified by the commercial sponsor a separate Form of Indemnity must be used for each party indemnified.

17.8 Where the sponsor is an overseas entity and party to the CTRA, the indemnity may be provided by the sponsor or by the CRO. If the overseas company is not party to the agreement, the CRO must provide the indemnity (backed up by an acceptable insurance policy) it cannot provide indemnity as an agent of the overseas company.

17.9 Amongst other things, the MA/MTAA Form of Indemnity provides that in the event of injury caused to a participant attributable to participation in the trial in question 'the Sponsor agrees to adhere to the MA "Guidelines for Compensation for Injury Resulting from Participation in a Company-Sponsored Trial" 2004.' Acceptance of such compensation does not limit the participant's right to pursue a civil claim.

17.10 As the Form of Indemnity is a legal document, the indemnifying party and PI must ensure:

- that the correct legal name appears for both 'the Indemnified Party' and 'the Sponsor'. The ABN and address must be included as part of the legal name. PIs are advised to check with the external party for the correct entity names and ABN (for Australian Sponsors and/or

CROs). For the site, the correct information for the indemnified party must be the legal name as stipulated in Section 2.11.2.1 "WA Health Research Governance Policy and Procedures" 2012;

- that all project details, including the protocol number and project title are consistent with the protocol; and
- other details that are to be confirmed on page 1 include identification of 'the Participants' and 'the Investigator' in paragraph 1.

Review by the RGO

17.11 Following submission to RGO, the draft Form of Indemnity will be checked to verify that the details for each party are correct, that 'the Participants' and 'the PI' have been identified in paragraph 1, and that the wording has not been altered, deleted or inadvertently omitted when completing the document details. If a CRO is providing the indemnity the wording 'sponsor' must be changed to 'CRO' to match the parties' title in the CTRA.

17.12 Any proposed changes to the wording of the Form of Indemnity by any party to the project, aside from those required above, must be made separate to this document. Generally this is done in Schedule 3 of the respective CTRA/CIRA. If the indemnifying party makes any changes to the body of the Form of Indemnity, RGO will need to have these reviewed by LLS.

17.13 Once the Form of Indemnity has been reviewed and approved by the RGO, the external party should send the complete signed originals (the number of copies must match the number of CTRAs/CIRAs) to the RGO to organise signing.

17.14 The RGO will arrange for the signing of the Forms of Indemnity (with the other approved documents) by the Chief Executive/delegate, once all the research governance requirements have been met. Once signed by the Chief Executive/delegate the original Form of Indemnity will be sent by the RGO to the PI and external party(ies) (as relevant) and retain an original on the project file.

SOP 18: Insurance for Research Projects

Purpose: To describe the process for reviewing insurance provisions for a research project

18.1 In research projects conducted within WA Health the insurance provisions must comply with Section 2.11.3 & 2.12.2 "WA Health Research Governance Policy and Procedures" 2012.

18.2 Reviewing other parties' insurance is a risk management strategy which seeks to ensure that research activities are adequately covered by robust insurance provisions. This not only protects the interests of WA Health but importantly, also protects the interests of research participants, as well as sponsors and CROs.

18.3 RiskCover manages the WA Government's self insurance arrangements, which incorporate the WA Health system, including research activities. RiskCover protects public sites under the legal liability cover and also provides insurance and risk management advice to its public clients. Where a research project is to be undertaken within WA Health, the project proposal must pass certain scrutinies by the RGO, including examination of the external parties' insurances. RiskCover provides a support service in scrutiny and advice regarding these insurances and the RGO operates under its guidelines.

18.4 In commercially sponsored trials, it is important to ensure the insurance held by a sponsor/CRO will actually cover the liability of the insured (sponsor) for injury or death, plus damage to property, as a result of the sponsor's performance under the CTRA. Scrutiny of the insurance by the RGO therefore becomes important because if the insurance does not have veracity, then the integrity of the clinical trial collapses e.g. No Fault Compensation insurance policies without legal liability clauses are often not acceptable.

18.5 The CTRA/CIRA stipulates which insurance requirements must be met. The Institution will review insurance limits with reference to the risks of the project however the minimum requirements for a sponsor and/or CRO are:

- public liability insurance for the minimum sum insured of AUD $5,000,000; and
- liability insurance covering:

(a) clinical trial/product liability (or equivalent) and professional indemnity; and
(b) the contractual obligations of the sponsor contained in the Agreement;

without limiting the indemnity obligations of the sponsor set out in Schedule 3 of the Agreement;
for minimum sum insured of AUD $10,000,000 any one claim and also in the aggregate and which does not contain an excess/deductible or self-insured retention amount greater than AUD $25,000 for each and every claim or series of claims arising out of one originating cause.

18.6 Where insurance is required, an insurance certificate of currency, as a minimum, must be provided with the governance application. For insurance companies based in Australia (and listed on the Australian Prudential Regulation Authority's **(APRA)** list of acceptable insurers), the certificate of currency is usually an acceptable evidence of cover.

18.7 If the insurance company is not APRA approved a full copy of the insurance policy wording is required by the RGO (in consultation with RiskCover) to assess the veracity of the policy. PIs are asked to request this document from the sponsor. Although the insurance industry uses common terms to describe the various classes of insurance, the actual policies offered by insurers within each class can vary significantly and the wording of the overseas policies may not always be clear. If the sponsor is unable to provide the policy wording information must be provided to address the following 13 points in **SOP 18.8**.

18.8 The RGO will assess the insurance information provided against the 13 points of insurance that have been outlined by RiskCover as the minimum amount of information that needs to be provided (listed in the CTRA/CIRA Schedule 4):

1 Name and address of the insurer, including its Internet website address.
2 Name and address of the insured. If the insurance extends to other parties relevant to the agreement, details should be provided. The site needs to be satisfied that the sponsor is actually an insured under the policy.
3 Policy number.
4 Period of insurance.
5 Class of insurance.
6 Sum insured per event including any sub limits.
7 Aggregate sum insured.
8 If applicable, any excess of loss/umbrella policy information.
9 Deductibles/excesses.
10 Whether the policy is constructed on an “occurrence” or “claims made” wording.
11 Scope of cover. For example, “Legal liability of the insured for death and bodily injury arising from clinical trials, including products liability risks”. There may be a need to quote the operative clause of the policy to capture the correct interpretation.
12 Territorial limits of the policy. It is essential that the policy respond to claims lodged and processed in an Australian jurisdiction. Notwithstanding that the cover may apply anywhere in the World, if there are any restrictions on claims in an Australian jurisdiction, these must be detailed (If an overseas sponsor is providing insurance, it needs to be clarified that if a claim were to be made that it would not be required to be heard in a court overseas).
13 Relevant policy exclusions and conditions should be listed and detailed if appropriate. (Exclusions relating to contractual liabilities, specific drugs and implements may be important as examples have been found in the past where the very product being trialled is listed as an exclusion on the insurance policy, rendering the insurance policy provided for that project invalid, thus leaving WA Health open to any claims arising from the trial.)

18.9 Where the 13 points of insurance information have not been provided, the RGO will contact the sponsor/CRO to provide the balance of information. Once this information is received by the RGO and deemed to be in order, then the insurance can be approved.

18.10 The RGO will contact RiskCover for further advice if the insurance does not comply with RiskCover’s recommendations or is difficult to analyse.

18.11 After consultation with RiskCover, if the insurance does not comply with requirements the RGO will consult with the Chief Executive/delegate to decide if the trial can proceed based on the insurance provisions provided.

SOP 19: Submission of an Application for Research Governance Review

Purpose: To outline the submission process to a Health Service RGO or Department of Health Data Custodian for governance review of a research project within WA Health.

Health Services

19.1 The PI must review the RGO contact details and application dates (if applicable) and ensure that the application is submitted before the close of business on the application closing date. If an application date does not apply the PI must submit the application as soon as the SSA/Access Request Form is fully completed (with all signatures) and supporting documents are available as per **SOP 19.7 and 19.8**.

19.2 In projects that require insurance, indemnity and legal documentation as outlined in the "WA Health Research Governance Policy and Procedures" 2012 the PI must submit them to the RGO at the earliest possible opportunity, as review of contractual documentation can be a lengthy process, refer to **SOP 19.3**.

19.3 When the PI submits the fully competed SSA/Access Request Form, the PI must endeavour to provide all supporting documents **(SOP 19.7 and 19.8)** or indicate why they are not available at the time of submission (e.g. Lead HREC approval letter not yet available). Some documents (e.g. indemnity and research agreements) may need to be submitted in draft format (without signatures) to allow the RGO to assess the documents and obtain legal or other review without delaying the overall governance process. The PI must submit the outstanding documents through the RGS to the RGO as soon as they become available to reduce delays in authorisation.

19.4 Any documents already submitted with the ethics application will be linked through the RGS with the governance application once it is submitted.

19.5 The PI must ensure that the Master PICF or Site Master PICF reflects the individual sites' details as per **SOP 3.6**.

19.6 One copy of the Lead HREC approval letter must be submitted by the PI to the RGO when available. Should the Lead HREC not grant approval for the research project the RGO must be notified immediately as per **SOP 9.14**.

19.7 Once the SSA Form is completed (including all signatures), the PI must lock the form, select the relevant RGO and then submit the form, ensuring that applicable support documents are attached, including:

- the ethics application form(s) and all supporting documents (listed in **SOP 5.11**) that have not already been submitted to the Lead HREC through the RGS;
- Master or Master Site PICF with site specific details;
- WA Health Research Conflict of Interest Form(s) (if applicable);
- WA Health Declaration of Confidentiality (if applicable);
- Lead HREC Approval Letter (when available);
- CTN/CTX Form (indicate that original hard copy sent separately to the RGO, confirm that the form has this been signed by the Lead HREC first);
- Indemnity Form(s);
- Insurance Certificate of Currency;
- Research Agreement;
- additional approvals e.g. other HREC approvals, Institutional Biosafety Committee, NHMRC Embryo Research Licensing Committee, Reproductive Technology Council, Radiation Safety Officer Report; and
- additional budget document (if required).

19.8 Once the Access Request Form is completed (including all signatures), the CPI must lock the form, select the relevant RGO and then submit the form, ensuring that applicable support documents are attached, including:

- Lead HREC Approval Letter (when available);
- the ethics application form;
- WA Health Research Conflict of Interest Form (if applicable);
- WA Health Declaration of Confidentiality (if applicable);
- all documents to be distributed through the sites within the Health Service; and
- written confirmation of approval from personnel of the sites through which the CPI is seeking access to participants, tissue or data.

19.9 When submitting support documents the PI must confirm the items that have been submitted electronically and note which documents will be sent to the RGO as hard copies if they cannot be attached electronically (e.g. protocol).

Department of Health Data Collections/Data Linkage

19.10 The CPI/PI responsible for applying for Department of Health data or data linkage where Department of Health WA HREC approval is required is responsible for submitting the relevant data application documents to either the Data Custodian or the Data Linkage Branch Managers in accordance with **SOP 11.9 and 11.10**.

19.11 Data governance review will be conducted in accordance with the Department of Health WA HREC SOPs by the relevant Data Custodian(s) and Data Linkage Branch Managers. Once the governance review is complete the CPI/PI must submit the Application for Data Form with the ethics application using the RGS **(SOP 5.16)** to the Department of Health WA HREC as an attachment.

19.12 The Department of Health WA HREC EEO will notify the Data Linkage Branch Project Officer of the outcome of the HREC review and the Data Linkage Branch Project Officer will prepare the data release papers for approval by the Data Steward to approve the use or disclosure of the data.

Withdrawal of a Governance Application

19.13 The PI may withdraw an application which has been submitted to a RGO at any time prior to approval. The PI must provide the RGO with notification that they intend to withdraw a submitted governance application, including the reason for the withdrawal. An acknowledgement email of receipt will be sent to the PI. Following notification, the RGO must review and document the withdrawal details on the RGS including the stage of the process when the application was withdrawn. The RGO has the ability to withdraw an application during the validation or review process when the application is not approved or the PI fails to provide additional information within the requested timeframe.

19.14 The RGO must send a letter to the PI (and WA Health HREC through the RGS) acknowledging withdrawal of the project. The letter must include but not be limited to:

- date of withdrawal;
- requested by whom; and
- reason for the withdrawal (and other relevant information).

Amend Application for Resubmission (prior to approval)

19.15 If the PI wishes to resubmit an application they must submit the amended application to the RGO (retaining the original PRN and HREC Reference Number). The PI must access the latest version of the application through the RGP, amend the application (with changes clearly marked) sign it electronically, 'lock' the form and resubmit it to the RGO. The PI will be able to track the resubmitted application through the review process.

Record Re-submission Receive Date

19.16 The RGO will receive a notification that an application has been changed with a new version and its status will be updated. The RGO must note/record the date the resubmission is received and reset the stop clock to zero, as this is treated as a new application (though retains the original HREC Reference Number and PRN). The 60 day measurement will commence from when the new submission is received. The RGO must validate the application **(SOP 20)** and the RGO will evaluate the resubmitted application **(SOP 21)**.

SOP 20: Acceptance and Validation of a Research Proposal by a RGO

Purpose: To outline the acceptance and validation of a research proposal by a RGO.

20.1 Following a submission by the PI, the RGO will receive a notification to review the governance application form and supporting documentation. An acknowledgement email of receipt will be sent to the PI.

20.2 The RGO will be able to search for a governance application by the PRN, date of submission, project title and type, protocol number, HREC Reference Number, Lead HREC name and subcommittee name (as applicable); and application outcome.

20.3 The RGO must conduct governance review (including validation) within 60 calendar days (allowing for a stop clock capability). The RGO must start the timing from the submission date or application date (if applicable) and stop the clock if additional validation information is required. The clock will be stopped from the time the request is issued to the PI to the time the additional information is received.

20.4 On receipt of an application, the RGO must check the application for validity within 7 calendar days (a reminder will be sent at 3 and 7 days). The RGO must record the version, date of submission (to start the clock) in the RGS. The application must be checked to ensure it is complete and accurate (including signatures). The project must be recorded as either research, quality improvement requiring HREC exemption letter, or authorised prescriber.

20.5 Following the validation review of the application, the RGO must record in the RGS the date of decision and the outcome, either as:

- application valid;
- application valid, modification required (record the modification required); or
- application invalid (record the reason for the invalid status).

20.6 The RGO must then send an acknowledgment notification to the PI within 7 calendar days of receiving the application. RGS standard outcome templates include:

- receipt of valid application;
- receipt of valid application, modification required (including additional information required); or
- receipt of invalid application (including reason).

20.7 If the application is valid, the acknowledgement should indicate the RGO who will be reviewing the application. Once an application has been validated revisions cannot be made. If revisions are required the PI must withdraw and resubmit the application **(SOP 19)**.

20.8 If the RGO requests additional information, the date, requesting party, information required and from whom; and the date the PI resubmits the application must be recorded (a resubmission notification will be generated). If the application still requires modification the PI/RGO will be alerted every month for 4 months. If additional information is not provided in this time, the project will be withdrawn **(SOP 19)**.

20.9 If the application is invalid, the WA Health HREC must be copied into the correspondence and the project will be withdrawn **(SOP 19)**. The PI should discuss the reasons with the RGO and if the issues can be resolved a new application can be submitted **(SOP 19)**.

SOP 21: Research Governance Review by a RGO

Purpose: To outline the research governance review process by a RGO.

21.1 The RGO must conduct governance review (including validation) within 60 calendar days (allowing for a stop clock capability) and recommend to the Chief Executive/delegate whether the project is authorised or not authorised **(SOP 22)**. The RGO will only consider matters concerning the site suitability of the research project. The timeframe is measured from the submission date or application date (if applicable) until written notification of authorisation is sent to the PI. The 60 day measurement will apply to the governance review only and does not apply to ethical review by the Lead HREC.

21.2 The 60 day measurement, allows for a stop clock capability (i.e. the timing stops when additional input is required by the RGO from a sponsor or PI). The clock is stopped on the day the request is sent to the PI/sponsor. The clock is recommenced when all the required information is received on a work day (either electronically or in hard copy) at the office of the RGO.

21.3 The 60 day measurement is a measure of the RGOs performance and the outcome does not have any implications for the review or approval of a research project or the charging of governance application fees (i.e. the review process and fees will be applied as normal). A Research Governance Officer review fee will be charged for the review of research projects by the RGO **(SOP 23)**.

21.4 Ongoing communication between the RGO and the project team will usually occur via the RGS but PIs are encouraged to contact the RGO directly at any stage to discuss the application process or particular issues with their research project.

21.5 The RGO will, at their discretion, discuss aspects of the application with relevant WA Health personnel, RiskCover, sponsors/CRO and the Lead HREC EEO (through the CPI).

21.6 If additional information is required by the RGO in order to make a decision, the PI will be sent a notification by the RGO to provide more information. The PI must provide a response within 4 months or the application will be withdrawn **(SOP 19)**.

21.7 When additional information is required, the RGO must stop the clock until the information is received and keep a record of information requested including:

- who requested the additional information and from whom;
- what information was required;
- the date the request was sent; and
- the date the additional information was provided.

21.8 Lead HREC approval must have been given prior to the RGO declaration being signed and final authorisation by the Chief Executive/delegate.

21.9 The RGO will conduct a full assessment of the governance application and document their findings on the RGS. As part of this process the RGO will review the:

- **Ethics Application Form**
  The RGO must review this for information regarding the project pertaining to their sites' involvement, matters pertaining to patient privacy and confidentiality, informed consent, professional safety, data transfer and storage and other matters of significance for a research project; and
- **Protocol**
  As well as scientific/ethical review by a Lead HREC and subcommittee the research protocol is also reviewed by the RGO in detail. This is to ensure that the research activities described in the protocol are consistent with other project documents and budgeted for in

the SSA. For example, if patients are to undergo CT scans or X-rays, then the RGO needs to check that the departments who provide those services have signed the SSA Form.

Site Specific Assessment

21.10 The RGO must assess the SSA application to ensure:

- all relevant questions on the application form have been completed;
- investigators have the necessary skills, training experience and authorisation to undertake their role in the research project;
- potential conflicts of interest have been identified;
- the site has suitable and adequate facilities, infrastructure and resources (personnel and support of on-going training) which are available for the duration of the project;
- funding sources have been identified and the actual monetary or 'in kind' cost of the project is detailed, including whether these costs can be met by the sponsor or the Health Service. Approval of this budget is documented (as evidenced by the Business Manager's declaration in the SSA Form);
- the Head of Department and Divisional Director (where the research will be conducted) has given a declaration of support in the SSA Form, that the research is appropriate to be conducted within that department and at the site. This includes:

  (1) confirmation of the feasibility and alignment of the project design to institutional and/or departmental strategic plans for research;

  (2) ensuring the project details are acceptable i.e. peer review of scientific, ethical and practical aspects of the proposed project;

  (3) ensuring there is sufficient resourcing (including participants) for the research project to be carried out at the site;
- the Heads of Supporting Departments have given declarations to provide support or services in the SSA Form;
- any legislative requirements, including notification, registration and licence applications have been addressed, including the clinical trial notifications. The RGO will review and process the CTN/CTX and any errors or discrepancies will be identified and reported to the PI, refer to **SOP 04**;
- risk management strategies are implemented i.e. adequate indemnity and insurance arrangements are in place. The RGO must review the research agreement and Forms of Indemnity to ensure WA Health liability requirements are met (refer to **SOP 17)**. The RGO must assess insurance provisions provided by commercial or non-commercial external entity to ensure that they comply with RiskCover's requirements (refer to **SOP 18)**;
- research agreements are in place with external commercial and non-commercial research and clinical trial sponsors, clarifying obligations, responsibilities and the rights of parties involved. The RGO will review the submitted agreement to ensure that the interests of WA Health, funds and IP are adequately represented and managed (refer to **SOP 15)**;
- research documents comply with the specific requirements of the WA Health sites; and
- there is HREC (comprising ethical and scientific) approval (this approval may not be available on initial submission).

Access Request Review

21.11 The RGO will review all the required documents in the Access Request Review application and determine that each site that is required to provide support for the project has been identified, approached and given approval for access to its participants, their tissue or data at its facilities, locations or services.

21.12 The RGO will review the application and determine if all the required documentation has been submitted. It will also ensure that each site that has been asked to provide access to participants, data or tissue has been identified, approached and agreed (as evidenced by written confirmation).

SOP 22: Authorisation to conduct a Research Project at a WA Health Site

Purpose: To outline the authorisation process to conduct a research project within WA Health.

22.1 Both Lead HREC approval and site authorisation following a SSA or Access Request Review are required before a research project can commence at a site.

22.2 Authorisation to commence a research project must be granted by the Chief Executive/delegate at a site. Only the Chief Executive/delegate has the authority to grant/not grant authorisation for a research project.

22.3 When the Lead HREC has given approval for the project and the RGO assessment is complete, the RGO will document in the SSA/Access Request Form their recommendation to the Chief Executive/delegate as to whether authorisation:

- is recommended;
- is not recommended; or
- requires consideration by the Chief Executive/delegate.

The RGO will provide reasons for their decision if authorisation is not recommended or requires consideration by the Chief Executive/delegate.

22.4 The RGO will send a notification to the Chief Executive/delegate that the completed form and a copy of the Lead HREC approval letter are available for review in the RGS. WA Health Chief Executives/delegates responsible for authorising research applications must request a user ID for access to the RGP **(SOP 5.4)**. The review by the Chief Executive/delegate must be conducted in an efficient and timely manner.

22.5 Any document that requires the signature of the Chief Executive/delegate in hard copy will be sent separately to the Chief Executive/delegate by the RGO (e.g. agreements, CTN/CTX). For clinical trials conducted under the CTN scheme, the Chief Executive/delegate is required to sign the CTN Form at Section 4. The RGO must return the original to the PI **(SOP 04).**

22.6 In making a determination, the Chief Executive/delegate must consider the governance form and the Lead HREC approval letter. Once a decision has been made the Chief Executive/delegate must sign the SSA/Access Request Form and applicable authorisation letter. The Chief Executive/delegate retains the right not to authorise commencement of a research project even if it has received Lead HREC approval.

22.7 Once the Chief Executive/delegate has made a decision, the RGO will receive notification to review the outcome. The RGO must notify the PI (copied to WA Health Lead HREC EEOs) within 7 calendar days of Chief Executive's/delegate's decision. The notification must be in writing signed by the Chief Executive/delegate and accompanied by a copy of the signed CTN and all authorised documents. RGS standard outcome letters include:

- Research Governance authorised; or
- Research Governance not authorised.

22.8 On notification the RGO will update the status of the project in the RGS and stop the clock, marking the end of the governance application review process.

22.9 The PI will be responsible for notifying the Lead HREC (through the CPI, refer to **SOP 28.2**) of the outcome of the decision. If authorisation is granted, the project can commence at the site. If authorisation is not granted the research project cannot proceed at the site. The WA Health Lead HREC will able to review the status on the RGS.

22.10 The RGO and PI must both keep a copy of all documentation relating to the governance review, including evidence of ethical approval and all supporting documentation for the SSA/Access Request Form. These documents must be maintained in a secure and confidential manner.

SOP 23: Managing Lead HREC and Research Governance Officer Review Fees

Purpose: To describe the process for managing Lead HREC and RGO review fees.

23.1 Lead HREC and Research Governance Officer review fees are charged in accordance with Health Services and the Department of Health's SOPs. The fees are applied to all projects that are fully sponsored by external commercial agencies, which require Lead HREC and/or RGO review of new applications and amendments. The payment will be invoiced directly to the sponsor/CRO by the Lead HREC EEO and RGO, following submission of the application, irrespective of whether the project commences.

23.2 Research payments from external sponsors (Debtor) can occur either by Direct Tax Invoice (Department created invoice through HCN; or by Recipient Created Tax Invoice **(RCTI)** (Debtor generated invoice).

Raising the Invoice

23.3 The EEO/RGO will record in the RGS the information required on a HCN Debtor Advice Form **(S60)** to raise an invoice for a research sponsor. Details include but are not limited to:

- debtor name and contact name;
- contact telephone, email, postal address;
- PRN and HREC Reference Number;
- project description (protocol number and short/long title);
- entity, cost centre, account code;
- fund;
- amount;
- tax code;
- date of invoice;
- amount owing;
- type of payment i.e. HREC or RGO fee; and
- receipt of payment - amount received, date paid, HCN receipt number.

23.4 The EEO/RGO must complete the HCN Debtor Advice Form and send it to HCN to request an invoice. An accompanying letter can be sent to sponsor regarding the payment. If requested HCN will send a copy of the invoice to the EEO/RGO to assist them to check the invoice number against records.

Recipient Created Tax Invoice – Debtor Created Tax Invoice.

23.5 Instead of raising an invoice, the debtor may send a remittance advice or a RCTI and project payments to HCN or to the EEO/RGO advising them of the trial name, protocol number, payment, date, debtor and costing (cost centre, account) details. A copy of the recipient created invoice should be sent to the EEO/RGO by the Debtor at the time of remittance. Once an invoice is raised by HCN the funds are immediately transferred into the recipient's account.

Payment Not Received

23.6 The EEO/RGO must record in the RGS if the payment has not been received and generate an email to be sent to the sponsor if requested by HCN.

SOP 24: Ethical Amendments to an Authorised Research Project

Purpose: To describe the process for making an amendment to an ethically approved research project that has been authorised to commence.

24.1 As a condition of ethical approval, the CPI must seek and gain approval from the Lead HREC (who granted initial approval) for proposed amendments to the research project, which may affect the ethical or scientific acceptability of the research project.

24.2 Exceptions to the amendment process may be made in circumstances where there is a serious threat to the health and safety of participants. As soon as possible, following the deviation or change, the CPI must notify the Lead HREC EEO and ensure that PIs notify the RGO at each relevant site.

24.3 An amendment consists of a change or addition made to the terms of the ethics application, the protocol, or any other supporting documentation (Investigator Brochure or PICF) after the study has started which may affect the ethical and/or scientific acceptability of the research project. These amendments are classified as either:

- An Administrative Amendment which is defined as:
  - minor corrections to project documents or an updated version of a project document (e.g. typographical or grammatical mistakes, changes in specimen handling or specimen analysis procedures, changes in drug descriptor [adopting new approved name, for example, not a change in drug identity]);
  - changes to the personnel on an approved HREC application (e.g. change to/or addition of a new CPI, PI, sponsor personnel etc.); and/or
  - addition of a new site.
- A Substantial Amendment is defined as any change to the protocol that lies outside the definition of an Administrative Amendment; and/or an extension of approval.

24.4 If necessary, the CPI should communicate with the Lead HREC EEO regarding the amendment. The CPI must communicate with the sponsor/CRO and PI(s) regarding the amendment process.

24.5 The CPI must review the Lead HREC meeting and application dates, and ensure that the amendment is submitted before the close of business on the subcommittee/Lead HREC application closing date.

Submit Amendment

24.6 If a research project requires an amendment that may affect its ongoing ethical and/or scientific acceptability, then a request for an amendment must be made by the CPI to the Lead HREC by completing an amendment form. The CPI must access the RGP using their User ID and access the original application documents associated with the PRN (refer to **SOP 24.7 & 24.8**). The CPI must create, complete and submit either a **WA Health Ethics Administrative Amendment Form** or **WA Health Ethics Substantial Amendment Form** under their original PRN, clearly indicting the amendments to the original application documents.

24.7 The ethics application form may be revised or changed following submission to the Lead HREC. The CPI must access the latest version of the form, amend the form (ensuring changes are clearly marked) sign it electronically, lock the form and submit it.

24.8 If any supporting documents require change, the CPI must track the changes (including new version number and date) and attach the document and submit them with the amended ethics application form and the amendment form. If the amendment is the inclusion of a new document (e.g. advertisement, poster) then a tracked copy is not required.

24.9 The RGS will provide a historical view of amendments made to the re-submitted application forms and supporting documents and clearly indicate the latest version. The CPI will be able to track the amendment through the review process.

24.10 If it is a requirement of the Lead HREC, the CPI must submit the required number of amendment hard copies as stipulated in the Lead HREC's SOPs.

Accept, Validate, Review and Notify of Outcome

24.11 The Lead HREC must conduct the ethical and scientific review of an amendment within 60 calendar days (applicable to valid applications only). The timeframe is measured from the HREC application closing date (associated with the meeting that the application is reviewed at) until written notification of the final ethical opinion is sent to the CPI. The 60 day measurement is conducted in accordance with **SOP 8.11 – 8.13**.

24.12 On receipt of the amendment the EEO will accept and validate the amendment and send an acknowledgement notification through the RGS to the CPI within 7 calendar days in accordance with **SOP 06**. The EEO will manage the amendment process for subcommittee/HREC meetings (or expedited review) in accordance with **SOP 07** and notification of the outcome in accordance with **SOP 09**.

Administrative Amendment

24.13 The Lead HREC will review the Administrative Amendment in accordance with the Lead HREC's SOPs which will include one of the following:

- HREC Chair;
- Delegate of the Chair; and/or
- full HREC.

A HREC Chair or delegate has the capacity to refer any amendment to a subcommittee or Lead HREC for review. If amendments are not reviewed by the full Lead HREC they will be tabled at the Lead HREC meeting as information only.

24.14 Following the Lead HREC meeting, the EEO must provide a letter of notification within 7 calendar days to the CPI (and WA Health RGO through the RGS) with the outcome of the amendment review. It is a responsibility of the CPI to send a copy of the letter to PIs and the sponsor/CRO. RGS standard letters include:

- HREC Administrative Amendment approved; or
- HREC Administrative Amendment, more information required.

24.15 If additional information is required **(SOP 9.5)**, the CPI must provide a response within 4 months; if not, the application will be withdrawn. If the amendment is not approved, the project could be suspended **(SOP 31).**

Substantial Amendment

24.16 The Lead HREC will review the Substantial Amendment in accordance with the Lead HREC's SOPs which will include one or more of the following:

- HREC Chair;
- Delegate of the Chair;
- subcommittee(s); and/or
- full HREC.

A HREC Chair or delegate has the capacity to refer any amendment to a subcommittee or HREC for review. If amendments are not reviewed by the full HREC they will be tabled at the Lead HREC meeting as information only.

24.17 Following review by the subcommittee the CPI will be sent a notification of the outcome (**SOP 24.19**). If additional information is required **(SOP 9.5)** by a subcommittee in order to make a decision, the CPI must provide a response within 4 months if not the application will be

withdrawn. The response from the CPI will be reviewed by the subcommittee Chair and if approved the CPI will be notified by the EEO and the submission will remain on the HREC agenda either for review or as information only (refer to **SOP 24.16**).

24.18 Following the approval by the subcommittee the amendment can either be reviewed by the full HREC or this responsibility can be delegated (e.g. HREC Chair or Delegate of the Chair). A delegate has the capacity to submit an amendment for review by the full HREC.

24.19 Following the subcommittee/Lead HREC meeting, the EEO must provide a letter of notification within 7 calendar days to the CPI (and WA Health RGO through the RGS) with outcome of the amendment review. It is a responsibility of the CPI to send a copy of the letter to PIs and the sponsor/CRO. RGS standard letters include:

- subcommittee/HREC Substantial Amendment approved;
- subcommittee/HREC Substantial Amendment, more information required; or
- subcommittee/HREC Substantial Amendment not approved.

24.20 If additional information is required **(SOP 9.5)**, the CPI must provide a response within 4 months; if not, the application will be withdrawn. If the amendment is not approved, the project could be suspended **(SOP 31)**.

24.21 The PIs must submit the approved amendment (both administrative and substantial) and a copy of the approval letter to the site's RGO for site authorisation before the amendment is implemented at their site (refer to **SOP 25**).

SOP 25: Governace Amendments to an Authorised Research Project

Purpose: To describe the process for making an amendment to a research project that has been authorised by the Chief Executive/delegate to commence at the site.

25.1 An amendment must not be implemented at a site until the ethical/scientific amendment has been approved by the Lead HREC **(SOP 24)** and the governance amendment has either been approved by the RGO (Administrative) or authorised by the Chief Executive/delegate (Substantial).

25.2 When it is intended to make an amendment to a research project the PI must submit both the Administrative and Substantial Amendments (refer to **SOP 24** for definition) to the RGO to determine whether or not authorisation is required before the amendment is implemented at the site.

25.3 Where the PI is of the opinion that the amendment does not impact on the ethical/scientific acceptability of the project, the Lead HREC is not required to be notified. This should be confirmed with the Lead HREC EEO and RGO prior to submission of the amendment.

25.4 As Substantial Amendments may have an impact on the SSA, they must be considered by the RGO and authorised by the Chief Executive/delegate. Administrative Amendments can be reviewed and approved by the RGO without authorisation by the Chief Executive/delegate.

25.5 The PI must review the RGO application dates (if applicable) and ensure that the amendment is submitted before the close of business on the application closing date. If an application date does not apply the PI must submit the application as soon as the amendment form is completed.

Submit Amendment

25.6 Once the CPI has completed the ethical component of the **WA Health Governance Administrative Amendment Form** or **WA Health Governance Substantial Amendment Form,** the PI must complete the site specific details before submitting it to the RGO.

25.7 The SSA Form may be revised or changed following submission to the RGO. The PI must access the latest version of the form, amend the form (ensuring changes are clearly marked) sign it electronically, lock the form and submit it.

25.8 If any supporting documents require change, the PI must track the changes (including new version number and date) and attach the document and submit them with the amended SSA Form and the amendment form. If the amendment is the inclusion of a new document then a tracked copy is not required.

Accept, Validate, Review and Notify of Outcome

25.9 The RGO must conduct the governance review of an amendment within 60 calendar days (applicable to valid applications only). The timeframe is measured from the date of submission until written notification of the final governance opinion is sent to the PI. The 60 day measurement is conducted in accordance with **SOP 21.1 – 21.3**.

25.10 On receipt of the amendment the RGO will accept and validate the amendment and send an acknowledgement notification to the CPI within 7 calendar days in accordance with **SOP 20**. The RGO will manage the notification of the outcome in accordance with **SOP 22**.

Administrative Amendment

25.11 Following review of the Administrative Amendment, if the RGO believes site authorisation is not required then they must notify the PI (copied to WA Health Lead HREC EEOs) in writing within 7 calendar days of the outcome. RGS standard letters include:

- Research Governance Amendment approved; or

- Research Governance Amendment, more information required.

25.12 If additional information is required by the RGO **(SOP 21.7)** in order to make a decision, the PI will be sent a notification by the RGO to provide more information **(SOP 25.11).** The PI must provide a response within 4 months or the application will be withdrawn. If the amendment is not approved, the project could be suspended **(SOP 31)**.

25.13 If approval is granted by the RGO, the PI may implement the amendment upon Lead HREC amendment approval being granted. The PI must forward a copy of the Lead HREC approval letter to the RGO once it is available.

25.14 If an Administrative Amendment only affects site authorisation and does not require ethics approval, the PI may implement the Administrative Amendment once they have been notified in writing by the RGO.

Substantial Amendment

25.15 The RGO must review the proposed Substantial Amendment and ensure the continuation of the ethical, legal, professional and financial standards of the research project. Upon review, the RGO must:

- determine if the amendment will result in any changes to the research project's vital documents e.g. CTRA or CTN;
- assess if the amendment will be included under the existing insurance provisions;
- conduct a SSA to determine if the amendment has any additional impact on resourcing; and
- assess whether the amendment documentation includes all the required changes and updated documents.

25.16 Following review, if additional information is required by the RGO **(SOP 21.7)** in order to make a decision, the PI will be sent a notification by the RGO to provide more information:

- Research Governance Substantial Amendment, more information required.

The PI must provide a response within 4 months or the application will be withdrawn. The response from the PI will be reviewed by the RGO and if approved the RGO will recommend authorisation to the Chief Executive/delegate.

25.17 If a Substantial Amendment only affects site authorisation and does not require ethics approval, the RGO may recommend authorisation to the Chief Executive/delegate.

25.18 Once approved the RGO will send a notification to the Chief Executive/delegate that the completed amendment form, HREC approval letter (if applicable) and recommendation are available for review in the RGS.

25.19 Once the Chief Executive/delegate has made a decision, the RGO will receive notification to review the outcome. The RGO must notify the PI (copied to WA Health Lead HREC EEOs) within 7 calendar days of Chief Executive's/delegate's decision. The notification must be in writing signed by the Chief Executive/delegate. RGS standard outcome letters include:

- Research Governance Substantial Amendment authorised; or
- Research Governance Substantial Amendment not authorised.

25.20 If the amendment is not approved, the project could be suspended **(SOP 31)**.

25.21 The PI may implement the Substantial Amendment once it has been authorised by the site's Chief Executive/delegate and they have been notified in writing by the RGO.

SOP 26: Extension of an Authorised Research Project to Additional Sites

Purpose: To describe the process for extending an authorised research project from a single-centre project to a multi-centre project, or adding an additional site to a multi-centre project.

Single-centre to Multi-centre

26.1 If a single-site research project has been approved by an HREC that is authorised to be a Lead HREC in either the WA Health Single Ethical Review or National Approach/Mutual Acceptance systems, then the original approval can be expanded to a multi-site approval, with agreement of the Lead HREC EEO, in accordance with the following:

- if the project was originally approved by a Lead WA Health HREC, then the ethical approval can be extended to additional WA Health sites in accordance with the WA Health Single Ethical Review scope and the Lead WA Health HREC's category of expertise (only after the process commences within WA Health); or
- if the project was originally approved by a NHMRC Certified Lead HREC, then the ethical approval can be extended to additional sites in accordance with the National Approach/Mutual Acceptance scope and the Lead HREC's certification (only after the process commences within WA Health).;

26.2 Once the conditions of **SOP 26.1** are satisfied, the CPI will submit an amendment to the Lead HREC **(SOP 24)**. The CPI must also send to the Lead HREC the details of the PI at the new site. The Lead HREC will review the new PI's competence and qualifications and other relevant details as per the National Statement.

26.3 If the new site is outside WA, the Lead HREC will have to take into consideration the other jurisdiction's legislative requirements when reviewing the amendment.

26.4 If approved, the Lead HREC will issue an approval for the research project listing the new site. This approval must be sent by the EEO to the CPI, who will forward it to the PI and the sponsor/CRO. The PI responsible for the conduct of the project at the additional site will then submit a SSA Form (with notification of original ethics approval by the Lead HREC and a copy of all documents previously approved by the HREC) to that site's RGO to apply for authorisation. If applicable, a CTN Form will be required for the new site.

26.5 The SSA will be conducted by the RGO in the usual manner. When HREC approval has been given and site authorisation has been obtained at the new site, the project can commence at that site.

26.6 If modifications or conditions are imposed by a Lead HREC, then these will apply to all approved sites. Sites that gain ethical approval from a Lead HREC will be required to comply with the ongoing monitoring and reporting requirements of the Lead HREC.

Addition of a Site to a Multi-centre Project

26.7 Where a project is to be extended to another site (and the conditions of **SOP 26.1** have been satisfied) the Lead HREC must be notified in accordance with the National Statement. This will require an HREC amendment process **(SOP 24). SOP 26.4 - 26.6** will also apply.

SOP 27: Monitoring

Purpose: To describe the responsibilities for monitoring the conduct of an authorised research project.

27.1 Monitoring of authorised research projects must be conducted in accordance with Section 2.19 "WA Health Research Governance Policy and Procedures" 2012.

Coordinating Principal Investigator

27.2 The CPI is responsible for notifying the Lead HREC that mechanisms for monitoring are in place, and satisfying the Lead HREC that the arrangements are commensurate with the risk, size and complexity of a research project and will cover the special conditions imposed on the conduct of research.

27.3 The CPI is responsible for project coordination and must be in regular communication with the Lead HREC, PIs and sponsors, keeping them up to-date with safety issues and submitting required reports in a manner that is consistent with the risk, size and complexity of the research project. The CPI must ensure there are:

mechanisms for reporting and reviewing serious adverse events **(SAEs)**, serious adverse drug reactions **(ADRs),** serious unexpected suspected adverse reactions **(SUSARs)**, serious adverse device events **(SADEs)** and unanticipated serious adverse device events **(USADEs)** in the conduct of a trial. In accordance with the AHEC position statement "Monitoring and Reporting of Safety for Clinical Trials Involving Therapeutic Products" 2009;

- monitoring arrangements in place as described in the trial protocol which could include:

  (a) for a large multi-centre trial, a Data and Safety Monitoring Board **(DSMB)**, a trial management committee or a pharmacovigilance group; or

  (b) for an investigator-initiated or collaborative group trial, there is a simpler review process e.g. an individual/committee to assist/advise the HREC about reports of SAEs; and
- mechanisms for informing the Lead HREC of any relevant emerging data from the DSMB etc. or any new safety information from other published or unpublished projects that may have an impact on the continued ethical acceptability of the trial or may indicate the need for amendments to the trial protocol.

27.4 The CPI is responsible for submitting to the Lead HREC:

- amendments, protocol violations and requests for waiver of protocol requirement (e.g. informed consent);
- notification of any sites that do not receive authorisation;
- notification when the project is discontinued before the expected date of completion;
- notification of any complaints, allegations of research misconduct, conflicts of interest;
- summary reports (with information from all the sites) at regular periods – reflecting the degree of risk to participants (if any), and at least annually and at the completion of the project – including information on:
  - progress to date, or outcome in the case of completed research;
  - maintenance and security of records;
  - compliance with the approved protocol (e.g. any deviations/violations);
  - compliance with any conditions of approval;
  - closure of the project; and
  - communication of final results to research participants.

27.5 In the case of implantable medical devices, the CPI must confirm the existence of, or establish, a system for tracking the participant, with consent, for the lifetime of the device; and reporting any device incidents to the TGA. The CPI should obtain consent fro tracking the device (which is the responsibility of the manufacturer) in the PICF. Forms for reporting medical device problems are available from the TGA website.

Principal Investigator

27.6 The monitoring role of the PI includes:

- monitoring the conduct of research through project management at the site; monitoring special conditions imposed on the conduct of research, communication with the CPI as necessary;
- reporting to the Lead HREC (through the CPI) any complaints, allegations of research misconduct, conflicts of interest, closure of the project;
- completion of requirements for closure of the project;
- submission of annual report and final report to the CPI for submission of a summary report to the Lead HREC and to communicate results to research participants;
- referral of HREC approved amendments to the RGO; and
- submission of reports to the RGO at regular periods – reflecting the degree of risk to participants (if any), and at least annually and at the completion of the project – including information on:
  - any locally occurring (site only) adverse events;
  - progress to date, or outcome in the case of completed research;
  - maintenance and security of records;
  - compliance with the approved protocol;
  - compliance with any conditions of approval;
  - closure of the project; and
  - communication of final results to research participants.

Lead HREC

27.7 The Lead HREC is responsible for reviewing:

- annual reports on the progress to date from the CPI (including compliance with the approved protocol, compliance with any special conditions of approval, extension of the project, maintenance and security of records, communication of results to research participants);
- progress reports on instances where there is any significant deviation from, or violation of, the project protocol;
- monitoring special conditions imposed on the conduct of research;
- conducting or coordinating audits of research projects, where required (HREC auditing should remain discretionary);
- reports on instances where the project is withdrawn, terminated or suspended before the expected date of completion (including reason);
- safety reports of serious adverse events/serious unexpected events in line with the AHEC position statement "Monitoring and Reporting of Safety for Clinical Trials Involving Therapeutic Products" 2009;
- protocol amendments, or changes to informed consent documents; and
- a final report on completion from the CPI when all sites are closed (including the outcome, a copy of the research results to facilitate communication to research participants, as required).

Research Governance Officer

27.8 The RGO is responsible for:

- monitoring the conduct of research at the site through review of annual and final progress reports submitted by the CPI (single-centre research) or PI (multi-centre research);
- monitoring special conditions imposed on the conduct of research;
- conducting or coordinating audits of research projects, where required **(SOP 27.9)**;
- reviewing and managing amendment documentation related to authorised research projects that have implications for the site (e.g. resourcing);
- processing complaints relating to the conduct of research at the site in accordance with institutional complaints policy and processes;

- receipt and investigation of allegations of research misconduct;
- review of required reports, and receipt and investigation of conflict of interest allegations;
- completion of requirements for project closure; and
- review of annual and final reports for the publication of research outcomes.

Monitoring Audit

27.9 In line with the NHMRC "Framework for Monitoring: Guidance for the National Approach to Single Ethical Review" 2012 auditing can be carried out by sponsors or regulatory agencies in the form of site visits. The TGA's "Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95)" 2000 requires that the sponsor ensures that trials are adequately monitored and the monitor should be appointed by the sponsor. Equally, institutions or HRECs can develop audit programs that are tailored to specific needs and operate within the constraints of available resources.

27.10 If a project is selected for monitoring, the RGO/monitor will send a notification to the PI through the RGS. The PI must send a response to the RGO acknowledging the date of the audit. Once the audit is complete the RGO will send a letter either approving the Monitoring Report or requesting further information. If additional information **(SOP 21.7)** is required the PI must submit a response in a prompt manner.

SOP 28: General Reporting

Purpose: To outline the ongoing reporting responsibilities of an authorised research project.

Project Commencement

28.1 Monitoring of authorised research projects must be conducted in accordance with Section 2.19 "WA Health Research Governance Policy and Procedures" 2012.

28.2 The commencement of a research project must be reported to the Lead HREC by the CPI and to the RGO by the PI when they submit their first progress report, refer to **SOP 28.3**.

Annual Progress Report

28.3 Progress of research must be reported annually (at a minimum) or as required by the Lead HREC. Continuation of ethical approval for a research project will be contingent upon receipt of a progress (annual or more frequent) report to the Lead HREC from the CPI. Continuation of site authorisation will be contingent upon receipt of a progress (annual or more frequent) report to the RGO from the PI. For annual reports (both to the HREC and RGO), the due date is one year from the date of the Lead HREC approval date.

28.4 The EEO and RGO will record in the RGS the frequency that progress reports are required. The RGS will send a reminder notification 1 month prior and at 1 day past the due date (with a follow up reminder at 1 and 2 months) to the CPI, PI, EEO and RGO for an annual progress report if the report is not received within 12 months of the project being approved (or the previous annual report).

28.5 The CPI is responsible for submitting the report to the Lead HREC (the Lead HREC report must contain collated information about the project from PIs at all sites) and the PI is responsible for submitting the (site specific) report to the RGO. The **WA Health Annual Progress Report Form** available on the RGS, must be used for submitting reports. The CPI must access the RGP using their User ID and create the form aligned with the PRN.

28.6 The WA Health Annual Progress Report Form must be completed by the CPI and then the CPI must send a request through the RGS to each PI to complete the site specific details.

28.7 If a site(s) has not provided the CPI with the appropriate annual report information, it will be at the discretion of the Lead HREC whether the participating site(s) will have ethical approval suspended until a report is submitted.

28.8 Once the PI has completed their details on the form; the PI must submit one copy through the RGS to the site's RGO and the CPI must be notified. Once all PIs from all participating sites have included their details on the WA Health Annual Progress Report Form the CPI must submit the form to the Lead HREC through the RGS.

28.9 If it is a requirement of the Lead HREC/RGO, the CPI/PI must submit a hard copy as stipulated in the Lead HREC's/RGO's SOPs.

28.10 Upon receipt of the report, the EEO and RGO will receive a notification and the investigator will be sent an acknowledgement of receipt. The EEO/RGO must then validate, review and record the date received, type and details of report in the RGS. The EEO must assign the report to be reviewed/tabled at a Lead HREC meeting. The decision of the HREC review will be sent to the EEO.

28.11 Once the reports from the CPI and PI have been reviewed by the Lead HREC/delegate and RGO respectively, the outcome must be recorded in the RGS; it must include the date of review and by whom and any additional information that is required **(SOP 9.5 & 21.7)**. A notification will be sent either approving the report or requesting more information by:

- the EEO within 7 calendar days of the HREC meeting; and

- the RGO within 7 calendar days of approval.

RGS standard letters include:

- Annual Progress Report approved; and
- Annual Progress Report, more information required.

If more information is required the CPI/PI can amend and resubmit the report

Project Closure at a Site

28.12 At the conclusion of a research project at one or more sites, the CPI/delegate must notify the Lead HREC and the PI must notify the RGO within 30 calendar days of the project completion.

28.13 If a single site is being closed, the CPI and that site's PI must complete and submit a **WA Health Final Progress Report Form** **as per SOP 28.5 – 28.9**. One copy must be submitted through the RGS by the PI to the site's RGO and one copy submitted by the CPI to the Lead HREC.

28.14 Once the reports from the CPI and PI have been reviewed by the Lead HREC/delegate and RGO respectively, the outcome must be recorded in the RGS; it must include the date of review and by whom and any additional information that is required **(SOP 9.5 & 21.7)**. Once this process is completed the EEO and the RGO will send a notification (in accordance with **SOP 28.11** timeframes) either approving the report or requesting more information. If more information is required the CPI/PI can amend and resubmit the report. RGS standard letters include:

- Final Progress Report approved; and
- Final Progress Report, more information required.

Final Report

28.15 If the research project is completed at all sites, the CPI must complete a WA Health Final Progress Report (including the final results) as per **SOP 28.5 – 28.9**, within 30 calendar days of project completion, submit one copy to the Lead HREC, and send a copy to all sites' PIs (for forwarding to the RGOs).

28.16 The date will be recorded and the EEO will send an acknowledgement of the report to the CPI as per **SOP 28.14**.

SOP 29: Safety Reporting

Purpose: To describe the requirement for safety reporting to the Lead HREC and RGO regarding adverse events **(AEs)**, including serious adverse events, serious adverse device events, suspected unexpected serious adverse reactions, unanticipated serious adverse device events and protocol deviations or violations.

29.1 Monitoring of authorised clinical research projects must be conducted in accordance with Section 2.19 "WA Health Research Governance Policy and Procedures" 2012.

Protocol Deviation or Violation Report

29.2 **Protocol deviations** are minor or administrative departures from HREC approved protocol procedures whereby data is unusable or not available, but which do not affect the scientific soundness of the research plan or the rights, safety, or welfare of research participants. Examples include: follow up visits that occurred outside the protocol required time frame because of the participant's schedule, or blood samples obtained at times close to but not precisely at the time points specified in the protocol.

29.3 **Protocol violations** are major departures from the HREC approved protocol procedures and/or regulatory guidelines which compromises the ethical acceptability of the project, and are generally more serious in nature than protocol deviations. Protocol violations are considered to potentially affect the scientific soundness of the research plan and/or the rights, safety, or welfare of research participants. Examples include: failure to obtain participant consent, participant inclusion/exclusion violations and compromises to data integrity.

29.4 The CPI/PI must not implement any deviation from or violation of the protocol without prior agreement by the sponsor and prior review and approval from the Lead HREC of an amendment, except where necessary to eliminate hazards to the participants or when changes involve only administrative aspects of the project (e.g. change in monitor, change in contact details).

29.5 As soon as possible, following a protocol violation, the CPI/PI must provide retrospective notification of the implemented violation, the reasons for it, and, if appropriate the proposed protocol amendment to the:

- Lead HREC/RGO for review and approval;
- sponsor for agreement (if required); and
- regulatory authorities (if applicable).

29.6 Protocol deviations do not require notification to or review by a HREC/RGO (unless they occurred to a significant proportion of the participants, refer to **SOP 29.7**). At the discretion of the PI a list of protocol deviations may be reported with the annual progress report, however this is not a requirement.

29.7 The CPI/PI must document and explain any deviation (affecting a significant proportion of the participants) or violation of the approved protocol **that either eliminate immediate hazards to trial participants, significantly affect the conduct of the trial, or increase risks to participants** in the **WA Health Protocol Deviation/Violation Notification Form**, available from the RGS or on the Research Development (ethics) website.

29.8 The WA Health Protocol Deviation/Violation Notification Form must be completed (using the RGS and aligned with the PRN) by the PI and sent to the CPI for signing. As soon as possible (following notification from the PI) the CPI must submit the form to the Lead HREC and a copy must be sent by the PI to the RGO.

29.9 Upon receipt of the report the EEO and RGO will receive a notification and the investigator will be sent an acknowledgement of receipt. The EEO/RGO must then validate, review and record

the date received, type and details of report in the RGS. The EEO must assign the report to be reviewed/tabled at a HREC meeting. The decision of the HREC review will be sent to the EEO.

29.10 Upon receipt of the report the Lead HREC will, in accordance with their SOPs, review the report and take the appropriate course of action **(SOP 31)**. The outcome must be recorded in the RGS, it must include the date of review and by whom and any additional information that is required **(SOP 9.5)**.The EEO will send a letter of notification outlining the outcome of the review within 7 calendar days of the Lead HREC meeting. RGS standard letters include:

- Safety Report acknowledged; and
- Safety Report, more information required.

If more information is required the CPI can amend and resubmit the report.

29.11 Upon receipt of the report the RGO will review the report and take the appropriate course of action **(SOP 31)**, the outcome must be recorded in the RGS, it must include the date of review and by whom and any additional information that is required **(SOP 21.7)**. The RGO will send a letter of notification **(SOP 29.10)** outlining the outcome of the review within 7 calendar days of the review. If more information is required the PI can amend and resubmit the report.

Adverse Event Report

29.12 Reporting of AE/SAE/SADE/SUSAR/USADE to the Lead HREC, RGO and sponsor must meet the requirements of the National Statement , the AHEC position statement "Monitoring and Reporting of Safety for Clinical Trials Involving Therapeutic Products" 2009 and the TGA's "Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95)" 2000.

29.13 As a condition of ethical approval, the Lead HREC must be notified by the CPI of anything that might warrant review of the approval of the project including serious and unexpected adverse events in accordance with **SOP 29.21- 29.25**. The Lead HREC may, as part of ethical approval, require more detailed and/or frequent reporting for clinical trials depending on the perceived risk of the research to the participants.

29.14 As a condition of authorisation, the RGO must be notified by the PI of anything that might warrant review of the approval of the project including serious and unexpected adverse events occurring at their site in accordance with **SOP 29.21- 29.25**. When PIs report this information they must provide their own opinion in regard to potential impact on the ethical acceptability and the need for action. The CPI must provide PIs with periodic information to facilitate the PI submission to the relevant RGO.

29.15 The PI must capture and report AEs, including SAEs which occur at their site to the sponsor in accordance with the protocol and TGA Good Clinical Practice guidelines. All SAEs must be reported to the sponsor within 24 hours, who is responsible for reporting to the TGA.

29.16 If the CPI is also the sponsor (i.e. in investigator or collaborative group sponsored projects) then they must keep PIs up to date with safety issues in a trial in a manner that is consistent with the risk, size or complexity of the proposed research. The CPI must communicate to investigators information which could adversely affect the safety of participants, materially impact the continued ethical acceptability of the clinical trial or that requires or indicates the need for a change to the protocol, including changed safety monitoring.

29.17 A **WA Health Adverse Event Notification Form** for AE/SAE/SADE/SUSAR/USADE reporting is available from the RGS or on the Research Development (ethics) website. The WA Health Adverse Event Notification Form must be completed (using the RGS and aligned with the PRN) by the PI and sent to the CPI for signing. As soon as possible (following notification from the PI) the CPI must submit the form to the Lead HREC and a copy must be sent by the PI to the RGO. The form will be validated, reviewed and recorded as per **SOP 29.9.**

29.18 Upon receipt of the WA Health Adverse Event Notification Form, the Lead HREC will review the report and take appropriate action which may include:

- acknowledging receipt of report;
- noting of the event;
- referral to the Lead HREC subcommittee for advice;
- immediate request for additional information from the PI;
- immediate suspension of ethical approval;
- immediate discontinuation of ethical approval; and
- other action as recommended by the Lead HREC.

The EEO will record the outcome and send a letter of notification **(SOP 29.10)** to the CPI outlining the outcome of the review within 7 calendar days of the Lead HREC meeting (or immediately if urgent action is required).

29.19 Upon receipt of the report the RGO will record the outcome **(SOP 29.11)**, review the report and take the appropriate course of action, which may include actions listed in **SOP 29.18** as well as other action recommended by the Chief Executive/delegate. The RGO will send a letter of notification **(SOP 29.10)** to the PI outlining the outcome of the review within 7 calendar days of the review (or immediately if urgent action is required).

29.20 Where the Lead HREC considers that the report requires immediate suspension or discontinuation of the ethical approval of the clinical trial, the Lead HREC EEO must immediately notify the CPI (who will notify the PI) and sponsor/CRO. This must be promptly followed by a notice in writing within 7 calendar days **(SOP 31).** The PI must notify the RGO.

Material Impact

29.21 Investigators must take prompt steps to deal with any unexpected risks. The PI must notify the CPI of an AE/SAE/SADE/SUSAR/USADE at their site where there is a **material impact** on the continued ethical acceptability, or the AE/SAE/SADE/SUSAR/USADE indicates a need for a change to the protocol. The CPI must report to the Lead HREC; and the PI must report to the RGO and the sponsor, the AE/SAE/SADE/SUSAR/USADE within 24 hours, the report must include information regarding the event and indicates whether it:

- materially impacts the continued ethical acceptability of the project; or
- requires, or indicates the need for, a change to the protocol and/or PICF, including changes to safety monitoring as recommended by the investigator or sponsor.

29.22 To avoid delay, the PI may contact the CPI and forward details of the AE/SAE/SADE/SUSAR/USADE directly to the Lead HREC. This is an exception to the general rule that the PI must always communicate with the Lead HREC via the CPI.

No Material Impact

29.23 If the PI considers that an event has **no material impact** on the continued ethical acceptability, within 72 hours, the:

- CPI (following notification from the PI) must notify the Lead HREC; and
- the PI must notify the RGO and the sponsor.

SUSAR/USADE Industry or DSMB Report

29.24 The CPI must provide to the Lead HREC (and the PI to the RGO) at least six-monthly (annually for USADE) an Industry or DSMB report:

- listing all SUSARs, Australian and international, related to the use of a compound; and
- including sponsor and investigator comment as to whether action is planned for the project on the basis of the reports (e.g. changes to safety monitoring or changes to the protocol and/or PICF).

29.25 The following must be provided at least annually by the CPI to the Lead HREC and by the PI to the RGO:

- an updated Investigator Brochure; or

When submitting a revised Investigator Brochure that is not part of a protocol or information sheet amendment, the investigator should advise the HREC that they have read the document and whether or not the changes in the brochure will impact on the conduct of the trial;

- annual safety report; [6] or

  The annual report must include a sponsor and CPI comment as to whether action is planned for the trial on the basis of the reports (e.g. changes to safety monitoring or changes to the trial protocol);
- current, approved product information, if appropriate (e.g. in a project where the product is approved in Australia or where an Investigator Brochure is no longer maintained); or
- other reports consistent with TGA Good Clinical Practice Guidelines;

  For trials where the CPI is acting as the sponsor and there is no investigator brochure, annual safety report or product information available, then a trial update and individual case safety reports may be submitted that provides appropriate review of safety information in the previous 12 months.

[6] The timing of annual safety report production by sponsors may not be synchronised with the timing of progress reports to the Lead HREC.

SOP 30: Complaints

Purpose: To outline the process in the event that a complaint is received about an authorised research project or the Lead HREC and RGO review processes.

Complaints Concerning the Conduct of the Project

30.1 Health Services and the Department of Health must handle complaints or allegations of misconduct involving the conduct of a research project in accordance with Section 2.18 "WA Health Research Governance Policy and Procedures" 2012 and the specific complaint management processes detailed in their SOPs. Complaints not related to the conduct of the research project must be referred to the institution's complaints coordinator (or similar).

30.2 The PICF must inform the participants that complaints concerning the research can be directed to the RGO and EEO. PICFs based on the national template must provide separate complaint contact details for matters relating to the site (RGO) and matters relating to an aspect of the research or the conduct of the research project (EEO).

30.3 The complainant should provide information (verbal/written) regarding the complaint/allegation directly to the RGO/EEO.

30.4 Once the complaint notification has been received either by the Lead HREC and RGO, the details must be entered into the RGS. A letter of acknowledgement must be sent within 7 calendar days to the complainant and a complaint notification letter must be sent by the EEO/RGO to the CPI/PI respectively.

30.5 The RGO and institution should deal with the complaint in a prompt manner. If the complaint concerns a matter related to the conduct of the research project the Lead HREC requires notification. The RGO must send details of the complaint in a complaint notification letter (available from the RGS) to the Lead HREC. The RGO and Lead HREC will liaise with each other to resolve the complaint. If a complaint is reported directly to the Lead HREC, the EEO must inform the RGO at the site where the complaint originated as soon as possible.

30.6 The Lead HREC (or delegate) and RGO will instigate an investigation of the complaint and its validity, and make a recommendation on the appropriate course of action. This investigation must not take longer than 30 calendar days from the time of the notification of the complaint, unless exceptional circumstances exist.

30.7 The outcome must be recorded in the RGS (in a de-identified manner); it must include the date of review and by whom and any additional information that is required **(SOP 9.5 & 21.7)**. A standard RGS letter (Complaint, more information required) will be sent to the complainant requesting more information if required.

30.8 Once the complaint has been resolved a standard RGS letter (Complaint resolved) will be sent by the:

- EEO to the complainant, CPI and RGO within 7 calendar days of the HREC meeting; or
- RGO to the complainant, PI and EEO within 7 calendar days of the resolution of the complaint.

Complaints Concerning the HREC's Review Process

30.9 Any concern or complaint received about the HREC's review process must be directed by the CPI to the attention of the Lead HREC Chair, outlining the grounds of the concern or complaint. The EEO will send a letter of acknowledgement to the CPI within 7 calendar days of receipt of the complaint.

30.10 The Lead HREC Chair will instigate an investigation of the complaint and its validity, (but may not be directly involved in the investigation) and make a recommendation to the Lead HREC

on the appropriate course of action. This investigation must not take longer than 30 calendar days from the time of the notification of the complaint, unless exceptional circumstances exist.

30.11 The outcome must be recorded in the RGS (in a de-identified manner); it must include the date of review and by whom and any additional information that is required **(SOP 9.5 & 21.7)**. A standard RGS letter (Complaint, more information required) will be sent to the CPI requesting more information if required.

30.12 Once the complaint has been resolved a standard RGS letter (Complaint resolved) will be sent by the:

- EEO to the CPI within 7 calendar days of the HREC meeting.

30.13 If the CPI is not satisfied with the outcome of the Lead HREC Chair's investigation, then the CPI can refer the matter to the Chief Executive/delegate, or request the Lead HREC Chair to do so.

30.14 The Chief Executive/delegate will consider the complaint, (ensuring that both the CPI and the Lead HREC provide submissions) and determine whether there is to be a further investigation of the complaint. Where no further investigation is to occur, the Chief Executive/delegate will inform the CPI and the Lead HREC Chair.

30.15 The Chief Executive/delegate will notify the complainant and the Lead HREC of the outcome of any further investigation.

Complaints Concerning the RGO's Review Process

30.16 Any concern or complaint received about the RGO's review process must be directed by the PI to the attention of the RGO. The RGO will send a letter of acknowledgement to the PI within 7 calendar days.

30.17 The RGO will instigate an investigation of the complaint and its validity, (but may not be directly involved in the investigation) and make a recommendation on the appropriate course of action. This investigation must not take longer than 30 calendar days from the time of the notification of the complaint, unless exceptional circumstances exist.

30.18 The outcome must be recorded in the RGS (in a de-identified manner); it must include the date of review and by whom and any additional information that is required **(SOP 9.5 & 21.7)**. A standard RGS letter (Complaint, more information required) will be sent to the PI requesting more information if required.

30.19 Once the complaint has been resolved a standard RGS letter (Complaint resolved) will be sent by the:

- RGO to the PI within 7 calendar days of the resolution of the complaint.

30.20 If the PI is not satisfied with the outcome of the RGO's investigation, then the PI can refer the matter to the Chief Executive/delegate, or request the RGO to do so.

30.21 The Chief Executive/delegate will consider the complaint, (ensuring that both the PI and the RGO provide submissions) and determine whether there is to be a further investigation of the complaint. Where no further investigation is to occur, the Chief Executive/delegate will inform the PI and RGO. The Chief Executive/delegate will notify the PI and the RGO of the outcome of any further investigation.

SOP 31: Suspension or Withdrawal of Ethical Approval or Site Authorisation

Purpose: To outline the process for the suspension or withdrawal of approval in an authorised research project.

Suspension or Withdrawal of Ethical Approval

31.1 In light of general, safety reports and complaints a Lead HREC may have reason to withdraw or suspend a research project that may relate to the welfare of the participants or the conduct of research that is not in accordance with ethical approval.

31.2 Where ethical approval for a research project is suspended or withdrawn by the Lead HREC, the CPI and sponsor must be notified immediately of the suspension/withdrawal of ethical approval. A suspension/withdrawal notification through the RGS must be provided within 24 hours. The CPI must inform the PI, and the PI must inform the RGO. Notification must include:

- reasons for withdrawal of approval/authorisation;
- conditions that may restore authorisation for the research to recommence; and
- recommended actions for participants currently enrolled in the project.

31.3 Where possible, the research participants should also be notified of the withdrawal or suspension of ethical approval.

31.4 The site, through the RGO, must ensure the PIs suspend the research once ethical approval has been withdrawn and that arrangements are made to meet the needs of the participants.

31.5 The research may not be resumed unless:

- the investigator subsequently establishes that continuance will not compromise participants' welfare; or
- the research is modified to provide sufficient protection for participants and an amendment is ethically reviewed and the modified research is approved; and
- approval from the Lead HREC and authorisation from the site to recommence the research project is given.

31.6 If the case to recommence research is accepted by the Lead HREC, the EEO will notify the CPI in writing, who must then inform the PIs and sponsor.

Suspension or Withdrawal of Site Authorisation

31.7 Where a Chief Executive/delegate decides that the site cannot continue to conduct the research project, site authorisation must be suspended or withdrawn.

31.8 The RGO must notify the PI and sponsor immediately of the suspension/withdrawal of site authorisation. A suspension/withdrawal notification through the RGS must be provided within 24 hours. The PI must inform the CPI and the CPI must inform the Lead HREC. Notification must include:

- reasons for withdrawal of approval/authorisation;
- conditions that may restore authorisation for the research to recommence; and
- recommended actions for participants currently enrolled in the project.

31.9 Research must not continue at a site if site authorisation has been withdrawn or suspended. Research cannot resume until the requirements of **SOP 31.5** are met.

31.10 If the case to recommence research is accepted, the RGO will notify the PI in writing, who must then inform the CPI and sponsor.

SOP 32: Early Termination/Abandonment/Suspension or Completion of an Authorised Research Project

Purpose: To outline the process for the early termination/abandonment/suspension or completion of an authorised research project.

32.1 The CPI and the PI will inform the Lead HREC and RGO respectively of a research project which is:

- abandoned – has never commenced;
- prematurely terminated – commenced at the site but terminated on ethical, safety, financial or other grounds;
- suspended – commenced at the site but temporarily stopped for any reason. The suspension applies to certain aspects of the project such as recruitment or the entire project; or
- completed.

Early Termination/Abandoned/Suspension of a Research Project

32.2 If a research project is abandoned, prematurely terminated or suspended by the sponsor, PI or CPI before the expected date of completion, the Lead HREC, RGO(s), sponsor and must be promptly notified.

32.3 A detailed written explanation, in an early termination/suspension notification letter, available from the RGS, of the reasons why a research project has been terminated must be submitted to the Lead HREC EEO by the CPI and the RGO by the PI at each site.

32.4 The CPI and PI must inform each other and the sponsor, if the research project is to be discontinued before the expected date of completion.

32.5 Wherever possible, the PI will notify research participants, if the research project is to be discontinued before the expected date of completion and discuss their ongoing management (if applicable).

Completion of a Research Project

32.6 On completion of a project, the CPI and PI must notify the Lead HREC and RGO respectively in accordance with **SOP 28.12 – 28.16**.

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